S. HRG. 106–956

OVERSIGHT OF THE SAFE DRINKING WATER ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON
FISHERIES, WILDLIFE, AND WATER

OF THE

COMMITTEE ON
ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

JUNE 29, 2000

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ADDITIONAL MATERIAL

OVERSIGHT OF THE SAFE DRINKING WATER ACT

THURSDAY, JUNE 29, 2000

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON FISHERIES, WILDLIFE AND WATER,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:30 a.m. in room 406, Senate Dirksen Building, Hon. Michael Crapo (chairman of the subcommittee) presiding.

Present: Senators Crapo and Smith [ex officio].

OPENING STATEMENT OF HON. MICHAEL D. CRAPO, U.S. SENATOR FROM THE STATE OF IDAHO

Senator CRAPO. This hearing will come to order.

This is the Subcommittee on Fisheries, Wildlife and Water hearing on pending issues relating to the implementation of the Safe Drinking Water Act.

As a schedule driven statute, the Safe Drinking Water Act deserves periodic and regular oversight. In 1999, this subcommittee held a hearing to receive testimony on matters that were of the highest concern to our stakeholders at that time. And it's our intention to provide a forum today for those matters that come to the forefront, both those matters that came to the forefront last year as well as any other issues that people are concerned about that feel we need to focus on during the next 12 months.

Although there is no shortage of issues to discuss in our limited time today, it's my expectation that our witnesses will focus on many of their pressing concerns and raise as many of those issues as possible. While the magnitude of certain matters will draw considerable attention today, I hope not to foreclose debate on any and all issues.

In 1996, Congress comprehensively reformed the Safe Drinking Water Act to accomplish several goals. Primary among these goals were the need to make regulatory implementation of health standards better reflect the availability of resources, science and actual risks. At the same time, a very rigorous schedule of rulemaking and other procedural steps was established to ensure that the Environmental Protection Agency, State environmental and health agencies, municipalities and the private sector would best serve the public.

These developments have served to highlight the complexity of implementing a regulatory regime that aims to serve every American but can exacerbate resource and funding shortfalls at the Fed-

eral and State levels and in the private sector. As new rules are increasingly applied to smaller systems, the reach and impact of the Act touches even more people.

I expect today for several witnesses to address the difficulties of establishing drinking water rules based on science that is constantly changing and open to different interpretations. Within this framework, the EPA is expected to produce standards that recognize the limitations of scientific understanding and the funding available to implement them. Rules will be instituted that ignore the realities of scientific uncertainty, with the knowledge the standards may have to be revised in the future to respond to information showing greater or lesser risks, and the finite resources available to respond to them are unrealistic and inappropriate.

The spectrum of views represented by our witnesses today should provide a perspective on many issues raised by the implementation of the Safe Drinking Water Act. I am looking forward to a full and stimulating discussion of these matters and then exploring possible solutions to them.

At this time, I ought to state to those present that we are going to have a bit of a problem with the voting schedule on the Senate floor. We are scheduled to have two votes back to back at 9:40, which means the votes probably won't start right at 9:40, and we will probably be able to go for about 10 minutes into the first vote before recessing to go over to vote.

Hopefully, the Senators this morning will all be on time and we will be able to make both of those votes in a short period of time and only have about a 15-minute delay. But because of that schedule, you probably won't see many of the other Senators making it here until after that break. That means, Mr. Fox, that they won't probably hear your testimony, but they will get to ask you questions.

[Laughter.]

Senator CRAPO. So I'm sorry about that.

We will proceed, Mr. Fox, to your testimony, and then see how far we can get through the questions I have before the votes are called. To the rest of you, I apologize. This is hopefully only going to mean about a 15-minute extension of the timeframe that we would have held you here today. But I apologize for the potential problem that we will have from interruptions from the Senate floor.

And with that, Mr. Fox, you may proceed.

STATEMENT OF J. CHARLES FOX, ASSISTANT ADMINISTRATOR, OFFICE OF WATER, ENVIRONMENTAL PROTECTION AGENCY

Mr. FOX. Thank you, Mr. Chairman. I will soon be joined by my colleague, Dr. Noonan, who is the Assistant Administrator for Research and Development. There's a lot of unusual traffic patterns out there today and I apologize for my lateness.

I am prepared to offer our detailed comments on how we are doing on the Safe Drinking Water Act, but if you'll indulge me, I need to start out with a comment on our favorite acronym. My understanding is that late last night, the Senate approved a rider to the supplemental appropriations bill that would have the effect of

rolling back the total maximum daily load program, which provides, I think, important protections for the people of this country.

I know the Senate prides itself on being a deliberative body, perhaps the world's greatest deliberative body. But I think you would agree that this is contrary to the well-established processes of fairness that the Senate considers various legislation. And it's obviously contrary to the jurisdiction of this committee.

This legislation, to my knowledge, was never voted out of this committee, never voted out of any committee in Congress. And unfortunately, we find ourselves now in a position of trying to deal with Clean Water Act legislation in the context of a military construction supplemental appropriations bill that will be considered under rapid consideration as the Senate tries to get out for the July 4th recess.

I will just say that I remain committed to working with members of this committee to address any outstanding issues that remain. That is how I have approached this process from the beginning. I would urge members of this committee to contact members of the appropriations committee and respect the processes and the forums that exist to have these important deliberations about the future of water in this country.

Senator CRAPO. Well, I appreciate your statement, Mr. Fox. I should clarify, I understand as well and I'm aware of the provision that was put into the military construction appropriations bill, and in fact strongly support the inclusion of that provision. It was not the legislation that is, the legislation that Senator Smith and I have introduced that is before this committee, and is not a rider in that sense. It is simply an appropriations provision prohibiting the EPA from expending funds to proceed with the implementation of the rule.

And as you know, you and I have a very big difference of opinion on whether the rule is an appropriate rule or a good rule for the water quality of the United States. And I respect that difference, and I do respect and acknowledge that you've been working with us very closely to address those issues.

However, what you have been, you, the EPA, has been unwilling to do at this point is to give us time to work out those differences. And the EPA has been consisting in stating that it is going to proceed with the adoption and finalization of the rule. That being the case, Congress is left with virtually no option but to say to the EPA that it cannot expend funds on the implementation of the rule until we have worked it out.

And last year, of course, we had Congressional action as well, as you know, to address slowing down the process. And given the fact that we were facing deadlines within literally a few weeks, we felt we had no other option other than to stop the EPA from proceeding.

Now, assuming that that is what happens and this legislation passes, I still intend to work closely and to address these issues and to pursue the other objectives in our legislation, which are to address the very water quality issues that you are seeking to address in the rule. So I would hope that we can continue our discussions and our collaboration on this issue. But I hear your point and I'm certain that your comments will be quickly reflected from this

hearing today to the other members of this committee and to the members of the Senate.

Mr. FOX. Thank you very much.

We are pleased today to be able to discuss EPA's implementation of the Safe Drinking Water Act Amendments of 1996. Nearly 4 years into implementation, EPA has completed all of the actions that are required of us to date. I think this is a remarkable record, not just for the Agency, but frankly for this committee in the work that they did in outlining not just an ambitious but ultimately a workable schedule for providing drinking water that is safe for all Americans.

As a result of the work of EPA, the States, water systems and the public, the United States has one of the safest drinking water supplies in the world. Over 90 percent of Americans served by community water systems receive water with no reported health standard violations.

The 1996 amendments moved us toward more comprehensive drinking water protection and gave us the framework to reduce emerging risks. The Safe Drinking Water Act revolving loan fund has been extremely successful in less than 4 years of operation. EPA has given out nearly $2.5 billion in grants to all 50 States, Puerto Rico, the District of Columbia and the territories. States have made over 1,000 loans totaling over $2 billion to water systems to address the most significant public health needs. States are also taking advantage of the set asides in the revolving fund to conduct source water assessments and buildup State programs.

Drinking water systems have also made outstanding progress in implementing the right to know provisions of the Safe Drinking Water Act. Consumer confidence reports give customers of drinking water systems the information they need to make their own health decisions. Today, approximately 253 million Americans have access to their first annual consumer confidence report and over 100 million Americans are able to read their reports on line.

Many residents in the District of Columbia's metropolitan area, in fact, are receiving their next report at this time, because there is a July 1st deadline for the second annual consumer confidence report.

Effective drinking water protection has to start with an understanding of the threats to the water sources, and States are making significant steps forward on their source water assessments. Forty-nine States and territories have approved source water assessment and prevention programs and are conducting assessments for their water supplies.

EPA is also working with the States to develop their capacity and operator certification programs to ensure that all water systems will be able to meet the demands of providing safe water.

In the past 2 years we have proposed or finalized a series of new rules that would extend coverage to microbial and other high risk contaminants. We have done this with extensive research, which my colleague, Norine Noonan, will describe, and stakeholder involvement. We have included special emphasis on the needs of small water systems and their consumers.

This spring, EPA proposed a groundwater rule and what's called the long term one enhanced surface water treatment rule to ad-

dress the needs of consumers of groundwater systems and small surface water systems respectively. When finalized, these rules will complete a cycle of microbial protection by covering all consumers of public water systems.

The risk-risk tradeoff between disinfectants and their byproducts is difficult. However, the extensive stakeholder process that EPA used to develop these complex rules gives us better supported and understood rules that strengthen human health protection. We are now concluding a new round of discussions of the second phase of these rules which will incorporate the results of the microbial and disinfection byproducts research that is currently ongoing.

In November 1999, EPA proposed the radon rule, which will have an important impact on reducing the human health risk from radon in drinking water as well as indoor air from soil. Recently also EPA proposed to lower the maximum contaminant level for arsenic, another high priority drinking water contaminant. The National Academy of Sciences found that the current arsenic standard of 50 parts per billion does not meet EPA's goal of human health protection and recommended that EPA lower this MCL as quickly as possible.

While the Agency is proud of its successes and accomplishments, we are also aware of many daunting challenges, both in the short and long term. We are certainly aware that the significant number of new requirements of the Safe Drinking Water Act represents a significant demand on the States and systems' ability to implement the wide variety of activities. I believe that they are manageable through the framework provided by the Safe Drinking Water Act but will require concerted effort by all participants in the drinking water community.

As EPA has implemented the Safe Drinking Water Act, we have attempted to ease some of the strain. We have had extensive stakeholder involvement in our actions, including a particular focus on small water systems.

The cost of providing Safe Drinking Water Act will continue to be a challenge. The increased complexity of future public health threats requires a new level of sophistication in the water industry. The drinking water industry has released its assessment of the annual drinking water infrastructure funding gap which you will hear about shortly. EPA's own drinking water needs survey identified over $138 billion in industry needs.

At this point, I will turn to my colleague, Norine Noonan, to talk about some of our important research priorities.

Senator CRAPO. Thank you. Dr. Noonan.

STATEMENT OF NORINE E. NOONAN, ASSISTANT ADMINISTRATOR, OFFICE OF RESEARCH AND DEVELOPMENT, U.S. ENVIRONMENTAL PROTECTION AGENCY

Dr. NOONAN. Mr. Chairman, EPA recognizes the critical importance of drinking water research to ensure scientifically sound decisions on regulations to protect human health and the environment. We're committed to the highest quality research in our drinking water program.

We've established drinking water research as one of our highest priority programs. We have more than doubled our annual invest-

ment from $20.8 million in fiscal year 1996 to almost $49 million in the fiscal year 2001 President's request. The fiscal year 2001 request is an increase of $5 million over fiscal year 2000 enacted, because we recognize the need for these additional resources to address key drinking water research issues.

These increases have come, I want to let you know, over a period of flat or declining budgets for ORD as a whole. We have delivered literally hundreds of peer-reviewed products that directly support both near term regulatory priorities such as microbial and disinfection byproducts, arsenic and the surface and groundwater rules. We've increased funding to enable us to expand our health research activities, including epidemiology studies on disinfection byproducts and arsenic, microbial pathogens and waterborne disease occurrence studies.

The peer-reviewed research strategies and plans guide our research. We have completed much of the research in our MDBP and arsenic research plans. In the contaminant candidate list research strategy, this strategy is scheduled for review by our own Science Advisory Board in August.

Wwe expect to complete the comprehensive drinking water research strategy in fiscal year 2001. We've also strengthened partnerships with outside research organizations. These partnerships leverage millions of dollars of additional funding for important areas of research such as sensitive subpopulations and waterborne pathogens. Examples include the National Institutes of Environmental Health Sciences, with whom we leverage over $5 million a year. Also the Centers for Disease Control Prevention and the American Water Works Association Research Foundation.

Our STAR, or Science to Achieve Results grants program, has successfully expanded the involvement of universities and other not for profit organizations in performing high quality research in support of drinking water research priorities.

In the area of microbial pathogens, EPA has provided new information and new methods to characterize and control the risks to safe drinking water posed by these organisms. We have also focused on the needs of small communities through engineering research on simple, effective and less costly treatment alternatives. In the area of arsenic, our research plan has been used both internally and externally as a guide for planning and carrying out short-term and long-term research.

EPA has completed the high priority short-term projects in the research plan, and we have also made significant progress in addressing the longer term research needs. In developing the proposed rule, the Agency considered the results of these studies as well as other research.

We have doubled our resource commitment to research on contaminants listed in the Contaminant Candidate List. The draft CCL research plan is complete and will be reviewed, as I said, by the SAB in August of this year. This draft plan has incorporated extensive input from a wide variety of stakeholders.

We have also placed considerable emphasis on research on sensitive subpopulations and life stages, from studies in laboratory animals on mechanisms and dose response to population based epidemiology studies. We will summarize all of this work in a report

to be transmitted to Congress later this summer, and that report is on schedule.

We have a comprehensive, coordinated approach to assess needs and make budgetary decisions for research to support all of the Agency's programs. For drinking water, the research planning process is collaborative, in partnership with the Office of Water and mindful of the views of external stakeholders. Based on our analysis, we believe that the funding level and the resources requested for fiscal year 2001 are sufficient to meet both the near term regulatory requirements as well as future needs.

Let me say, though, that we are committed to an annual review of resources for this as well as other priority activities, and to making appropriate adjustments where necessary.

We place a high priority on sharing information with stakeholders to ensure that they are informed and can provide appropriate input to research needs and priorities. We meet with the drinking water community on a regular basis, and we are in the process of establishing a new research working group under the National Drinking Water Advisory Council to further strengthen the long-term liaison with stakeholders.

We have strong internal systems in place to assure accountability for resources and for research. Over the past year and in response to the needs of the Office of Water, we have been working intensively to develop a tracking system that will improve the availability of information on all of our drinking water research. We intend for this system to be widely available both within and outside EPA.

Last, Mr. Chairman, we are meeting the challenges, the research challenges, posed by the SDWA Amendments of 1996. We've planned our research to address the highest priorities and we've adhered to a rigorous process of peer review to ensure science of the highest quality. The increased funding devoted to this research within a flat overall budget is clear evidence of the priority we assign to this work, and we remain committed to assuring adequate funding for fiscal year 2001 and beyond.

I thank the Chairman.

Senator CRAPO. Thank you very much, Dr. Noonan and Mr. Fox.

We are about 8 or 9 minutes into the first vote—10 minutes into the first vote. And I need about 5 minutes to get over to the Senate floor to vote. So I think what I will do is recess the hearing at this point before beginning questions. I will let all of the other committee members who are probably over on the Senate floor doing the same thing know that they still have a chance to ask questions of the first panel and encourage them to get back over here.

And again, I apologize for this interruption. It's one of those hassles that we deal with in our life up here. But at this point, I will recess the committee, and we will reconvene very shortly after the second vote is called. This committee is recessed.

[Recess.]

Senator CRAPO. The hearing will come to order.

Once again, I appreciate everyone's accommodation of our voting schedule. And it's a very busy morning, we expect other Senators to soon join us. But until they do, I'll get to ask all the questions I can.

And let me start out, Mr. Fox, and Dr. Noonan and Ms. Dougherty, we welcome you to answer among yourselves, whomever has the most appropriate information.

The first question I have is, what are the current EPA guidelines in determining whether a public water system is a large or small water system?

Mr. FOX. My understanding, Mr. Chairman, and if I get this wrong, the Director of our Ground Water and Drinking Water Office, Ms. Dougherty, whom I didn't introduce earlier, will correct me. A large public water system is considered anything that supplies drinking water to over 10,000 residents. A small system is considered under 10,000. The definition as to whether it is public or not depends on how many people are actually connected to the system, and that number is 25 people or 15 connections.

[Additional information supplied for the record follows:]

Public Water Systems: Five Size Categories

System size	Population served
Very small	25–500
Small	501–3,300
Medium	3,301–10,000
Large	10,001–100,000
Very large	> 100,000

Senator CRAPO. OK. On what basis does EPA determine whether a regulation is affordable for a small system?

Mr. FOX. The 1996 Amendments included a number of provisions related to affordability to assure that the regulations we develop are affordable to small systems. For example, they gave us an opportunity to come up with alternative technology that might be something slightly less than the best available technology if it was still affordable.

The Act actually asked us to define what we meant by affordable. We went through a process involving development of criteria and public comment and came up with a conclusion that affordable generally represented 2.5 percent of the median household income, which is roughly, on a national average, about $750 a year. And then we evaluate this affordability based upon the existing suite of rules and regulations and costs that might apply to a drinking water system in assessing whether or not an individual rule is in fact "affordable."

Senator CRAPO. So 2.5 percent of the median family's income is what the EPA's understanding is of what would be affordable for a family to be expending for their share of water quality systems?

Mr. FOX. That's correct.

Senator CRAPO. And that is just the water quality, that's not any other cost impact from other EPA regulations?

Mr. FOX. That's correct.

[Additional information supplied for the record follows:]

The per household cost used by EPA in comparing the 2.5 percent of median household income is the per household reflection of the total cost of a rule. That cost includes all elements of a rule's impact: monitoring, State costs, system treatment costs, and other administrative costs. All of these costs are ultimately designed to result in a particular water quality.

Senator CRAPO. Can you give me a little perspective on that? To me that seems like a pretty high percentage. I'm just reacting to it. Can you give me a perspective on that?

Mr. FOX. Yes. Again, speaking in gross generalities, and it always gets awkward, because there are such differences throughout this country, but on average, people spend today, I think the figure is about $250 a year for drinking water services. The Congress asked us to evaluate what is affordable in the context of the suite of new requirements that Congress included in the 1996 SDWA amendments.

We went through an exercise of figuring out, what is the appropriate level. Then as you would imagine, if we set that level too high, it would end up being not affordable. And I must admit that I had some of the initial reflections that you had when I saw this.

If we set it too low, of course, then we are in effect saying that our public health protection standards are going to be also low. Because of the way the Act is structured, we always have to make an affordability determination. And based on these kinds of criteria, we went through the process and came up with the number that we did.

Senator CRAPO. And if I understood you correctly, you used the figure of $750. Is that what the 2.5 percent translates into per family?

Mr. FOX. Right, on a national average.

Senator CRAPO. On a national average?

Mr. FOX. That's right.

Senator CRAPO. And that prior to promulgation of these or implementation of the requirements of the Safe Drinking Water Act, it was at a $250 level?

Mr. FOX. That is the estimate of the current average annual water bills. But I also want to make a point here that based on the suite of regulations that we have developed so far pursuant to the amendments, we are not approaching the affordability criteria. Because when you look at the suite of regulations that we've done, radon, for example, and arsenic, most recently proposed, they don't affect all systems throughout the country. These requirements would affect only those systems that have to do additional treatment. And so we evaluate each rule on its affordability based on our expectation as to which systems would be impacted by it.

Senator CRAPO. So different systems would be impacted by different rules, each of which would have a cost to them. And you're trying to keep the cost of the rules applicable to a particular system under 2.5 percent of the median family average in the community.

[Additional information supplied for the record follows:]

By applying its affordability criteria to prospective rules to determine whether or not rules will be affordable, we are trying to determine, on average, how the rule will impact systems. Since these are national rulemakings, we cannot ensure that any particular system will or will not find the rule affordable. Other programs are designed to address disadvantaged communities.

Mr. FOX. Right. And that's what the statute provided for us. And I would say, too, just for clarification, the statute also specifically said that we were not to include the microbial rules in our consideration of affordability.

Senator CRAPO. Now, I would assume that if the average is $750 for the Nation that a community that was below that average would have a lower dollar figure, using the same percentage. Let's just take a hypothetical. Let's say there was a community where the 2.5 percent for that community was $500 instead of $750. Does that mean that the EPA's decisionmaking on how to implement the standards of the Safe Drinking Water Act for that community would impose no greater than a $500 burden, or would the EPA be using the national average of $750?

Mr. FOX. We do it based on the national average, not by community.

Senator CRAPO. So the poorer communities could see even more percentage of their median family income taken by these rules?

Mr. FOX. That is possible.

Senator CRAPO. In fact, if I know my math right, it would be a large, something approaching half. Would that be right? Would those falling below the median, this shows that I don't remember my mathematics, what percentage of families in the country would fall below the median and average income?

Mr. FOX. You're asking me, too, to remember my difference between medians and means. If I could get that for the record.

Senator CRAPO. Is there a mathematician in the audience?

[Laughter.]

Mr. FOX. Dr. Noonan has a Ph.D.

Dr. NOONAN. For the median, 50 percent for the median. Fifty percent of the households are above and 50 percent are below.

Senator CRAPO. OK, that's what I thought. But I didn't want to step out and make a mistake.

But that would mean, then, that 50 percent of the families would be paying more than 2.5 of their median family income under this approach.

Mr. FOX. That's correct.

Senator CRAPO. Obviously I have several concerns that just come to mind. If we're paying on average now $250, and what is determined to be affordable is $750, that's a 300 percent increase, 200 percent increase.

Mr. FOX. Right. And I don't disagree with the math, and I don't disagree with the fundamental premise of your line of questioning here, Mr. Chairman. But I think the other context important to keep in mind is that when this committee passed the Safe Drinking Water Act Amendments, we also included for the first time significant new Federal funds that would be available to communities to help them comply with the new amendments.

Senator CRAPO. And do those funds count against the affordability figures?

Mr. FOX. The way the affordability is calculated involves the total cost of implementing the regulations, so that when we can provide loans and other assistance to these communities, we are helping them meet their affordability criteria. And then basically my point was simply that we now have truly a multi-billion dollar program. The initial statistics are that 75 percent of these loans are going to small communities. So we really are succeeding in, I think, helping supplement some of the needs of the smaller communities throughout the country.

Senator CRAPO. Well, that is helpful, and I appreciate that. But also, I hope that you can appreciate that what you're telling me is that the EPA is determined that under this legislation, the average family in American can expect to see their family income that is attributed to water quality to triple, or to go up to triple what it is now.

Mr. FOX. I would say that slightly differently. Under this legislation and under the rulemaking the national median never exceed tripling. We've developed this in a way that we will keep an ongoing budget, a running budget, if you will, on this index through all the regulations that we are going to be developing under the Safe Drinking Water Act.

Senator CRAPO. I'm curious, how did the EPA determine what is "affordable"? And how was it that it went from what is now being paid by families that I think are all strapped to three times that, and that's still considered to be affordable? Is there some kind of a formula that is being used in the country these days for those kinds of determinations?

Mr. FOX. I will turn to Cynthia Dougherty to give you more detail. But developing affordability guidelines was a specific requirement of the statute and we went through a public notice-and-comment period to get additional ideas as to what people thought was affordable. I know we had had some general index in the past on the wastewater side as to what was affordable that the Government had been using for the better part of a decade or two. But maybe Cynthia has some additional information.

Ms. DOUGHERTY. We can get you some more specific information for the record, including the actual document that we used for the criteria.

Senator CRAPO. I'd appreciate that.

Ms. DOUGHERTY. We basically did cost comparisons of other household expenses, and other risk reduction activities that people undertake, such as using bottled water and home treatment, point of use, point of entry devices that they do. So we did those comparisons and looked at the costs as we knew them and came up with the based on our findings.

Senator CRAPO. All right. You know, I recognize that you have a statutory responsibility to make this determination, and I think that that is a proper determination to be making. It's just an interesting issue, and I'd be interested to see just how an Agency does determine what a family, what is affordable for a family in this context or in any other. So I would appreciate the details of that being provided to the committee.

Mr. FOX. We will do that.

[The information referred to follows:]

United States
Environmental Protection Agency | Office of Water 4607 | EPA 815-R-98-003 September 1998

EPA

Variance Technology Findings for Contaminants Regulated Before 1996

See page 26 of the transcript

chapter 3 of this document describes the affordability criteria

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3.0 NATIONAL-LEVEL AFFORDABILITY

Section 3.1: Introduction

Section 1412(b)(15)(C) of the SDWA requires EPA to list any assumptions used in determining affordability, taking into consideration the number of persons served by such systems when variance technologies are listed. Even though EPA did not list variance technologies in the August 6, 1998 Federal Register notice (EPA, 1998a), the affordability criteria used by EPA for these findings were included in the notice. These affordability criteria were used to identify affordable compliance technologies for some of the regulated contaminants. EPA compared technology cost estimates for each small size category against an affordable technology criterion for those regulations where a small system variance could be granted. The affordable compliance technologies are discussed in "Small System Compliance Technology List for the Non-Microbial Contaminants" (EPA, 1998b).

The size category-dependent affordable technology criteria are collectively referred to as "national-level affordability criteria." This nomenclature has been used to distinguish the national-level affordability criteria from the "system-level affordability criteria" that States will use for determinations affecting individual systems. EPA published information regarding these system-level affordability criteria in February, 1998 (EPA, 1998c). This information was required by Section 1415(e)(7)(B) of the SDWA. There are three provisions of the SDWA that refer to these system-level affordability criteria. Section 1415(e) provides for affordability-based variances, under certain circumstances, for small drinking water systems. Section 1416 allows for exemptions that provide systems facing compelling economic factors additional time to comply with SDWA requirements. Small systems could receive as long as nine additional years to comply. Finally, Section 1452(b) provides that affordability on a per household basis shall be one of the three factors used to prioritize systems for assistance from the new Drinking Water State Revolving Fund (DWSRF). The system-level affordability criteria can be different for different purposes. For example, States can use different affordability criteria to make decisions about whether a system should receive a small system variance and when a system should receive additional subsidization from the DWSRF. In fact, the threshold used for additional assistance for systems meeting a NPDWR would likely be lower than the threshold used to determine when a system would operate at a level that does not provide an equivalent level of protection as meeting the MCL.

The national-level affordability criteria for the affordable variance technology determinations will also be different from the system-level criteria used by the State to determine if a system should receive a small system variance. Technologies determined to be "unaffordable" under the national-level affordability criteria may still be affordable for a specific system within the size category, in which case the system may install that technology if it so chooses. Conversely, if a financially disadvantaged small water system out of compliance with a NPDWR cannot afford any of the compliance technologies that are determined to be "affordable," one option for that system would be to apply to the State for an exemption. This

process is available for regulations promulgated after 1996. Such a system cannot apply for a new exemption for the regulations issued prior to August 6, 1998. Those small systems with existing exemptions for rules in effect on August 6, 1998 may continue to get renewals of their exemptions until the exemption period has run out. That means that a small system can have no more than 9 years after the Section 1412 compliance date to meet the applicable MCL/treatment technique even if the exemption was issued prior to the 1996 SDWA Amendments.

Section 3.2: Role of National-Level Affordability Criteria

The role of the national-level affordability criteria was discussed briefly in Section 1.3 of this document. Figure 2 in that section showed the role that national-level affordability criteria play in the treatment technology arena. The primary function of the criteria is to determine whether a system of a given size/source water quality combination should proceed down the compliance or variance technology pathway. The secondary function is to define the universe of technologies within the compliance or variance technology pathway. Since affordable compliance technologies were identified for all of the regulated contaminants, the variance technology pathway will not be utilized at this time. The secondary function of the national-level affordability criteria is demonstrated in the compliance technology tables (EPA, 1998b). For the smallest size category, technologies that met the national-level affordability criteria and those that did not meet the national-level affordability criteria were identified.

The primary function of the national-level affordability criteria is to determine whether the treatment goal of the water system should be compliance with the NPDWR or whether the system should proceed down the variance pathway towards obtaining a small system variance. A variance technology must be installed to obtain a small system variance. The variance technology may not achieve compliance with the NPDWR, but will achieve the maximum reduction or inactivation that is affordable considering the size of the system and the quality of the source water. Thus, the treatment objective for a variance technology might be a concentration that is higher than the MCL. This higher concentration must be protective of public health, considering the quality of the source water and the expected useful life of the technology. Variance technologies cannot be identified if they are not protective of public health [see Section 1412(b)(15)(B) of the SDWA]. The treatment goal under a small system variance is to be within the range identified as being protective of public health. This range would start at the MCL and would go up to the maximum concentration that is still protective of public health based on the expected useful life of the technology. The actual treatment goal is to be as close to the MCL as is affordable within the protective of public health range.

The national-level affordability criteria help define the range of options available to a small system that is out of compliance with a NPDWR. The overall range of options are: 1) install a technology to comply with the NPDWR; 2) receive an exemption and then install a technology to comply with the NPDWR; or 3) obtain a small system variance (if option is available). For the two compliance options, the system is not required to install a compliance technology identified by EPA. The compliance technology list is intended as guidance to provide small systems with

information concerning the types of technologies that can be used to comply with the NPDWR. Systems can install other technologies that are not on the list to comply with the NPDWR. Alternate source and regionalization options are also available for a system to comply with a NPDWR. The compliance option can be characterized as a "pay now" approach. The exemption followed by compliance option can be characterized as a "pay later" approach. The small system variance option can be characterized as "pay less for less" approach. These systems will not have the same level of protection as systems complying with the NPDWR during the duration of the small system variance. Households in these systems will likely have lower water bills than they would if the system were in full compliance with the NPDWR. There are NO no-cost options available for violations of NPDWRs. All three options have treatment costs associated with them. When a variance technology is installed, there are additional administrative costs associated with the small system variance procedures. These procedures are detailed in the final Variance and Exemption Rule (EPA, 1998d). The national-level affordability criteria will determine when the "pay less for less" option will be available.

Section 3.3: Unit of Measure for the National-Level Affordability Criteria

Public water systems fall into one of three categories. A community water system (CWS) is a public water system which serves at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents. A non-transient non-community water system (NTNCWS) is a public water system that is not a community water system and that regularly serves at least 25 of the same persons over 6 months per year. A transient non-community water system (TNCWS) is a non-community water system that does not regularly serve at least 25 of the same persons over six months per year.

Community water systems can absorb water service cost increases by directly charging their customers in the form of increased water bills. Community water systems serve both residential and non-residential customers. The majority of the customers in small systems are residential or household connections. System size and the percentage of non-residential customers are directly related. Thus, the typical system in the smallest size category relies almost exclusively on residential customers. Since there are so few non-residential customers, the ability of these systems to spread the cost of SDWA compliance beyond the household level is restricted. The other two size categories have a larger percentage of non-residential customers, but residential customers still account for the majority of the revenues received by the water system. The national-level affordability criteria for CWSs are based on the ability of household customers to shoulder the additional costs of installing a technology to meet a NPDWR. For more information on the selection of the household as the most sensitive user for cost increases, see "National-Level Affordability Criteria Under the 1996 Amendments to the Safe Drinking water Act" (EPA, 1998e).

For non-community water systems, the operation of the system is generally peripheral to some other type of business or activity. These systems are generally engaged in an enterprise other than water supply and do not rely directly on households to recover water production costs.

A second document evaluated non-community water systems (NCWS) and compared their vulnerability to cost increases with households in community water systems [see background document entitled "An Assessment of the Vulnerability of Non-community Water Systems to SDWA Cost Increases" (EPA, 1998f)]. The conclusion was that the categories of NCWSs were either not vulnerable to SDWA-related treatment cost increases or were less vulnerable to SDWA-related treatment cost increases than a typical household.

One other element in the 1996 Amendments to the SDWA provides a very cost-effective solution for NTNCWSs. Since variance technologies are only an option for chronic contaminants, point-of-use devices are an available compliance technology option. Most NTNCWSs only provide a very small portion of the water for drinking purposes. Point-of-use devices could be installed on all taps where water is used for human consumption or food preparation. Treatment costs would be much higher if all the water provided by the system was treated to meet drinking water standards.

TNCWSs are only required to treat for acute contaminants. These include microbial contaminants and nitrate. As discussed in Chapter 2, there are statutory prohibitions against variance technologies for these contaminants. Therefore, variance technologies are not an option and national-level affordability criteria are not needed for this category of public water systems.

Since the household was determined to be more vulnerable to treatment cost increases than the various categories of non-community water systems, national-level affordability based on households would serve as an adequate surrogate for NTNCWSs as well as CWSs. Therefore, whether treatment is affordable depends upon how treatment costs compare with existing household water costs. The selected approach was to equate user burden to the increase in annual household water bills that would result from installation of treatment. To determine if there are any affordable compliance technologies for a given NPDWR, the national-level affordability criteria are compared against the cost projections for the applicable treatment technologies. If there are no affordable compliance technologies, then variance technologies would become an option.

Section 3.4: Derivation of the National-Level Affordability Criteria

A summary of the methodology used to determine the national-level affordability criteria is described below. The household is the focus of the national-level affordability analysis. Treatment technology costs are presumed affordable to the typical household if they can be shown to be within an affordability index range (defined as a range of percentages of median household income) that appears reasonable when compared to other household expenditures. This approach is based on the assumption that affordability to the median household served by the CWS can serve as an adequate proxy for the affordability of technologies to the system itself. EPA has chosen to express the water system financial and operational characteristics using their median values, which is a measure of their respective central tendencies. EPA believes that the national-level affordability criteria should describe the characteristics of typical systems and

should not address extreme situations where costs might be extremely low or excessively burdensome.

The national-level affordability criteria have two major components: current annual water bills (baseline) and the affordability threshold (upper limit for water bills). The current annual household water bills were subtracted from the affordability threshold to determine the maximum increase that can be imposed by treatment and still be considered affordable. This difference was compared with the converted treatment costs to make the affordable technology determinations. This difference is called the available expenditure margin.

The affordability threshold was determined by comparing the cost of public water supply for households with other household expenditures and risk-averting behavior (such as use of bottled water or point-of-use devices). National expenditure estimates were derived to illustrate the current allocation of household income across a range of general household expenditures. This consumer expenditure data provided a basis for determining the affordability threshold by comparing baseline household water costs to median household income (MHI) to determine the financial impact of increased water costs on households.

Section 3.4.1: Derivation of Baselines

Baselines were determined for the three parameters needed to perform the affordable technology analysis. These parameters are: annual household consumption, current annual water bills, and median household income. Separate baselines for the three parameters were established for each of the three system size categories. Annual household consumption was used to convert treatment cost increases into household impacts as discussed in Section 4.4 of this document. Current annual water bills were subtracted from the affordability threshold to determine the available expenditure margin. The median household income was used to translate the threshold percentage into an actual dollar figure.

The baselines for annual household water consumption and the current annual water bills were derived from data in the 1995 Community Water System (CWS) Survey. EPA began the 1995 CWS Survey in the fall of 1994. In June 1995, the surveys were distributed to a stratified random sample of 3,700 water systems nationwide. Community water system respondents had until February 1996 to return the completed questionnaires. Slightly more than 54 percent of the systems that received questionnaires responded to the survey. For more information on the 1995 CWS Survey and an overview of the results, see "Community Water System Survey Volume I: Overview" (EPA, 1997a). For detailed survey result tables and copies of the survey questionnaires, see "Community Water System Survey Volume II: Detailed Survey Result Tables and Methodology Report" (EPA, 1997b).

EPA's goal was to define a typical system within each small system category for affordability purposes. This is very similar to the model systems approach that is used to evaluate the cost of treatment. Under that approach, a typical system is created with the

following parameters: design flow, average daily flow, and population served within the size category. Water systems that purchase 90% or more of their water were excluded from the baseline determinations. These systems were assumed to obtain high quality finished water from larger systems that can achieve economies of scale necessary to mitigate the increased cost of SDWA treatment requirements. Data from water systems with zero values for critical variables were also excluded from the baseline determinations. The data for current household water bills was one such critical variable. The remaining observations were graphed as a scatter plot to examine the dispersion of data points. After evaluating this data, all data outside of three standard deviations (+/-) of the mean value were excluded from the analysis.

Two data sources were required to derive the median household income (MHI) for small systems. The median household income data were derived by linking the CWSS data with data in the 1990 Census using zip codes. The CWS Survey provided information on zip codes served by individual water systems. The Census income data were converted from 1990 dollars to 1995 dollars using the consumer price index to facilitate comparison with the CWS Survey data. Some data had to be excluded from this analysis because it did not represent a typical small system. Zip codes were reported using either the three-digit zip codes or five-digit zip codes depending upon the water system's service area. The use of the three-digit zip code placed several large metropolitan areas in the overall sample. Because the three-digit zip codes observed in the CWS Survey data consistently represent large metropolitan area, these values were removed from the analysis of small system income.

The "National-Level Affordability Under the 1996 Amendments to the SDWA" (EPA, 1998e) presents data for the annual water consumption, current water bills and median household income. Both means and medians were determined for each parameter for each size category. Mean values can be considered better estimates of items in their given distributions and are better suited to further mathematical manipulation. However, median values, are considered a better estimate of typical systems because the median represents the middle value and are not affected by extremely high or low values. Stakeholders were asked whether mean or median values for the three parameters should be used to establish the national-level affordability criteria. Stakeholders recommended consistency rather than a preference for using means or medians. EPA selected median values for all three parameters. EPA has chosen to express the water system financial and operational characteristics using their median values, which is a measure of their respective central tendencies. EPA believes that the national-level affordability criteria should describe the characteristics of typical systems and should not address extreme situations where costs might be extremely low or excessively burdensome. The mean values were higher than the median values for all of the parameters and size categories. For a given affordability threshold, the available expenditure margin was lower when median values were used.

The annual water consumption rates derived from the CWS Survey data are contained in Table 2. Only the median values for water consumption are included for each size category. The data are reported in 1,000 gallons per connection (kgal/connection). These consumption rates are considerably lower than the 100,000 gallons per household per year that was used in the

development of the regulations before 1996. This consumption rate was based on large systems and was extrapolated to all system size categories. The use of the annual consumption rate in making affordable technology determinations is discussed in detail in Chapter 4.

Table 2
Residential Consumption at Small Water Systems

System Size Category (Population Served)	Median Annual Consumption (kgal/connection)
25 - 500	72
501 - 3,300	74
3,301 - 10,000	77

The current annual water bills were also derived from the CWS Survey data. The CWS Survey did not directly ask for data on annual water bills. The CWS Survey did ask for data on annual sales revenue per connection by customer type. The data on residential connections were used to represent the total amounts that customers were billed during the year.

EPA evaluated the effect of source type on current annual water bills during the development of the national-level affordability criteria. Since the surface water treatment rule was promulgated in 1989, in-place treatment might be much more extensive in surface water systems than ground water systems. Since existing treatment would likely lead to higher costs, EPA looked at current water bills in both types of systems. For this analysis, the ground water systems were those systems that relied exclusively on ground water. All mixed systems were placed in the surface water system category. Ground water systems significantly outnumbered the surface water systems in all three size categories, even with the inclusion of mixed systems in the surface water category. This relationship is consistent with the profile of CWS in that ground water dominates as the source in smaller systems and surface water dominates as the source in larger systems. Table 3 contains the current annual water bills by source type for each size category. Table 4 contains the current annual water bills for all systems for each size category.

Table 3
Baseline Household Water Bills by Source Type

System Size Category (Population Served)	Current Annual Water Bills ($/household/yr)	
	Surface Water Systems	Ground Water Systems
25 - 500	$179	$211
501 - 3,300	$228	$183
3,301 - 10,000	$225	$173

Stakeholders were asked if separate baselines should be established for ground water systems and surface water systems. Stakeholders stated that separate baselines should be established, but that the distinction between ground water and surface water systems was less significant in small systems because most rely on ground water. EPA evaluated the data in Table 3 and determined that there was very little distinction between current annual water bills for ground water systems as compared to surface water systems. Thus, separate baselines were not established and the data in Table 4 were used for each size category. If separate baselines are established in the future, an in-place treatment baseline would also need to be established for surface water systems since most filtration technologies can be modified to remove other contaminants. Thus, future treatment decisions would likely involve modification of the existing process rather than installation of a new process. The technology cost evaluation is discussed in more detail in Chapter 4.

Table 4
Baseline Household Water Bills

System Size Category (Population Served)	Median Current Annual Water Bills ($/household/yr)
25 - 500	$211
501 - 3,300	$184
3,301 - 10,000	$181

The baseline annual household water bills include existing water quality, water production, and water distribution costs. Water production costs include labor and energy for pump operation to supply water to customers. Water distribution costs include costs of infrastructure

repair (mains and service lines) and administrative costs (customer billing and meter checking). The existing water quality costs include both treatment and monitoring. The CWS Survey data were collected in 1995, so treatment costs for many of the regulated contaminants may already be accounted for in the baseline. For the majority of the small systems, the bulk of the current annual household water bills are related to water production and distribution. Most ground water systems do not have extensive treatment trains.

The median household income data were derived from the 1995 CWS Survey and the 1990 Census. The linking procedure was discussed earlier. A MHI value was derived for each zip code served by the system. An average MHI was then determined for those systems that reported serving multiple zip codes. Means and medians were determined after the MHIs for each system were then grouped by size category. The median of the system-MHI values is presented for each size category in Table 5.

Table 5
Baseline Median Household Income

System Size Category (Population Served)	Median System-MHI (Census MHI - updated to 1995$)
25 - 500	$30,785
501 - 3,300	$27,058
3,301 - 10,000	$27,641

It should be noted that the data in Table 15 - National-Level Affordability Criteria - published in the Announcement of Small System Compliance Technology Lists for Existing National Primary Drinking Water Regulations and Findings Concerning Variance Technologies 63 Fed. Reg. p. 42046 (August 6, 1998) presented mean values for current water bills instead of median values. Use of mean values in Table 15 was in error. As stated in the Federal Register notice, EPA's intent was to use the median values, and this intent has not changed. The data in Table 4 are the median values for current annual water bills. The median household income for the two smallest size categories in Table 5 is slightly higher than the values in Table 15 of the Federal Register notice. A verification run of the MHI data produced slightly higher MHIs for these two size categories. The calculations using the data in Tables 4 and 5 of this document do not alter the affordability determinations discussed in the Federal Register notice in any way.

Section 3.4.2: Derivation of the Affordability Threshold

The affordability threshold was determined by comparing the cost of public water supply for households with other household expenditures and risk-averting behavior. National expenditure

estimates were derived to illustrate the current allocation of household income across a range of general household expenditures. This consumer expenditure data provided a basis for determining the affordability threshold by comparing baseline household water costs to median household income (MHI) to determine the financial impact of increased water costs on households.

Chapter 3 in "National-Level Affordability Criteria Under the 1996 Amendments to the SDWA" (EPA, 1998e) describes how comparative household expenditures were used to identify a range of options for the affordability threshold. The options range from 1.5% to 3.0% MHI. This approach is summarized below.

Data from the Consumer Expenditure Survey (CES) conducted by the Bureau of Labor Statistics (BLS) were used as the source for many of the household expenditures. The BLS defines an individual household as any of the following: 1) all members of a particular household related by blood, marriage, adoption, or other legal arrangements; 2) a financially independent person living alone or sharing a household with others, including a private home, lodging house, or permanent living quarters in a hotel or motel; or 3) two or more individuals living in the same residence, utilizing their combined income for joint expenditure decisions. For the second criterion, financial independence is defined as sole responsibility for any two of the following three expenses: housing, food, and other living expenses.

Direct comparisons between the CES data and the data derived from the CWS Survey are not possible for several reasons. The BLS's survey methodology is not designed to establish an exclusive cost for drinking water. CES data are based on reported household expenditures for water and other public services. This category includes wastewater and solid waste collection expenditures. In addition, the CES data values represent the average for all consumer units within specific demographic strata, such as size of consumer unit, income level, and region. Some expenditures may appear lower than anticipated because the value for this expenditure category is averaged over all consumer units regardless of whether they purchased the item. Another factor that may make the water expenditures appear lower is that data from households in large systems are included in the CES data. These households may experience lower water bills due to the greater economy-of-scale in large systems. The impact of these two factors is illustrated by comparing the CES data for water and other public services with the current water bill baseline for households in small systems. The CES data indicate that households are paying about 0.7% of their before tax income on water and other public services. Using the data in Tables 4 and 5, current water bills range from 0.65% to 0.69% of the median household income in the three small system size categories. Wastewater and solid waste collection will be higher than 0.05%, so direct comparison of the two data sources is not possible. However, the CES data can be used as a relative benchmark to compare the cost of water with other expenditures.

The complete range of household expenditures is described in the National-Level Affordability Document. A subset of the complete list was selected for use as comparable expenditures. In the CES data, there is a category for utilities, fuels, and other public services.

Water and other public services is included in this category. Expenditures for natural gas, electricity, and fuel oils and other fuels are also included in this category. These three utilities are competitors for power and heating, so households that do not purchase one or more of these utilities would bias the individual percentages. These three utilities were combined into one category called energy and fuels in the analysis in the National-Level Affordability Document (EPA, 1998e). The subset of comparable expenditures from the CES data is contained in Table 6.

Table 6
Summary of Select Consumer Expenditures for All Consumer Units - 1995$

Item	Consumer Expenditure as % of Income before taxes
Housing	28.3%
Transportation	16.3%
Food	12.2%
Energy and Fuels	3.3%
Telephone	1.9%
Water and other Public Services	0.7%
Entertainment	4.4%
Alcohol and Tobacco	1.5%

EPA identified an initial range of options using the CES data for the national-level affordability criteria. A floor of 1.5% of income was based on the expenditures for alcohol and tobacco in the CES data. The upper limit of 3% was based on rounding down the energy and fuels percentage listed in Table 6. Stakeholders were presented with an initial range for the affordability threshold of 1.5% to 3% of the MHI for each size category. Stakeholders, in general, did not express a strong opinion about where the affordability threshold should be set within the range. EPA selected 2.5% based on the rationale described below.

The National-Level Affordability Document contained several other comparable expenditures that were used to identify a specific affordability threshold within the range of 1.5% to 3%. The telephone expenditures in Table 6 would support an affordability threshold of 2%. The other two expenditures looked at risk-reduction activities for drinking water. Installation of a point-of-use device or the use of bottled water as an alternative to the water supplied by the system was examined.

Section 1412(b)(4)(E)(ii) of the SDWA identifies both Point-of-Entry (POE) and Point-of-Use (POU) treatment units as options for compliance technologies. A POE treatment device is a treatment device applied to the drinking water entering a house or building for the purpose of reducing contaminants in the drinking water distributed throughout the house or building. A POU treatment device is a treatment device applied to a single tap used for the purpose of reducing contaminants in drinking water at that one tap. POU devices are typically installed at the kitchen tap.

The SDWA also identifies requirements that must be met when POU or POE units are used by a water system to comply with a NPDWR. Section 1412(b)(4)(E)(ii) stipulates that "point-of-entry and point-of-use treatment units shall be owned, controlled, and maintained by the public water system or by a person under contract with the public water system to ensure proper operation and maintenance and compliance with the MCL or treatment technique and equipped with mechanical warnings to ensure that customers are automatically notified of operational problems." Other conditions in this section of the SDWA include: "If the American National Standards Institute has issued product standards applicable to a specific type of POE or POU treatment unit, individual units of that type shall not be accepted for compliance with a MCL or treatment technique unless they are independently certified in accordance with such standards."

A supporting document entitled "Cost Evaluation of Small System Compliance Options: Point-of-Use and Point-of-Entry Treatment Units" (EPA, 1998g) summarizes EPA's approach to meeting the SDWA requirements on these devices as compliance technologies. Since programs for long-term operation, maintenance, and monitoring must be provided by water utilities, this option is probably limited to the first size category (25 - 500 people). A system serving 500 people probably has between 150 and 200 households. The system would be responsible for operation, maintenance, and monitoring of a unit at or in each of these households. This is probably the realistic upper bound for the effective management of either of these options. The median number of connections for systems in the 25 - 500 size category is 50. The data in Tables 4.4.3 of the POU/POE report were used to evaluate the cost of centrally-managed POU and POE options. Household cost increases for this option were developed for several technologies: reverse osmosis, anion exchange, activated alumina, and granular activated carbon. The affordability threshold would need to be at or above 2% for the POU treatment units option to be affordable. The affordability threshold would need to be above 2.5% for the POE treatment unit option to be affordable once waste disposal costs were included. EPA does not believe that the affordability threshold should be set so low that two options specifically identified in the SDWA as compliance technologies would never qualify as compliance technologies. As it is, POE devices would not be listed as an affordable compliance technology using the selected affordability threshold. The POU costs support an affordability threshold between 2 and 2.5%. The POE costs support an affordability threshold of 2.5% or greater.

The cost of bottled water as an alternate source of water that meets the NPDWRs was also investigated as a risk-reduction activity. For this analysis, a household of three people was assumed. Water consumption was estimated at 2 liters per person per day. This same

assumption is used to derive the drinking water equivalent level (DWEL) that was discussed briefly in Section 2.2.3. The DWEL is used to determine the MCLG for the regulated non-carcinogenic contaminants. A cost per gallon rate of $0.98 was used for this analysis. This rate is the average price for home delivery from the International Bottled Water Association. A cost per household per year of approximately $570 was derived from these data. The bottled water costs would be in addition to what the household is currently paying for water. The bottled water costs support an affordability threshold of 2.5% or higher, depending upon the size category.

Another factor in the decision of where to set the affordability threshold was that EPA believes that small system variances are intended to be very rare, based on the requirements of the SDWA. Variance technologies are intended for systems with very poor source water such that the costs of compliance would not be affordable. Thus, the affordability criteria should be set, in EPA's view, high enough that the majority of the systems will proceed down the compliance pathway. The compliance and variance pathways are illustrated in Figure 2 in Section 1.3. The right-hand side of this figure shows the steps that a small system must pass through before receiving a small system variance and installing a variance technology.

The first step is to determine if there is an affordable compliance technology. Variance technologies are only identified when there are no affordable compliance technologies. As long as one potential compliance technology can pass the affordability criteria, there won't be variance technologies. If there are five potential compliance technologies and only one passes the affordability criteria, variance technologies would not be identified for that system size/source water quality combination. This shows that the goal for most systems should be compliance with the NPDWR, since only one technology needs to meet the affordability criteria to eliminate the availability of variance technologies. When affordable compliance technologies are not available, variance technologies will be identified. However, small systems must evaluate the affordability of treatment, alternate source, and restructuring at the system-level before a small system variance can be considered. Thus, the structure of the SDWA requirements indicates that small system variances should be considered as a last resort.

The approach to establishing the national-level affordability criteria did not establish a baseline for in-place treatment technology. The baseline for annual water bills was determined for each size category rather than creating many smaller sub-categories based on the degree of existing treatment. There were two reasons for this approach. The difference between annual water bills in ground water and surface water systems was not significant even though there would be differences in existing treatment. The second reason is that the sample size of the data that would be used to determine the baseline for annual water bills would be very small for some of the sub-categories. One consequence of this approach is that some of the treatment costs for the regulations covered in this guidance are already included in the baseline of annual water bills. The regulations for the contaminants that were initially eligible to receive small system variances were promulgated between 1986 and 1992. The CWS Survey was conducted in 1995. Some of the treatment costs are already incorporated into the baseline for current annual water bills. A group of five small surface water systems with annual water bills above $500 per household per

year were examined. All of these systems had installed disinfection and filtration technologies to comply with the surface water treatment rule (SWTR). The SWTR was promulgated in 1989. The treatment cost comparisons in Chapter 4 assumed that there was no existing treatment capable of removing the contaminant or being modified to remove the contaminant. This is a conservative assumption for some systems (especially surface water systems) because they have already made an investment in technology that is reflected in the customer's annual water bills. The assumption that these systems would need to install a new technology overestimates the costs of compliance for these systems.

Another important factor is that under this approach to national-level affordability criteria, the affordability threshold is set at 2.5% of MHI for existing and future regulations. The baseline for annual water bills will increase as treatment is installed to comply with regulations and as backlog infrastructure needs are met. EPA intends to conduct the Community Water Supply Surveys every five years and will be able to track the increases in water bills due to treatment or infrastructure repair. In the interim, between CWS Surveys, EPA will adjust the baseline for annual water bills to incorporate the projected impact of regulations. For example, if arsenic follows the disinfection by-product, and radon rules, the impact of these rules will be incorporated into the baseline annual water bills used to make the affordable technology determinations for arsenic. Since the baseline water bills will be higher, the available expenditure margins for comparison with arsenic treatment costs will be lower than that listed in Section 3.5. The consumer price index data shows water prices increasing at a faster rate than all items over the last 10 years (EPA, 1998e). This implies that water prices should increase faster than median household income and that the available expenditure margin will decrease over time. The impacts of new regulations will further decrease the available expenditure margin over time. Thus, while variance technologies are not available for the currently regulated contaminants, a decreasing available expenditure margin increases the likelihood of variance technologies for future regulations.

The final piece of supporting rationale is that EPA believes that the goal of the SDWA is still to provide the same high quality drinking water for all customers of public water systems. The SDWA does not, in EPA's view, envision a two-tiered approach for standards where large systems are complying with the NPDWR and small systems are operating at some level above the MCL that is protective of public health for the duration of a small system variance. The small system variance option should be the exception and not the rule. Ideally, only a small subset of small systems would ever operate under a small system variance. If the affordability threshold were set so low that variance technologies were needed for regulations that were promulgated at least six years ago, then affordability would be a significant issue for all future regulations. Under such an affordability threshold, the small system variance option would become the rule rather than the exception.

Section 3.5: National-Level Affordability Criteria

The national-level affordability criteria are based on an affordability threshold of 2.5% of

the median household income (MHI). As discussed in Section 3.4.1, the baseline values for median household income and current water bills have changed slightly from the Federal Register notice. The correct baseline water bills ranged from 0.65% to 0.69% MHI in the three size categories. Thus, the available expenditure margins were approximately 1.8% MHI for each size category. Table 7 summarizes the national-level affordability criteria and shows the maximum increase that could occur using these criteria.

Most systems would not be expected to actually experience cost increases of this magnitude if a compliance technology was installed. Many compliance technologies impose substantially lower household costs. For example, the screening process examined several technologies that imposed less than $300/household per year increases in all three size categories. The treatment costs used for the affordable technology determinations were based on treatment of all of the water to achieve the maximum removal efficiency. Most systems will not need the maximum removal efficiency to comply with a NPDWR. As was noted in Section III of the August 6, 1998 Federal Register notice, blending is an option to reduce the cost of treatment when lower removals are needed for compliance. A portion of the influent stream can be treated and blended with an untreated portion to still meet the MCL. Under this scenario, both capital and operating and maintenance costs would be lower than the estimates for the full stream treatment. Since blending would lower the rate increase for water, household costs would be lower.

Another factor that would result in lower household costs is that the approach to establishing the national-level affordability criteria assumes that all treatment costs are borne by the systems and passed along to customers. The national-level affordability criteria do not consider the impact of financial assistance from State Revolving Fund loans or Rural Utility Service. Loans or grants would reduce the amortized capital costs in these systems. This would lead to lower impacts at the household level in those systems that qualify for financial assistance. There are other mitigating measures that can reduce the impact on households. Rate design, consolidation strategies and regionalization approaches are discussed in Appendix F of the "National-Level Affordability Criteria Under the 1996 Amendments to the Safe Drinking Water Act" report.

Table 7
National-Level Affordability Criteria

System Size	Baseline			Affordability	Available Expenditure
Population Served	MHI ($/yr)	Water Bills ($/hh/yr)	Water Bills (%MHI)	Threshold (2.5% MHI)	Margin ($/hh/year increase)
25 - 500	$30,785	$211	0.69%	$770	$559
501 - 3,300	$27,058	$184	0.68%	$676	$492
3,301 - 10,000	$27,641	$181	0.65%	$691	$474

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4.0 AFFORDABLE TECHNOLOGY DETERMINATIONS

Section 4.1: Overview

The two-stage screening process for variance technologies was described in Chapter 2. Only 5 of the 80 regulated contaminants passes through this screening process and remained eligible for variance technologies. These five contaminants were: antimony, asbestos, atrazine, di-(2-ethylhexyl) phthalate, and lindane. The national-level affordability criteria were described in Chapter 3. Table 6 lists the derived criteria for each of the three size categories. This chapter describes how the affordable technology determinations were made for these five contaminants.

Section 4.2: Results of SDWIS Run of Violations

The last screen in the two-stage screening process utilized the violation data in the Safe Drinking Water Information System (SDWIS) to identify systems that might need to install treatment to comply with one of the existing NPDWRs (EPA, 1997a). MCL violations were found in SDWIS for the five contaminants that passed through the screening process. There were 142 MCL violations listed for these five contaminants. The breakdown was as follows: 34 violations for antimony, 6 for asbestos, 92 for atrazine, 8 for di-(2-ethylhexyl) phthalate and 2 for lindane. The concentration listed in SDWIS as the MCL exceedance was examined for all 142 violations. The States were contacted to inquire about the compliance status of the system and to verify the concentration reported in SDWIS. The compliance status was checked to see how many of these systems had already complied with the NPDWR after the violation occurred. The concentration listed in SDWIS was verified because several appeared to be reported using incorrect units. Some values were reported in μg/L instead of mg/L. It was important to get the correct units for the violations because this data was used to estimate the removal efficiency needed to comply with the NPDWR. Asbestos posed a unique problem since it has different units than the other chemical regulations. The MCL for asbestos is measured in million fibers per liter rather than milligrams per liter. For asbestos, violations had to be verified because some were reported as fibers per liter instead of million fibers per liter. The asbestos violations were also checked to determine the source of the asbestos. Asbestos can be found in the raw water entering the treatment plant or it can occur from the corrosion of asbestos-cement pipe in the distribution system. Different treatment technologies would be applied depending upon the source of the asbestos.

The States indicated that 140 of the 142 systems were back in compliance with the NPDWRs. The two systems that were not yet in compliance had violations of the asbestos standard. The source of the asbestos in both of these systems was the corrosion of asbestos-cement pipe. Even though the vast majority of the systems were back in compliance, the violation data was used to determine if affordable compliance technologies existed for these five contaminants. The concentrations for the highest violations (after verification of the units) were used to compare with the MCL to determine the maximum removal efficiency needed for compliance. This maximum removal efficiency was used to estimate treatment costs that were

compared with the national-level affordability criteria. If the treatment costs for one technology were found to be affordable, then variance technologies were no longer available. This approach is very conservative on the cost side because the worst-case system was used to determine the removal efficiency.

For the five contaminants, the derived maximum removal efficiency exceeded 80 percent. Since most treatment technologies are generally capable of achieving removal efficiencies between 90 and 95 percent, treatment costs were based on this upper limit of performance. Thus, the costs assume treatment of all of the water. Treatment of a portion of the influent water and blending it with an untreated portion to reduce costs was not assumed in the development of the treatment costs. When the concentration above the MCL is low enough, blending can be used to reduce costs while still meeting the MCL. Both capital and operating and maintenance (O&M) costs can be reduced by blending as described above. For the systems that do not need the maximum removal efficiency, the treatment costs used to make the affordable technology determinations are an overestimate of the costs their customers would see if a technology were installed for compliance.

Section 4.3: Treatment Cost Models

The potential compliance technologies identified for these five contaminants included both central treatment options and point-of-use (POU) options. Under the central treatment options, all of the water supplied by the system is treated. Under the POU options, only the water at one tap within a residence is treated. All of the other water in the house is not treated to reduce contaminant concentrations. It was assumed that the kitchen tap would be treated for these options.

For the central treatment options, three cost models were used to make treatment cost estimates. The cost models have different ranges of applicability based on design flow. The design flow is related to the production capacity of the treatment unit and is larger than the peak daily flow for the system. The design flow is used to estimate capital costs for the system. The average daily flow is used to make estimates for the O&M costs. Thus, the treatment unit is sized based on production capacity and the operating costs are based on the volume of water being treated for distribution.

The first cost model is for very small systems with a design flow below 270,000 gallons per day. The document entitled "Very Small Systems Best Available Technology Document" provides equations for estimating capital and O&M costs for these systems (EPA, 1993a). The Water Model is a set of cost curves for various technologies contained in the document entitled "Small System Water Treatment Costs (EPA, 1984). The third model is the WATERCO$T model (Computer Software for Estimating Water and Wastewater Treatment Costs, Version 2.0, 1994). This is a computer model used for the estimation of costs for systems with flows larger than 1 million gallons per day. The costing models generate discrete cost estimates corresponding to specific design and average daily flow inputs.

A byproducts stream is produced by some of the technologies used to treat drinking water contaminants. These byproducts streams are typically associated with the treatment of inorganic contaminants. Coagulation/filtration and lime softening produce sludges that require disposal. Membrane technologies produce a concentrate stream. Ion exchange and activated alumina produce brine streams. Two additional cost models are used to estimate the costs of disposal of these residual byproduct streams. The document entitled "Small Water System Byproducts Treatment and Disposal Cost Document" (EPA, 1993b) provides equations for capital and O&M costs for technologies to dispose of residual byproducts. These cost equations are intended for systems in the first two size categories (25 - 500 and 501 - 3,300 people). The equations for capital and O&M costs for systems in the 3,301 - 10,000 people served category were taken from the document entitled "Water System Byproducts Treatment and Disposal Cost Document" (EPA, 1993c).

For the POU options, the document entitled "Cost Evaluation of Small System Compliance Options: Point-of-Use and Point-of-Entry Treatment Units" (EPA, 1998a) was used. This document contains capital and O&M cost equations for a variety of POU and POE options. Table 4.4.3 contains the data on total costs that was used to generate the equations for each of the processes.

Section 4.4: Model Systems

As described in Section 4.3, the capital costs are based on design flow and the O&M costs are based on average daily flow. The capital costs were amortized over 20 years at an interest rate of 7%. The annualized capital costs were combined with the annual O&M costs to determine the total production costs. The units for the total production cost are dollars per thousand gallons ($/kgal).

In order to derive capital and O&M costs for central treatment options, design and average daily flows are needed for a typical system within each size category. The selected design and average daily flows are based on the flows that were used in the regulations developed during the early 1990s. The design and average daily flows for the five size categories that were used to derive the flows for this analysis are contained in Table 8. For small systems, the design and average daily flow are reported in thousand gallons per day (kgpd). Since the categories used in the regulations are more stratified than the small system categories in the SDWA, a weighted average of the flows was derived for each of the first two SDWA small system categories from the data in Table 8. The number of systems within each size category in Table 8 was used for the weighting factor in determining the flows for the SDWA categories. The design and average daily flows used to derive costs for the affordable technology determinations are contained in Table 9.

Table 8
Design and Average Daily Flows Used for Regulations (early 1990s)

System Size Category (population served)	Design Flow (kgpd)	Average Daily Flow (kgpd)
25 - 100	24	5.6
101 - 500	87	24
501- 1,000	270	86
1,001 - 3,300	650	230
3,301 - 10,000	1,800	700

Table 9
Design and Average Daily Flows Used for Affordable Technology Determinations

System Size Category (population served)	Design Flow (kgpd)	Average Daily Flow (kgpd)
25 - 500	58	15
501 - 3,300	500	170
3,301 - 10,000	1,800	700

As discussed in Section 3.4.2, the centrally-managed point-of-use options is probably only cost-effective in the 25 - 500 size category. In the POU/POE report (EPA, 1998a), costs for POU and POE options were compared against central treatment costs. The costs for the centrally-managed POU option had to be converted to the same flow basis for this comparison and to make the affordable technology determinations. The cost estimates for the centrally-managed POU treatment options are presented in dollars per thousand gallons used by the household. This is very different than the cost per gallon treated by the POU device. By converting the cost per gallon treated into the cost per thousand gallons used by the household, the POU costs are comparable with central treatment costs. The breakpoint for POU options was between 70 and 180 households depending upon the technology. The central treatment costs did not include waste disposal costs. The inclusion of waste disposal would shift the breakpoint for central treatment costs being cheaper than centrally-managed POU costs to a higher number of

households. It is unlikely that the centrally-managed POU would be more cost-effective than central treatment after the 25 - 500 size category (upper bound of approximately 200 households). Due to increasing administrative costs and increasing coordination difficulties, it is not expected that larger communities will find the implementation of centrally-managed POU or POE devices to be cost-effective. However, affordable technology determinations were made for the larger size categories.

The POU option cost equations use the number of households as the dependent variable. The subset of data from the Community Water Supply Survey (EPA, 1997a) that was used to develop the baseline for current water bills also contained data on residential connections. This data was used to determine the median number of residential connections within each size category. The number of connections was assumed to be the number of households for each size category. The POU costs were derived using the number of households in Table 10.

Table 10
Number of Households by Size Category for POU/POE Options

System Size Category (population served)	Number of Residential Households (Median for size category)
25 - 500	50
501 - 3,300	425
3,301 - 10,000	1935

Both the central treatment and the POU treatment costs provide the rate increase associated with the installation of treatment. The treatment cost models produce rate increases measured in dollars/thousand gallons ($/kgal). Annual household water consumption (kgal/year) is needed to convert the treatment technology costs into the increase in annual household water bills. The water consumption data in Table 2 were used with the cost increases derived by the models to estimate annual household cost increases for each treatment technology. The water consumption estimates in Table 2 were multiplied by 1.15 to account for lost water due to leaks. Since the water lost to leaks is unbilled, the water bills for the actual water used were adjusted to cover this lost water by increasing the household consumption. The adjusted consumption rates were then multiplied by the rate increase imposed by treatment to determine the annual cost increase for the household. This annual water bill increase was compared with the available expenditure margin to determine if there was an affordable technology.

Section 4.5: Treatment Cost Estimates

Affordability only played a role in removing some of the options in the smallest size

category. In the larger two size categories, all of the treatment technologies produced annual household water bill increases below the available expenditure margin. However, in the smallest size category, the centrally-managed POU option was typically the only affordable option. The cost estimates for the centrally-managed POU options were all below $400 per household per year in all of the size categories. For antimony, the only affordable treatment option was the centrally-managed POU reverse osmosis option. For the three SOCs (atrazine, di-(2-ethylhexyl)phthalate, and lindane), the centrally-managed POU granular activated carbon units were one of the two technologies identified as affordable in the 25 - 500 size category. The other affordable compliance technology was powdered activated carbon. This technology is only affordable when the system already has a process train that includes basins, mixing, precipitation or sedimentation, and filtration. Since the affordability of this technology is linked to existing treatment, the centrally-managed POU GAC option is the only affordable option identified for the majority of the systems in this size category. The affordable compliance technologies and the technologies that did not pass the affordability criteria are identified in Table 11. For a detailed description of the compliance technologies for the five contaminants, see the Compliance Technology List for Non-Microbial Contaminants Regulated Before 1996 (EPA, 1998c).

Table 11
Affordable and Other Compliance Technologies in the 25 - 500 Size Category

Contaminant	Affordable Compliance Technologies	Other Compliance Technologies
Antimony	POU RO	RO, C/F
Asbestos	DF, DEF, CC	C/F
Atrazine	POU GAC, PAC	GAC
di-(2-ethylhexyl) phthtalate	POU GAC, PAC	GAC
Lindane	POU GAC, PAC	GAC

KEY: POU = Point-of-Use RO = reverse osmosis
C/F = coagulation/filtration DF = direct filtration
DEF = diatomaceous earth filtration CC = corrosion control
PAC = powdered activated carbon (for plants with existing filtration)
GAC = granular activated carbon

As previously discussed, the worst-case system based on occurrence was selected to determine the removal efficiency for treatment costs. Since many of the other systems that exceed an MCL would need lower removals to comply with the MCL, other treatment alternatives may be affordable through the use of blending. Systems and States should consider the technologies in the "other compliance technologies" category when blending can be

performed to reduce costs while still meeting the MCL.

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5.0 SUMMARY OF VARIANCE TECHNOLOGY FINDINGS FOR CONTAMINANTS REGULATED BEFORE 1996

As previously discussed, compliance and variance technologies are mutually exclusive. The two compliance technology lists developed by EPA for contaminants regulated before 1996 identified compliance technologies for all of the 80 regulated contaminants, including affordable compliance technologies for all classes of small systems where appropriate. The two-stage screening process removed all but five contaminants. Affordable compliance technologies were identified for those five contaminants as discussed in Chapter 4. *Thus, EPA will not, at this time, be listing variance technologies for any existing NPDWR..*

Because this is the first time that EPA has undertaken the variance technology analysis required under the amended SDWA (which includes new findings concerning "affordability" and "protectiveness") and given the relatively short time for development of this analysis, EPA considers the methodology described here and the resulting finding of no variance technologies to be an initial screening effort, rather than a final determination of any kind. In addition, by enabling EPA to list compliance and variance technologies rather than specifying them by regulation, the statute specifically contemplates that this analysis (and any resulting list) will be subject to revision based on new information and petitions from interested parties. EPA would be very interested in suggestions from the public, and particularly from States, about how to improve the methodology outlined here and discussed in the guidance and in variance technologies that EPA should consider in revising and updating any future variance technology list. EPA identified several elements of the methodology in this document that would undergo further review over the course of the next year.

EPA stated in Chapter 2 that the procedures used to determine unreasonable risk to health (URTH) values were under review. EPA will issue a revised guidance manual for determining URTH as a result of that process. The URTH values listed in Table 1 will be modified or recalculated using the new procedures for determining URTH values. The revised URTH values for the 19 contaminants removed from consideration for variance technologies by the URTH screen will be examined to see if there is a level above the MCL that may be protective of public health for the expected useful life of a technology. Contaminants for which this screen is no longer applicable would continue through the remainder of the screening process before proceeding into the affordable compliance technology determination step.

EPA stated in Chapter 2 that it would re-examine the SDWIS violation data to see if violations were reported for the contaminants removed by the "lack of violation" screen. There were five contaminants removed by this screen. If MCL violations are found in a subsequent SDWIS run, then the violation data would be used to determine if there is an affordable compliance technology.

EPA indicated in Chapter 3 that a link was not established between baseline annual water bills and existing treatment in the national-level affordability criteria. EPA will examine whether

this link should be established including an examination of the sample sizes. If a baseline for treatment is deemed necessary, then separate baselines would need to made for each source type because surface water systems should have a more extensive treatment technology baseline.

EPA will evaluate the comments that are received on the initial variance technology findings. If these evaluations indicate a need for variance technologies for the contaminants regulated before 1996, then a list with variance technologies may be issued in August 1999; or sooner, if warranted.

Senator CRAPO. And this might be a good opportunity for me to divert from the specifics of the Safe Drinking Water Act to a general question that I have that relates to this issue, and to virtually all of the other regulatory issues we face in the country. And that is, the cost of regulations. Regardless of whatever regulation we're dealing with, particularly when they deal with the public health, the argument is that if we don't do whatever it is that the regulation proposes, that we're going to see a reduction in the quality of life or a reduction in the quality of health in the country.

A dimension of that argument has been brought forward in the last few years that each of these activities has a cost to it. We've been discussing the cost here. And that each time you take from a family resources, in this case, say we're taking $250 or $500 from a family, you are impacting that family's ability to provide for its own health care, provide for its own quality of life and so forth. And that there is a reduction in the public health by taking resources from the family and from the community at large.

The argument in response, I would think, seems to have to be that the benefit that is being gained by taking those resources from the community is greater than the benefit of leaving those resources in the community. And you've probably seen the same studies I have. Some studies say that that's rarely the case and some studies say that that's always the case, or they justify it in each individual case.

I just want to, on a sort of a policy or principle level, ask your opinion, Mr. Fox, and Dr. Noonan and Ms. Dougherty, you're welcome to jump in on this. Do you agree that each time we pass regulatory requirements into law that cause a financial impact on society that that does by taking from society those resources, it does have an impact on the quality of life?

Mr. FOX. There's no question that there are economic impacts on all sides of the ledger as a result of the actions we take. I can tell you from the drinking water standpoint, and certainly all the Water Office regulations that I'm familiar with, we do fairly extensive cost benefit analysis of these various proposals. And some of them are easier to do than others.

When there is a drinking water rule with documented, significant public health benefits, we can attribute some dollars associated with those benefits. Sometimes it's easier than others. Cancer, for example, is sometimes a very difficult risk to cost, because it's often very subtle, it's often very long-term. We're often talking about a very small number of the population that are particularly affected by it.

But some of our microbial rules, for example, have much more immediate and frankly acute effects, such as some of the effects of Cryptosporidium or E. coli and the like. We try to do our best to evaluate this. I will be the first to say that I've spent a good deal of time with economists, and not unlike lawyers, you can get them to hold a wide variety of opinions as to ultimately what the predictable impact of something is. But we really do our best to evaluate costs and benefits to give that information to the public, take comment on it, and ultimately come up with a sound rule as a result of it.

Senator CRAPO. I'm assuming that you identify risks associated with whatever situation you're dealing with, and somehow quantify those risks.

Mr. FOX. That's correct.

Senator CRAPO. And I am also assuming, in fact, I've seen analyses that try to quantify the risk of taking resources from the community. If we can trust our quantification of these respective risks, I assume you didn't compare those two risks. Is that what's being done?

Mr. FOX. We so not compare those risks specifically, but it gets a lot more complicated, because there are so many risks that you can't quantify and they become much more qualitative. And you then have to make certain judgments about the risks. I suspect we will spend this morning some time this morning on the subject of arsenic, for example. There is a good deal of information about some cancer endpoints associated with arsenic that we can quantify. There's a lot of information about some cancer endpoints that we can't quantify very well, and there's certainly a lot of information about completely non-cancer end points that we have a very difficult time quantifying.

So these judgments do become fairly qualitative at some fundamental level. This is all the information that we try to put together. One of the other judgments that's fascinating—I spend a good deal of time with economists trying to do this on the Clean Water Act—is determining the value of clean water. There is an interesting set of statistics about what people perceive concerning the value of clean water. In other words, "What is it worth for me to know that I have a stream nearby that is clean." There is a value to that, and economists even try and quantify that.

So it is very difficult and certainly an important and emerging science.

Senator CRAPO. I've seen some of those formulas. Dr. Noonan?

Dr. NOONAN. Actually, Mr. Chairman, I'd like to address your question about the premise that if we don't implement rules, somehow the public health will be reduced from a baseline. That assumes that we can measure a baseline for public health.

But I think the other way of looking at it is, in many cases when we implement rules, we actually improve public health from the baseline. In which case you're actually putting resources back into the community that might have been spent on mitigation of bacterial disease, might have been spent on hospitals stays, might have been spent on doctor visits, that won't be because we have implemented rules that will mitigate microbial contaminants.

Senator CRAPO. Sort of the prevention side of the issue.

Dr. NOONAN. Exactly. And I think that one of the things that is increasingly obvious is that the country as a whole needs to consider much more in terms of preventive medicine rather than curing disease once we have it.

Senator CRAPO. I would agree with that.

Dr. NOONAN. And I will also say one other thing, and that is we are sponsoring, in ORD, a lot of work in environmental economics and social sciences that may help us to elucidate some better mechanisms for evaluation of these kinds of currently unquantifiable benefits. In fact, if I may say, we are currently the largest funder

of environmental economics research now in the Federal Government, and nearly all of that work is done in universities.

Senator CRAPO. Well, thank you. And I'm very interested in that. So if there are any primers or papers that you have on that that don't take a scientist to read, I've love you to send them in to me and let me review them. Because that's a very interesting topic to me.

Another aspect of this topic, though, gets back to what I've always called and heard referred to as the old 80–20 rule, or the idea that you get a major part of your benefit, like 80 percent of your benefit from the first 20 percent of the dollars you spend. And as you get closer and closer and closer to those ultimate refinements, you spend much, much more money to get each added incremental increase in whatever it is that we are working on. And that does relate directly back to questions like arsenic and some of those rules.

And here's the question I raise, in a broader context or you can answer this in the context of arsenic, if you want to use it as an example. But it seems to me that we very often approach these kinds of issues with an assumption that seems to say that each increased reduction of a pollutant or a contaminant in whatever water supply or whatever it is that we're dealing with increases the public health in sort of a straight line basis, whatever that increase has been for the earlier reductions, we assume that it is that way for even the later reductions.

And as we are able to technologically able to calculate and to identify smaller and smaller percentages of pollutant in a water source, to take an example, I raise the question of whether the cost benefit analysis remains the same as the cost for removing that extra one part per billion triples and the benefit of the removing that last little one part per billion plummets. And it seems to me that that question has to come into play as we look at whether to go from 50 parts to billion to 5 parts per billion, or maybe 1 part per trillion or whatever it is that the next scientific advance will let us measure.

Would you respond, Mr. Fox?

Mr. FOX. Yes. In fact, you hit on precisely the deliberations that I faced on arsenic and making a decision about what number to propose. The conventional wisdom is exactly as you suggest, and the experience in the wastewater area was precisely that. The cost per pound removal for the first 90 percent is X, and then for the next 10 percent becomes 2X, 3X as you get further and further.

I think it was that paradigm, if you will, that led this committee to draft an amendment to the Safe Drinking Water Act that allowed us to consider cost in establishing a drinking water standard. It was the principle that public health protection can be maximized at minimal cost. When I was first briefed on arsenic, I asked staff to let me see this beautiful asymptotic curve that's going to show me precisely where to pick the arsenic number, but it didn't come out that way.

The unfortunate reality with arsenic, it that it is very linear. What we ended up seeing because of the nature of the treatment technologies is that any given arsenic level I picked ended up providing a certain amount of protection to a certain amount of people

at a certain amount of cost. And this graph ended up being pretty much linear.

So I was faced with having to decide how many million Americans do I want to protect, and what is the appropriate cost. It wasn't the wonderful curve that I had hoped to see in environmental protection.

Senator CRAPO. Well, let me ask you a question. I'm assuming that there is some point at which the level of arsenic in the water is so low that it's probably below background for what is normal in water in naturally occurring circumstances. Are you telling me that if we can identify one part per trillion that that one part has to be removed?

Mr. FOX. No. Let me make it specific using arsenic as an example. The way we normally do drinking water regulations and the way the statute directs us is to start from what we call feasible: that is, what is the feasible level. Feasibility is a cost and monitoring test, and it is generally the number that we try to pick.

In arsenic, the feasible number would have been three parts per billion. We moved off from the feasible level based on an evaluation that, in fact, there were some economic considerations that we had to consider.

Senator CRAPO. Let me ask you a question. When you say feasible, you mean, leaving cost aside, it's what we technologically can achieve?

Mr. FOX. No. Feasible is: what can you technologically achieve, taking costs into consideration, and what do our monitoring capabilities allow us to measure down to.

Senator CRAPO. That was three parts per billion?

Mr. FOX. That's correct. For large systems.

Senator CRAPO. For large systems, OK. How about for small systems?

Mr. FOX. The feasibility history only applies to large systems.

Senator CRAPO. Then proceed. Then you add a cost analysis, a cost benefit analysis?

Mr. FOX. Right. Staying with arsenic for just a second, the National Academy of Sciences issued a report on arsenic. Depending on how you evaluate the study, and I would truly believe that we followed it to the best that we could, they said 50 parts per billion was clearly unsafe. In fact, they said 50 parts per billion was a risk range of about 10 to the minus 3. If you do extrapolate the National Academy of Sciences study down, you're probably in the range of 4 to 6 parts per billion, and I'm sure other witnesses are going to have different opinions on this. But that's certainly where we ended up coming down on this one.

If you end up considering the normal Agency risk range, how we've done these things in the past, which is typically 10 to the minus 4 to 10 to the minus 6 for a cancer range, your arsenic number would actually be well below three.

Dr. NOONAN. About 2 parts per billion.

Mr. FOX. About 2 parts per billion to 10^{-4}. So tradition, if you will, for drinking water was leading us to an arsenic number that was very low. The National Academy was pulling this way down, our traditional agency risk range would have even been below three, and the feasibility analysis would have taken us to three.

Given this pressure on arsenic, we then took the new language of the Safe Drinking Water Act that allows us to consider costs, and it gave us the ability to move off of what was feasible based on a consideration of cost, and that's basically how we ended up at five.

As I discussed earlier, when you look at these various cost estimates, it truly became very linear. And as the cost doubled the number of populations served doubled, and that was related to a halving of, in effect, a halving of the arsenic standard. And it ended up staying at that relationship through much of the line.

Senator CRAPO. Is arsenic naturally occurring in water?

Mr. FOX. Yes. Arsenic is a naturally occurring substance. But it is also a byproduct of other, if you will, industrial activities. Mining is one of the most common.

Senator CRAPO. And do we have an understanding of what the natural occurrence—I realize that varies I'm sure from regions.

Dr. NOONAN. It varies. It's quite geographically variable.

Senator CRAPO. But what is the range of naturally occurring arsenic?

Mr. FOX. We have good country maps that we can get to you. Generally speaking, in the southwestern and western regions of the country, arsenic levels in ground water are fairly high. There actually are pockets in New Hampshire, for example, and other States around the country.

[The information referred to follows:]

USGS
science for a changing world

Attachment I

Arsenic in Ground-Water Resources of the United States

Arsenic is a naturally occurring element in rocks, soils, and the waters in contact with them. Recognized as a toxic element for centuries, arsenic today also is a human health concern because it can contribute to skin, bladder, and other cancers (National Research Council, 1999). Recently, the National Research Council (1999) recommended lowering the current maximum contaminant level (MCL) allowed for arsenic in drinking water of 50 µg/L (micrograms per liter), citing risks for developing bladder and other cancers. The U.S. Environmental Protection Agency (USEPA) will propose a new, and likely lower, arsenic MCL during 2000 (U.S. Environmental Protection Agency, 2000). This fact sheet provides information on where and to what extent natural concentrations of arsenic in ground water exceed possible new standards.

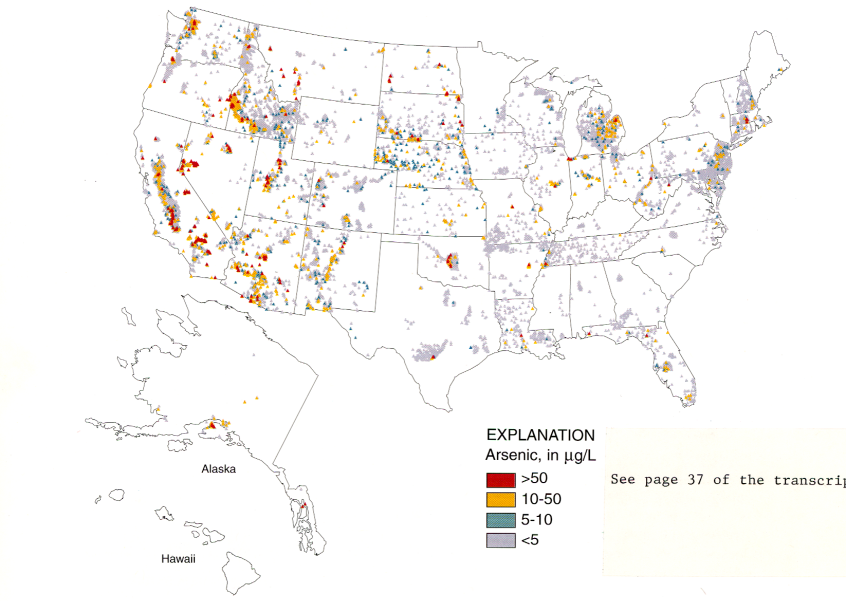

Figure 1. *Arsenic concentrations in ground water of the United States.*

U.S. Department of the Interior
U.S. Geological Survey

Fact Sheet FS–063–00
May 2000

The U.S. Geological Survey (USGS) has collected and analyzed arsenic in potable (drinkable) water from 18,850 wells in 595 counties across the United States during the past two decades. These wells are used for irrigation, industrial purposes, and research, as well as for public and private water supply. Arsenic concentrations in samples from these wells are similar to those found in nearby public supplies (see Focazio and others, 1999). The large number of samples, broad geographic coverage, and consistency of methods produce a more accurate and detailed picture of arsenic concentrations than provided by any previous studies.

Where do high concentrations of arsenic in ground water occur in the United States?

Arsenic concentrations in ground water generally are highest in the West. Parts of the Midwest and Northeast also have arsenic concentrations that exceed 10 µg/L, the World Health Organization's (WHO) provisional guideline for arsenic in drinking water (World Health Organization, 1999). Arsenic concentrations appear to be lower in the Southeast, based on a smaller amount of data. Arsenic concentrations also could be high at locations not shown on figure 1 because data are not available everywhere. Even at sampled locations, concentrations might differ between shallow and deep waters. Nonetheless, these data illustrate how arsenic concentrations vary across broad regions of the country.

How frequently are arsenic concentrations in ground water likely to exceed possible new maximum contaminant levels?

To look at the Nation as a whole, arsenic data were grouped by county and linked to the number of public-supply systems withdrawing ground water in each county (Focazio and others, 1999). Estimates of the percentage of small public water-supply systems which exceed six targeted arsenic concentrations in their ground-water resource are shown in figure 2. Systems were called "small" if they served between 1,000 and 10,000 persons. Focazio and others (1999) provide similar information for both smaller and larger sized systems. The highest concentration evaluated is at the current MCL of 50 µg/L, along with several lower concentrations, one of which may become the new MCL.

As the concentration for a possible new MCL decreases, the likelihood of exceeding that standard increases. Just over 13 percent of small systems used water with arsenic concentrations greater than 5 µg/L, compared to fewer than 1 percent exceeding the current 50 µg/L MCL. Public systems exceeding a new, lower MCL will be required to either treat their water or find alternative sources of supply. This choice undoubtedly will increase costs for consumers while decreasing their exposure to arsenic. Although homeowners with private wells are not regulated, a lower drinking-water standard would mean that more homeowners will be consuming water with concentrations that exceed a standard.

USGS information provides a broad picture of arsenic concentrations in ground water throughout the United States. In 24 percent of the U.S. counties where data were available, at least 10 percent of samples had arsenic concentrations exceeding 10 µg/L, the WHO provisional guideline for arsenic. Water users in these counties (colored darkest brown in fig. 3) are the most likely to have ground water exceeding new standards for arsenic.

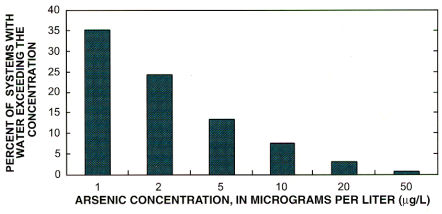

Figure 2. *Percentage of small public water-supply systems estimated to exceed targeted arsenic concentrations in their ground-water resource (µg/L, micrograms per liter).*

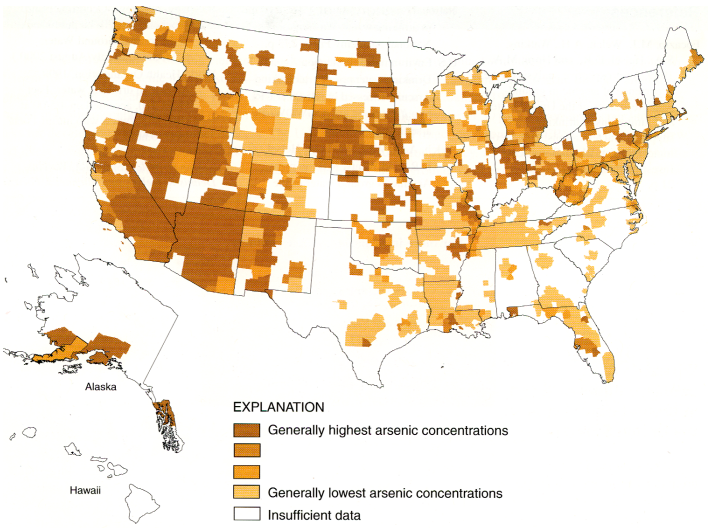

Figure 3. *Counties with arsenic concentrations exceeding possible new MCLs in 10 percent or more of ground-water samples.*

Counties with arsenic concentrations exceeding 10 µg/L in 10 percent or more of samples.

Counties with arsenic concentrations exceeding 5 µg/L in 10 percent or more of samples.

Counties with arsenic concentrations exceeding 3 µg/L in 10 percent or more of samples.

Counties with fewer than 10 percent of samples exceeding 3 µg/L, representing areas of lowest concentration.

Counties with insufficient data in the USGS data base to make estimates.

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—Alan H. Welch, Sharon A. Watkins, Dennis R. Helsel, and Michael J. Focazio

For more information, please contact:

Dennis Helsel
U.S. Geological Survey
Box 25046, MS 415
Denver Federal Center
Denver, CO 80225–0046
dhelsel@usgs.gov

http://co.water.usgs.gov/trace

Senator CRAPO. Now, you said that the tradition or the 10 $^{-4}$——
Dr. NOONAN. Let me try to explain, Mr. chairman.
Senator CRAPO. How do we get to that?

Dr. NOONAN. Typically what we look at what level of a particular pollutant or substance causes obvious adverse health effects. In other words, where do you begin to see real frank adverse effects in people. In this case, for arsenic, what we looked at, and what we had the best evidence on, was cancer risk—bladder cancer and skin cancer.

Senator CRAPO. Now, it's going to be different for different substances, right?

Dr. NOONAN. Oh, yes. Absolutely. Absolutely.

In the case of arsenic, you begin to see obvious adverse effects that are lethal, that is, bladder cancer and skin cancer, at a level of somewhere between 200 and 500 parts per billion. Typically what the Agency does in a risk assessment, it says, OK, we need a margin of safety below that adverse effect level. And our typical margins of safety bring us down to somewhere between 10^{-4} and 10^{-6} risk range. So we often have to go down 4 to 6 orders of magnitude below the level at which you see these frank adverse effects, or lethal effects in this case.

Senator CRAPO. Can you tell me why we resulted, or how we came to that determination that we had to go 4 to 6 levels lower?

Dr. NOONAN. Well, typically, that has to do with variability in the population, the susceptibility of individuals and the realization that, and I think I could defer to some of my risk assessors, this is a tried and true methodology for dealing with cancer risk, particularly, that you want to go down about several orders of magnitude below the adverse effects level.

Senator CRAPO. I'm sorry to keep interrupting you, but has that general determination been subjected to a rigorous cost benefit analysis? In other words, if you go down two levels, it's going to cause so much, four levels, so much, six levels, so much?

Dr. NOONAN. It depends on the pollutant and on the rule that you're writing, whether or not that health standard is subjected to a cost benefit analysis. My understanding is for drinking water it typically is, when you——

Mr. FOX. And I would just say that this is a history of the Agency that I know for 20 years anyway, on the cancer end point public health protection we generally try and protect the population in the 10 to the minus 4 to the 10 to the minus 6 risk range. This has been something, as I think Norine said, that has been well established, that has been extensively used for a long time.

Dr. NOONAN. Peer reviewed, I mean, this is not methodology that hasn't been tested.

Mr. FOX. We don't always get there. Arsenic tends to be at the low end of that risk range because of cost. Some other contaminants, because of the cost effectiveness, we can end up with 10 to the minus.

Senator CRAPO. Well, the reason I ask is because in recent years there have been a lot of questions raised at the Congressional level as to whether we build conservative default after conservative default after conservative default into our rules to the point where they become beyond the level of common sense and beyond the level of science and extremely expensive. And that's the question I'm getting at.

Dr. NOONAN. And we understand that, Mr. Chairman, and I think we try to reevaluate the methodologies and the guidelines that we use to set those risk ranges on a periodic basis, so that we are confident that the methodologies that we are using to assess risk reflect the most up to date and the most excellent thinking in the scientific community, not just in EPA, but around the country. Our folks are actually in very much a leadership role, particularly in risk assessment, among their peers in the country. I have a person who works for me who is currently the President of the Society for Risk Analysis, elected president. And that's a professional society of people who do this for a living and who work on risk issues.

So I think, though, if we get back to arsenic for a minute, let's just finish the calculation.

Senator CRAPO. Yes.

Dr. NOONAN. If the frank adverse effect that we see for cancer is between 200, somewhere between 200 and 500 ppb, that's where they begin, for the average person, and people are not generally average except in Lake Wobegon, where they're all above average——

Senator CRAPO. I'm glad you added that last part!

Dr. NOONAN. But if we do the calculation, if we go down ten-fold, that would be about 20 parts per billion. Let's pick the mid-range, 300, that would be 30 parts per billion. If we go down a hundredfold, that's only 10^{-2}, we're now at 3 ppb. You can see where we're going. I mean, we're currently essentially less than 100fold below the obvious adverse effect level.

That quite frankly from a health perspective gives us not an insignificant bit of concern, but we also have bearing down on us the cost element of this. And so what we've tried to do is pick the number that is both affordable, from my colleague's standpoint, and a number that is the most protections of human health that we can get to.

Senator CRAPO. If you were to go to 10 to the minus—here comes my math, distance from my math classes again—if you were to go to 10 to the minus 6, let's say 10 to the minus 5, because that's in between the 4 and the 6, that would be what, 100,000?

Dr. NOONAN. Well, let's keep going. At 10^{-2}, it's 3 ppb. We're going to pick the mid-range. At 10^{-3}, it's 0.3 ppb. At 10^{-4}, 0.03 ppb. At 10^{-5}, it's .003 ppb, or about 3 parts per trillion.

Senator CRAPO. Can we measure that, 3 parts per trillion?

Mr. FOX. No, as I said, our feasible level that we determined was basically 3 parts per billion. And this gets into reliability of laboratories across the country.

Senator CRAPO. And I've got to believe, and again, I'm not a scientist, and I will listen to the scientists, but I've got to believe there is some point at which a human being can consume water that has some tiny little fraction of these materials in it that is not going to be lethal or even a significant risk. Is that not a valid assumption? Is there some point?

Mr. FOX. Many people smoke cigarettes all their lives and never get lung cancer.

Senator CRAPO. Well, I'm not talking about that. That's a risk. I'm talking about, does water have to be absolutely devoid of any foreign substance for us to drink it?

Dr. NOONAN. No. Absolutely not. Of course not.

Mr. FOX. It won't be.

Senator CRAPO. I know you're not saying that. But my question is, isn't there some point for arsenic at which is it naturally occurring in most water and which has historically not been a health risk?

Mr. FOX. Well, there is some tension and difficulty in this line of questioning, if you will. I know you're just really asking for information here, but Cryptosporidium is a naturally occurring organism, Giardia is naturally occurring, E. coli at some level is naturally occurring. I really look at our job as trying to provide multiple pathways of public health protection, so that people can turn on their tap with confidence that they're not going to get sick to their stomach or they're not going to contract skin cancer or lung cancer.

Dr. NOONAN. Over a lifetime of exposure.

Senator CRAPO. Well, I am, too, but I want them to have enough money to own a television, so they can turn it on and find out about their health needs.

Dr. NOONAN. I understand that, Mr. Chairman. I think, though, that we have struck a balance here, particularly in the arsenic rule, that is as protective of public health as we can get, taking into consideration the kinds of affordability criteria for American families. I know that you share the goal of protecting public health. And I think it's our conviction that we've got it right here from that standpoint.

Mr. FOX. Let me make this clear, too. This is not a slam dunk, if you will. We proposed a number of five parts per billion. You will hear, I'm sure, from a number of other witnesses, that there's a lot of uncertainty in the science behind these numbers. I fully acknowledge that, and we really want to go through a rigorous public debate to figure out what the right numbers should be.

We actually proposed five, but we are also taking comment on a number of other values, so that in the end, if the Agency wanted to make a different decision, it would be able to do so.

Senator CRAPO. Well, you just led to my next question. Because you're right, there will be others who will testify, I assume, that the science is uncertain and that the cost is too low, the cost is too high, the cost benefit analysis does not justify this standard. The question I have in that context is that if the EPA does adopt a five part per billion standard at this point, it's my understanding that under the law, that would not be reviewable for 6 years. And so we would be living with that for 6 years while we would then see the science presumably come in to tell us whether it was the right decision.

First of all, am I right in terms of my assumption about how the law works? And second, is it not quite risky to do that, given the fact that we do have uncertainty in the science?

Mr. FOX. My understanding of the law is that the Agency is required to review these every 6 years, but we would have the option of reviewing them at a sooner period.

Senator CRAPO. So if science came up that said, oh, we made a mistake here, it could easily have been at 10 or 20 parts per billion, and we could save the public tremendous amounts of money and resources to put into other health improvement efforts, you could take that action?

Mr. FOX. That's right. I would say that. I appreciate very much the line of questioning and that's among the facts we have to consider. History generally shows it goes the other way.

Senator CRAPO. I do understand that. Although again, some of us are concerned that the history we had is one of an approach to this which accumulates conservative default standards, or whatever the terminology is that I want to use, that have an effect of driving costs up with very low benefits, at the point when we get to that outer end of the range when the benefit of each incremental increase is much more expensive.

Mr. FOX. Right.

Senator CRAPO. Well, I appreciate this discussion we've had. Because I believe that the discussion, whether it is a specific discussion of arsenic or the general discussion of how we are approaching cost benefit analysis and these difficult questions of where we best put our resources, and the level of confidence that we want to achieve is one of the more critical regulatory issues that we face in America today.

And I do believe that our quality drinking water is one of the most important objectives that we can achieve, and one of the most important responsibilities that you have. And we share that commitment. And I certainly do not believe that we should do anything that would diminish our ability to assure that Americans have safe, clean water to drink. It is a very high value. And I can understand why you would be placing a high value on it in your cost benefit analysis.

By the same token, we want to be sure that with all of the other areas in which we need to apply resources at the Federal level, let me say at the governmental level, through the use of tax dollars, as well as the demands that we will be placing on people and their own pocketbooks as they achieve these objectives, we want to be sure we do it in the most effective way possible, and that we aren't violating some very common sense considerations, and some good science that hopefully we can get to help us make these determinations.

And I would again invite you on this issue to think of me when you come across papers or analyses or whatever that help elucidate a better understanding of it. Because I truly want to be able to achieve this objective. You mentioned the NIEHS in your initial remarks, one of you did.

Dr. NOONAN. I did.

Senator CRAPO. Dr. Noonan, you did. I toured their facilities in North Carolina. They're at the Research Triangle down there, I believe.

Dr. NOONAN. Yes. Our new building is being built directly across the lake.

Senator CRAPO. And I have actually toured the EPA facilities, which, I don't know if that was in the new building, this was several years ago.

Dr. NOONAN. Those were the old facilities.

Senator CRAPO. I've toured the EPA research facilities there, too, and I've met with some of your scientists and their scientists and others. And I have a very strong interest in this. And the way I approach it is that, I think that good science has to drive our deci-

sionmaking. It will never give us all the answers, because we have to give the cost benefit analysis too and make the public policy decisions in the arena that we have here before us today.

But good science has to give us the key to what is achievable and then what the benefits of that are going to be. And I'm very confident that we have the ability in this country to generate that kind of science. I just want us to be sure that we use it effectively.

And I appreciate your commitments to this. I think that we as a Nation have shown the world that we have a commitment to protecting our environment and protecting our public health. And in that context, as I've said, safe, clean drinking water is one of the highest and most significant priorities in that system. And so I look forward to working with you on that.

I have no further questions, and I know there were other Senators who must have been delayed who would like to raise some, but I guess they'll have to submit them in writing.

Did you want to say something, Mr. Fox?

Mr. FOX. I was just going to make an observation that in my job, there are a lot of tough decisions. But I can tell you unequivocally, the hardest one is picking an MCL. Because you have to weigh so many different factors, there's so much uncertainty. But it is also, as you point out, one of the most important decisions we can make for public health.

Senator CRAPO. Well, I appreciate that and understand what you're saying. And I also appreciate the fact that you are stating here today that you are ready to listen to the concerns from the stakeholders and others who are involved in our national and local drinking water systems and hopefully we'll be able to find some consensus in terms of what is the best step to take here.

Mr. FOX. Cynthia will be staying. As you can imagine, I have other pressing business to attend to this afternoon.

Senator CRAPO. Maybe we ought to tie you up here all day.

[Laughter.]

Dr. NOONAN. Mr. Chairman, if I might, I just want to reiterate and thank you very much for your comments. I think the whole reason for the existence of my organization is to provide or to fund the kind of excellent and high quality science that underpins the actions that the Agency takes. I think we call upon our colleagues in the scientific community and the industrial community and anywhere in the country where we can find such expertise, and in our own laboratories. I think we have a number, many, very high quality people who are in leadership positions in their disciplines.

We share your commitment to the highest quality science to be used in the soundest way possible. I will say with regard to arsenic, I thank very much, one of the witnesses you will hear from later from the National Academy of Sciences, because they have essentially compiled in this book, in this report, probably the most extensive compilation of analysis and work on arsenic that exists today. I think what it showed us is that indeed we were on the right track. It gave us greater confidence in the studies that we used to underpin the decisions that we made on arsenic.

And so I think it did show that we can work very effectively in delivering high quality science to the Agency, and I thank you for your words to that effect.

Senator CRAPO. Well, I appreciate your commitment to that. One of the comments that was made to me by one of the scientists down in North Carolina when I was down there a few years ago was, we were talking about these issues as well. And at the time, I don't remember what the issue was, but there was something where there was a big concern as to whether we were going overboard in our effort. And this particular scientist, on this particular issue, said, you know, I think that the science on this is going to show that we are going too far and that we could achieve our objective in a better way.

But he said, the key here is, we need the science to tel us that answer. And I said to him, I think you would find that those who are fighting that situation or this situation, if they could be sure they had good science and they trusted what the science was telling them, that there would be much higher level of consensus, that either we do or we don't take this next step or we take a different step. Because we would have confidence in where we were headed and that it was needed, and that the risk was a real risk as opposed to a risk that may have been more generated by political activity than scientific analysis.

And so that's why it's so critical that your efforts proceed. And I should say also, I have a lot of other questions I want to ask, I'm going to submit them. As usual, we don't have enough time for the full discussion that we'd like to have. So I would encourage you to respond to these questions promptly in writing.

But they relate, some of them, to how the Agency is prioritizing its research and things like that. Because I'll tell you what, I'm a very strong ally of getting the necessary funding to the research, so that we can get some of those answers. When those scientific answers come in, then when they come down on my side of an issue, I'm going to be happy. When they come down against my side of an issue, I'm going to have to change my point of view.

Mr. FOX. Well, we might have some new funds to apply research.

[Laughter.]

Senator CRAPO. We're going to try to make you some funds available.

Dr. NOONAN. Thanks, sir. We look forward to welcoming you to our new facilities when we move in next year. We hope you will come and visit them.

Senator CRAPO. All right, thank you very much. And again, Mr. Fox, with regard to the TMDL issue, I do commit to you, as you have committed to me, that we will, regardless of how this all comes out in the short term, we'll continue to work on this.

Mr. FOX. Actually, that will be a problem. Because I just was advised of the language, and apparently the language is written such that I'm not allowed to do any work on it. So we actually will not be having any conversations.

Senator CRAPO. Well, we'll work on that. Thank you.

Thank you very much for your patience, ladies and gentlemen. We will now call up our second panel. And I apologize, this panel has eight people on it. We made the decision to do one panel of eight instead of two panels of four, because we've found that the give and take we get, at least I've found, the give and take we get with everybody sitting at the table is more productive than if we

have to have one panel come next and say, well, I would have liked to have talked with Mr. or Mrs. so and so, and didn't get a chance to.

So we will now have the panel as follows, and we'll ask you to testify in this order. Mr. Gregg Grunenfelder, and please excuse me if I foul up on any of your names. Mr. Grunenfelder is the Director of the Drinking Water Division of the Washington Department of Health. Mr. Gurnie Gunter, the Director of the Kansas City Water Services Department. Mr. William Hirzy, the Senior Vice President of the National Treasury Employees Union, Chapter 280. Dr. Michael Kosnett, the Associate Clinical Professor at the Division of Clinical Pharmacology and Toxicology at the University of Colorado Health Services. Mr. Erik Olson, Senior Attorney with the Natural Resources Defense Council. Mr. David Paris, the Water Supply Administrator, Manchester Water Treatment Plant, Manchester, New Hampshire. And I should say that some of these folks are testifying on behalf of national associations. I'll go back and pick that up in a second.

Mr. Richard Tompkins, the President of the National Association of Water Companies. And Mr. Randall Van Dyke, the General Manager of the Clay Regional Water.

Now, let me go back and indicate that Mr. Grunenfelder is speaking on behalf of the Association of State Drinking Water Administrators. Mr. Gunter is speaking on behalf of the Association of Metropolitan Water Agencies. Mr. Hirzy, on behalf of the Union and the interests that are of concern there. Mr. Kosnett on behalf of the National Research Council Subcommittee on Arsenic in Drinking Water. Mr. Olson on behalf of the Natural Resources Defense Council. Mr. Paris on behalf of the American Water Works Association. Mr. Tompkins on behalf of the National Association of Water Companies. And Mr. Van Dyke on behalf of National Rural Waters Association.

Now, gentlemen, let me remind all of you of the rules. With such a large panel, we have to watch our time very closely. We have the clock here, the lights here which will give you 5 minutes for each of you to conclude your testimony. And the green light will be on for the first 4 minutes. When 1 minute remains, you will have the yellow light come on. And when the red light comes on, it's time for you to wrap up.

We ask you to please pay attention to the lights, and if you do go over very far, I will lightly rap the gavel to remind you. The reason is because we like to have a lot of give and take with you. We do have your written testimony, we have reviewed it. And you will also get an opportunity in the question and answer period to cover some of the things you may not have been able to cover in your 5 minutes.

We are very aware that your 5 minutes is going to run out before you've run out of things to say. But we ask you to please follow the lights and we will try to help you be reminded of that.

Now, before we start with the panel, we've been joined by the Chairman of our full committee, Senator Smith. If you'd like to make a statement, Senator Smith, I'd be glad to give you the time at this point.

Senator SMITH. Well, I'll defer on the statement, Mr. Chairman, but just to thank you for your leadership on this issue and for holding the hearing. I'll just listen to the witnesses and then participate in the questioning. Thanks.

Senator CRAPO. Thank you very much.

Then we will proceed in that order. Mr. Grunenfelder, you're first.

STATEMENT OF GREGG L. GRUNENFELDER, DIRECTOR, DRINKING WATER DIVISION, WASHINGTON DEPARTMENT OF HEALTH

Mr. GRUNENFELDER. Thank you very much. Mr. Chairman, good morning, and thank you for the opportunity to provide a State's perspective to the Safe Drinking Water Act discussion today. I am the Director of the Division of Drinking Water for the Washington State Department of Health. And I'm here speaking on behalf of the Association of State Drinking Water Administrators.

The Association represents the State drinking water administrators in the 50 States and 6 territories who have the responsibility for implementing the many provisions of the Safe Drinking Water Act and ensuring the delivery of safe water. State public health agencies have been implementing drinking water protection programs for many years. In 1974, these efforts came under the purview of the Safe Drinking Water Act.

The 1996 amendments added significant new requirements to this core public health protection program, and with those, significant new challenges, challenges in the form of things like the radon rule, the arsenic rule, disinfection, disinfection byproduct rule, enhanced surface water treatment rule and consumer information programs like the consumer confidence report and public notification rule.

To be successful in this implementation and meeting these new challenges, I want to highlight two things that I think we need. We need significant new resources and staff to do the job. Laws on paper do nothing to protect public health. The laws need to be implemented.

Second, we need reasonable regulatory schedules and integrated thinking into how we'll move forward to meet these new complex requirements. In other words, the laws need to be implementable.

Things are not going smoothly. And in fact, the trends we are seeing are diluting an already stressed public health system. A few of the areas I want to highlight for you today, one again addresses the issue around inadequate funding and apparent unwillingness to address cumulative costs and program integration.

States are clearly under-resourced to do the job Congress envisioned in 1996. The way I visualize it is that in 1996, many new things got added to the safe drinking water table. And that table grew to about 12 feet long. But States were left with a table cloth that was about 6 feet long. So significant parts of the Safe Drinking Water Act table are not being covered. On our own, States are being forced into making tough prioritization decisions on what parts of the table will be covered and what parts won't with the resources we have available.

Another issue to highlight is early implementation. In spite of this clear lack of resources, we see a continued insistence on early implementation of rule requirements prior to States adopting their own rules within the statutory framework of 2 years from the data of rule promulgation. States need time to establish basic regulatory and enforcement authorities, enhance data systems and inform water systems and train water system owners and operators of the new requirements.

The EPA regions are in no position to assume implementation activities. We need thoughtful implementation plans that are worked out in conjunction with States.

Third, we see a trend for changing roles and expectations. We're seeing a shift in the basic public health model of oversight and assurance to one of being more of a consulter and an implementer. Daily operation and maintenance have always been the primary responsibility of water systems, certified operators, licensed professional engineers, with technical assistance from States and other providers when needed. We're seeing a trend to get State programs more directly involved in consulting roles with utilities on the operation and maintenance side of their business, rather than providing basic regulatory oversight. We simply don't have the resources to take on these new responsibilities.

And finally, increasing record keeping and reporting burdens. With the new rules coming down, each of them contains numerous data and reporting requirements which are overwhelming data systems, many of which are not fully functional now. Required reporting requirements should be carefully considered in the context of all of the Safe Drinking Water Act requirements, not rule by rule, and each must provide meaningful, useful information which are linked to real public health issues.

In conclusion, as you said, Mr. chairman, safe and reliable drinking water is vital to the health of every community, and assuring safe drinking water should be a top priority for all of us. Given the current path we're on, full implementation of the Safe Drinking Water Act is not doable.

State drinking water administrators want to succeed in assuring safe and reliable drinking water supplies in our country. But it will take a fundamental shift in direction to make this happen. It will take, No. 1, significantly more resources directed toward implementation. No. 2, a more thoughtful, coordinated and manageable approach to achieve your vision that is contained in the Act.

And No. 3, it will take EPA working with States as partners, or Congress working with States as partners, to achieve meaningful success in assuring safe drinking water.

Thank you for the opportunity to comment, Mr. Chairman.

Senator CRAPO. Thank you very much, Mr. Grunenfelder.

Mr. Gunter?

STATEMENT OF GURNIE GUNTER, DIRECTOR, KANSAS CITY WATER SERVICES DEPARTMENT

Mr. GUNTER. Good morning, Chairman Crapo and Chairman Smith. I'm Gurnie Gunter, the Director of the Kansas City, Missouri Water Services Department. And on behalf of the Nation's

largest municipal drinking water agencies, thank you for holding this hearing.

I'm a board member of the Association of AMWA and my testimony today is on that Association's behalf. We represent the largest municipal drinking water agencies in the United States. Together AMWA member agencies serve clean, safe drinking water to over 110 million people.

First, I would like to commend EPA's Office of Groundwater and Drinking Water for its remarkable efforts to implement the 1996 amendments. The Act sets out to a demanding regulatory schedule and EPA has made it their business to meet that schedule. State regulators deserve a commendation also. The list of Federal regulations that the States must implement becomes larger and more demanding each year. Yet, the Federal contribution to this effort covers only 35 percent of the bill.

Today I will highlight only a few points contained in our written testimony, so I ask that the full written testimony be included as part of the record of the hearing.

Senator CRAPO. Without objection, it will be. That will be the case for all of your written testimony.

Mr. GUNTER. Our main priority is the implementation of drinking water standards based on sound science. Congress and the Administration share this goal and enacted it in a bipartisan fashion in 1996.

Congress took a major step when it gave EPA the flexibility to let science determine drinking water standards. We believe that this is the cornerstone of the amendments and it recognizes that the most serious threat to public health should be addressed first, and that resources are limited at all levels of Government. It also recognizes that the public ought to receive true value for what they are being asked to spend.

Nevertheless, the Association has concerns with how EPA is incorporating science into its standard setting program. For instance, EPA recently finalized the maximum contaminant level goal of zero for chloroform, despite noting in the final rule that the best available peer-reviewed science indicated a non-zero value is more appropriate. And there are other examples.

It would be unreasonable to expect perfection, given an ever changing base of scientific knowledge. But the importance of meeting the science provisions is paramount. And if satisfying these provisions means altering statutory deadlines for rule development, we hope that the subcommittee and the full committee will be amendable.

The filtered backwash rule is a case in point. AMWA recommends that the subcommittee and Congress consider an extension of the August 2000 deadline so that EPA may repropose the rule to consider basic knowledge of risks, costs and benefits. Similarly, when the comment period closes on the arsenic proposal, EPA will be left with only a few months to finalize the rule prior to the January 2001 deadline. We ask the subcommittee and Congress to consider a 6-month extension to give the Agency adequate time to consider stakeholder comments.

Today, AMWA also recommends that the subcommittee request an independent review by the National Academy of Sciences or

General Accounting Office of how well EPA is incorporating science into regulatory decisions. We believe it would benefit the Agency, as it seeks to implement the 1996 amendments.

Also in the amendments, Congress calls on EPA to develop health risk reduction and cost analysis documents to be published for public comment at the same time a rule is proposed. So far, EPA's cost and risk analyses are not published for comment in the Federal Register, along with the proposed rule. Additionally, the analyses stray from normal cost benefit practices. For example, EPA chooses to discount costs but not benefits. Thus, the Agency compares apples to oranges.

Moving from the specific mandates, I would also like to mention three related issues. Since I am running out of time, I will just indicate what they are. One is the issue of MTBE, another is the issue of funding infrastructure, and the other is the issue that involves liability reform against suits against water suppliers, which is creating a situation that will make the statute really not-relatable. The courts will decide what we do.

Thank you again for giving me the opportunity to testify.

Senator CRAPO. Thank you very much, Mr. Gunter. And we will carefully review those three points in your written testimony.

Dr. Hirzy?

STATEMENT OF WILLIAM HIRZY, SENIOR VICE PRESIDENT, NATIONAL TREASURY EMPLOYEES UNION, CHAPTER 280

Mr. HIRZY. Good morning, Chairman Smith, Chairman Crapo and fellow staff workers. Thank you for the opportunity to appear today to present the views of the Union on the issue of fluoridation of public water supplies.

Our union represents the staff scientists, lawyers and others who analyze hazard exposure and economic data and advise management how to use them in public health protection. We're not here today to speak for EPA, but rather the union, founded 17 years ago to protect EPA workers from unethical pressure by EPA managers. It was on that basis in 1985 that we first got involved in this issue.

In 1997, we voted to oppose fluoridation and our opposition has grown stronger as more adverse data on the practice have come in. In the interest of time, let me state our recommendations first. We ask that you order an independent review of the cancer bioassay of sodium fluoride mandated in 1977 by Congress. Evidence for carcinogenicity in that assay was systematically downgraded by a special executive branch commission appointed and run by the very agencies that Congress did not trust to run the bioassay in the first place. That action saved fluoridation temporarily.

We ask that you order chronic toxicity studies on the two waste products that are now used in 90 percent of fluoridation programs. EPA says there are at present no chronic toxicity data on them, and we ask that you order EPA to set an MCL for fluoride that's truly protective of all American citizens, infants and adults alike. Because the current one does not, in violation of the Safe Drinking Water Act.

We ask that you order epidemiology studies using dental fluorosis as an index of exposure to determine the extent of other toxic effects, especially effects on the brain and bone in the population

that are attributable to fluoride. We ask that you convene a joint Congressional committee to give this issue the full airing that it deserves. It's been 23 years since the last one and it's high time for a new one.

I offer the following in support of these recommendations. The American people and especially our children are getting way too much fluoride. Two-thirds of children living in fluoridated communities have dental fluorosis in at least one tooth. Dental fluorosis is the visible manifestation of toxic over-exposure to fluoride during their developmental years.

The initial findings of the cancer bioassay were for clear evidence of carcinogenicity and that is consistent with several epidemiology and many mutagenesis studies. The protected pollutant status that fluoride enjoys within EPA and other Federal establishments is remarkable, as the charts over here show.

EPA stated regarding the chemical used in 90 percent of fluoridated communities that, "By recovering fluosilicic acid from fertilizer manufacturing, water and air pollution are minimized, and water authorities have a low-cost source of fluoride." In other words, EPA's solution to pollution by this waste product is dilution. As long as it's not dumped into rivers and lakes but rather into drinking water systems.

Congressman Calvert of the House Science Committee has letters of inquiry out to EPA and other Federal entities on this subject.

The 1983 report of the Surgeon General's panel on fluoride to EPA was altered without consultation or notification of the panel members so as to help EPA justify an outrageous set of drinking water standards promulgated in 1986. The results of the 50-year experiment conducted in Kingston and Newburg, New York, show that there's no overall difference in dental caries rates between the two communities. But there is a significantly higher incidence of dental fluorosis in the fluoridated community.

Since 1994, there have been six studies that show adverse effects of fluoride on the brain, even at the so-called optimal level of one part per million. The epidemiology studies that we recommend above should make a prime effort to look at brain effects, given the national concern over attention deficit and hyperactivity disorder and autism in our children.

Three trial judges since 1978 made findings of fact that water fluoridation poses an unreasonable risk to the American people. Fluoridation proponents like to say that there's no real controversy about fluoridation, and they're right. When these three disinterested trial judges heard weeks of testimony, they came to the same conclusion that our union did about the unreasonable risks involved. The findings of fact remain untouched in those trials today.

Recent publications indicate a link between the use of silicofluorides for fluoridation and elevated blood levels in children and anti-social behavior. And leading dental researchers are changing their views on the safety and efficacy of fluoridation. Drs. John Culquhon and Hardy Limeback, both former spokespersons for fluoridation, have published recantations of their former position.

On behalf of EPA's professional community, I urge the subcommittee to convene a select committee for a national review of water fluoridation. It's high time we do that. I'd be happy to take questions. Thank you.

Senator CRAPO. Thank you very much, Dr. Hirzy.

Dr. Kosnett?

STATEMENT OF MICHAEL KOSNETT, ASSOCIATE CLINICAL PROFESSOR, DIVISION OF CLINICAL PHARMACOLOGY AND TOXICOLOGY, UNIVERSITY OF COLORADO HEALTH SCIENCES

Mr. KOSNETT. Thank you, Senator Crapo, Senator Smith, staff members and other guests.

I'm Michael Kosnett. I'm a member of the committee on Toxicology of the National Research Council. I'm also a former member of the Subcommittee on Arsenic in Drinking Water. I serve as an associate clinical professor at the University of Colorado Health Sciences Center in the Division of Clinical Pharmacology and Toxicology. I'm happy to be here today to discuss some aspects of the National Research Council's Subcommittee on Arsenic in Drinking Water's findings regarding the health risks of arsenic in drinking water.

As you know, the National Research Council is an independent organization. It's a branch of the National Academies of Sciences. It's non-governmental, yet it often is called upon to convene panels and to perform scientific studies to address health issues and other issues at the request of the Federal Government or other parties.

In 1997, in the spring, the NRC convened a panel at the request of the U.S. Environmental Protection Agency. The charge to this subcommittee included a request that the committee review EPA's characterization of the human health risks posed by arsenic in drinking water. We were asked to determine the adequacy of EPA's current maximum contaminant level for protecting public health and also to identify priorities for research to fill data gaps.

The subcommittee was comprised of a group of experts selected by the Chair of the NRC on the basis of their knowledge and expertise in a variety of topics that were covered by the charge to the committee. It's important to note that the committee consisted of an international grouping of experts from multiple disciplines, including toxicology, epidemiology, biostatistics, chemistry and nutrition.

As with all National Research Council committees, the selection process was attentive to achieving balance and scientific perspective and to avoiding conflicts of interest. It should be noted that the members were drawn from academic institutions, national health agencies, private corporations, industry sponsored research organizations and private consultants. The subcommittee adhered to a collective writing process and the report reflects the scientific consensus of its members.

Moreover, the subcommittee report was subjected to internal National Research Council institutional oversight and to external peer review by public and private sector experts drawn from a broad range of backgrounds and perspectives. Every comment and ques-

tion submitted to the subcommittee by these peer reviewers was addressed before the final report was issued.

The 310-page report of the National Research Council Subcommittee on Arsenic in Drinking Water was released in the spring of 1999. I have included as part of my written testimony two key sections of the report, the executive summary and a short but important chapter entitled Risk Characterization. And these sections highlight the key findings and recommendations of the subcommittee.

Thank you.

Senator CRAPO. Thank you very much, Dr. Kosnett.

Mr. Olson?

STATEMENT OF ERIK OLSON, SENIOR ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL

Mr. OLSON. Good morning and thank you, Senator Crapo and Senator Smith.

I wanted to try to put some of the issues that we're discussing today into a little bit of historical perspective. We believe that some of the difficulties that the committee is going to hear about today and already has heard about in the drinking water industry are a result of what is a revolution going on right now in the industry. We call it, and many others do, the "Third Revolution" in water delivery in the world.

The first revolution occurred in Biblical times, and through the Roman Empire, when piped water began to be provided. The second revolution occurred around the turn of the last century, before World War I, when water systems began to switch to sedimentation, coagulation, filtration and chlorine. There were enormous public health benefits. In fact, the Centers for Disease Control and Prevention recently found that this second revolution, occurring about the time of World War I, was one of the largest public health benefits and accomplishments of the entire century.

The third revolution is what is going on now. It is going to cost a lot of money, but clearly it is necessary. That revolution will result in basically three barriers to contamination of public water supplies. First, there will be prevention and source water protection. I assume Mr. Paris may talk about that, because his utility has been one leader in achieving that kind of prevention.

A second is broad spectrum treatment, advanced treatment using advanced technologies that now we believe will start being used by utilities across the United States over the next 20 years. And third, that the pipes that deliver the water to our houses will be overhauled. Many of them are 100 years old or older. In fact, the drinking water that came out of the tap here that many of us are drinking flowed through pipes many of which were built during the Lincoln Administration. And we are still dealing with that in many cities across the United States.

We have massive microbial risks across the country continuing, unfortunately. We think many of them have been addressed. But the Milwaukee waterborne disease outbreak that occurred several years ago that sickened 400,000 people and killed about 100 people is a reminder that we need to deal with those risks. Similarly, an outbreak that just happened in Ontario with E. coli in drinking

water that killed between 4 and 15 people of E. coli from their tap water is another reminder that we cannot let our guard down.

There have been many major challenges, and I just wanted to briefly mention three that are of most importance and maybe concentrate mostly on the arsenic issue. Because we believe that this is a major public health risk.

The National Academy's arsenic study, and you just heard from one of the panelists, found that the current EPA drinking water standard is inadequate. Let me quote from the panel's conclusions: "It's the subcommittee's consensus, the current EPA's MCL for arsenic in drinking water does not achieve EPA's goal for public health protection, and therefore requires downward revision as promptly as possible."

The committee also found that the bladder cancer risk at the current EPA standard is about a 1 in 1,000 cancer risk. In addition, the Academy said that if one considers the total cancer risk, that cancers could easily result in a combined cancer risk of on the order of 1 in 100, at the current EPA standard.

What I think is quite significant is that that cancer risk is approximately 10,000 times higher than EPA's usual targeted cancer risk. For example, the entire United Sates Senate just three and a half years ago voted for legislation called the Food Quality Protection Act that set a standard of one in a million for food, one in a million cancer risk is the maximum acceptable cancer risk for pesticides in our foods.

What I think is significant is that the cancer risk posed by arsenic in tap water at the current standard is approximately 10,000 times higher than that. It is a very significant risk that we cannot pretend does not exist. Why is the arsenic issue so important? Well, we've been dealing with this standard that was set in 1942. Congress has repeatedly told EPA to update that 1942 standard now three times, the first in 1974, the second in 1986 and now in 1996. The standard remains the same. We feel it's a very important public health issue. And EPA's proposed rule, although we would like to see a somewhat lower standard, something that is feasible, three parts per billion, we certainly believe EPA has taken a major step forward.

Thank you and I've got many more points in my testimony, but I'll leave it at that.

Senator CRAPO. Thank you, and we will review it carefully.

Mr. PARIS. I understand you're from our Chairman's home State.

STATEMENT OF DAVID PARIS, WATER SUPPLY ADMINISTRATOR, MANCHESTER WATER TREATMENT PLANT, MANCHESTER, NEW HAMPSHIRE

Mr. PARIS. I am. I'm proud to be from New Hampshire, a lifelong resident of that State. And this is really a privilege and an honor for me this morning to be able to address the subcommittee.

I am from Manchester Water Works, the water supply administrator, meaning that my job with them is to run a water supply for about 125,000 people. Today I'm appearing on behalf of American Water Works Association, which is really the world's largest single group of water suppliers, scientists, regulators, manufacturers and suppliers of water treatment and water supply equipment.

We represent, I believe, most of the water companies that would be in your constituent districts. And we consider these people the people that we act on behalf of, in particular.

I'd like to address today American Water Works' position on a number of the issues that you see before you in our written testimony that is on the record, and try to draw some analogies and some real world comparisons to how these rules will impact on my home State up in New Hampshire.

The 1996 amendments created a huge challenge for EPA, as Erik I think correctly paraphrases. We are in a State currently where our rulemaking and our science has changed dramatically and continues to change very rapidly. The Office of Ground Water and Drinking Water I think has done an admirable job to meet those demands and those challenges.

I'm going to speak today with some degree of criticism about certain aspects of what they have felt that they need to do. Our major concern will be that they in our estimation, have compromised sound science, in some cases, for statutory deadlines. We are all certainly committed to seeing these rules take place and be implemented if in fact they are to our constituents' benefits and to our constituents' best welfare.

However, when deadlines take precedence over science that is in progress, we take exception. You will hear that from me this morning.

AWWA fully supports the President's current budget allocation of $49 million for drinking water research, research that supports science, the science necessary to build a strong drinking water program, one that we can all buy into. That's a short-term goal, though, because as you're hearing, there are not only the rules that you see in front of you to consider. The 1996 amendments created a candidate contaminant list which will every 5 years put a mandate before the Agency to either regulate or not regulate five additional candidate contaminants. That is a very strong and extraordinarily challenging demand, I think, for EPA to meet without the proper resources available to support the science to get it done.

Arsenic is a good example of a rule that has arrived ahead of its science. Neither AWWA, nor I, nor anybody else at this table disputes that the 50 part per billion standard that was established in 1942, as Erik said, was in need of some review and alteration. Our concern is that the consideration of sound science and cost-benefit analysis driving that rule to lowered MCLs becomes extraordinarily important when those MCLs start impacting, as you mentioned before, Senator, the 80th percentile and then to get from the 80th percentile to the 10th percentile.

In New Hampshire, it will impact about 20 percent of our 600 groundwater supplies, putting the same people in these small communities on notice that they'll need to add treatment for arsenic as well as for radon. Radon is another high impact rule that is out there and we want to compliment the 1996 amendments for recognizing the background of contribution of radon to the air as well as to water.

But at this point in time, we're looking for a way to actually get that done. Gregg Grunenfelder, initially talked about how these rules tend to cluster and accumulate on the plates of the State

drinking water people. They're having a really hard time discerning how to implement the air mitigation program as part of the drinking water rule. We'd like to suggest that the Indoor Air Radon Abatement Act might be a better place to put some of that responsibility.

In other rules here concerning disinfection byproducts, the stage two regulations, I have been active with AWWA in its negotiation process for the Federal advisory panel to establish new drinking water standards. It's an extraordinary success, and it is one of the parts of the 1996 amendments we fully support and would like to continue to see the public participation process work.

On infrastructure, and unfortunately I will not be able to really speak to this, we feel that there is a funding gap that will inevitably develop here in the next 20 years and Congress could do much to help support the State drinking water revolving loan fund to help utilities and water suppliers meet some of those deficits that they will inevitably see.

MTBE, is another New Hampshire concern and one close to my heart. MTBE has become one of those contaminants that we truly compliment this committee, Chairman Smith, Chairman Crapo, Chairman Inhofe, Senators Boxer and Feinstein, for their very quick actions in helping to deal with this emerging contaminant, which is of huge importance to the drinking water industry. In New Hampshire alone, as you'll see in our comments, Manchester has had to deal with this in a supply that is fully protected and that only allows power boating. It's just one of those unfortunate side products of what we thought was going to be a good program for controlling air pollution.

In conclusion, despite these comments, I compliment EPA for their efforts. They would need, I think a little more time, something that this committee and Congress could give them to help them with their statutory deadlines, to be sure that they don't compromise good science.

Thank you very much.

Senator CRAPO. Thank you very much, Mr. Paris.

Mr. Tompkins?

STATEMENT OF J. RICHARD TOMPKINS, PRESIDENT, NATIONAL ASSOCIATION OF WATER COMPANIES; PRESIDENT, MIDDLESEX WATER COMPANY

Mr. TOMPKINS. Good morning, Chairman Smith and Chairman Crapo. I am President of Middlesex Water Company, which is an investor owned water company located in central New Jersey. Like David Paris, I am responsible for the provision of safe and adequate water service to over 200,000 people.

At present time, I am the President of the National Association of Water Companies, which is the non-profit trade organization that exclusively represents the Nation's private and investor owned drinking water industry. I am offering this testimony today on behalf of the NAWC, which has over 300 members in 43 States, and serves reliable drinking water to over 23 million Americans every day.

We represent the capital investment segment of the water utilities. Our member companies pay State, local and Federal taxes.

The National Association of Water Companies commends you and your subcommittee for conducting these oversight hearings. We feel these add a very important perspective to our continuing efforts to provide safe, adequate and proper service to our customers.

My testimony presents comments on six areas of concern. And I'd like to note that these are constructive comments. They're not meant to criticize anyone, but to build better regulation for the future. These areas of concern, which are included in my written statement, are the proposed radon rule, the proposed arsenic rule, MTBE contamination of drinking water, the implementation of the drinking water State revolving fund, the threat to national drinking water standards posed by tort litigation, and drinking water infrastructure needs.

With respect to the radon rule, NAWC does not believe that the proposed MCL of 300 picocuries per liter or any level below 1,000 picocuries per liter can be justified by cost benefit analysis. I have a study from NAWC's California chapter, the California Water Association, which documents in detail the deficiencies of EPA's cost estimates, and I would like to submit this statement for the record.

Senator CRAPO. Without objection.

Mr. TOMPKINS. In summary, NAWC believes that the nationwide implementation of effective State multi-media mitigation programs is essential for the radon rule to achieve its intended goals. We urge Congress to consider legislation that would place the requirements of the multi-media mitigation program in EPA's air program where it belongs, and to provide States with sufficient resources to implement it.

The effective MMM programs implemented in every State plus a drinking water MCL of 4,000 picocuries per liter will provide far greater health benefits at a more reasonable cost than the drinking water standard of 300 picocuries per liter alone.

With respect to the arsenic rule, I think you've heard enough discussion on that. The NAWC also urges EPA to reconsider the available body of scientific evidence and to consider a final standard of no less than the 10 parts per billion that is currently used by the World Health Organization.

The MTBE contamination of drinking water, use of MTBE as an oxygen additive in reformulated gasoline has created a significant and unacceptable risk to drinking water, both surface and groundwater, in many areas of the country. Recently, EPA recommended that Congress amend the Clean Air Act to significantly reduce or eliminate the use of MTBE as a fuel additive. In New Jersey, the Clean Water Council, of which I am a member, has recommended that MTBE be banned immediately.

Water contamination tort litigation was mentioned by other witnesses. NAWC is working with its sister organizations who represent the water industry to propose legislation that will make compliance with the Federal standards a defense against potential tort litigation such as the lawsuits that are ongoing in California at this time. There are other areas where we all face potential litigation. I think all of the associations will endorse this legislation. We will be asking Congress to pass this legislation in the future.

The last item is the drinking water infrastructure needs. We've identified about $385 billion that is needed over the next 20 years

to improve the infrastructure. We look to the Government to make low interest funding available, and we urge you not to consider a grant program, but to promote self-supporting operations in all aspects of the water utility industry.

Thank you very much.

Senator CRAPO. Thank you very much, Mr. Tompkins.

Mr. Van Dyke?

STATEMENT OF RANDALL VAN DYKE, GENERAL MANAGER, CLAY REGIONAL WATER; PRESIDENT, NATIONAL RURAL WATER ASSOCIATION

Mr. VAN DYKE. Good morning, Senator Crapo and Senator Smith.

My name is Randy Van Dyke, and I'm the General Manger of Clay Regional Water, a rural water system in northwest Iowa. I'm also president of the National Rural Water Association, which represents about 17,000 small utilities in communities and rural water systems. And on behalf of those small communities, I would like to thank you for this opportunity to be here this morning.

I would like to focus my comments on the review of three key principles in the Safe Drinking Water Act of 1996. One, the use of sound science and cost benefits in rulemaking. No. 2, input from stakeholders in that process. And three, the emphasis on flexibility in the law. In my written testimony I've got many examples, and I'll just mention a few.

First, sound science and cost benefit. We see that EPA has not taken the initiative to obtain adequate data and sound science, including the use of the most recent occurrence information, reasonable health effect study and reasonable compliance cost information when they're promulgating their new rules. Frequently, that good science and good research are started too late. And that research selection and data collection, lag far behind the timing when EPA is to write and finalize these new regulations.

Consequently, old information and inadequate science is utilized as best available science, creating weak or wholly inadequate conclusions, which place devastating financial impacts on small systems across the Nation.

Without anybody holding EPA accountable, only a strong emphasis on statutory deadlines is accomplished. Selective science is used instead of good science, and appropriate cost-benefit analysis that was envisioned in the 1996 Safe Drinking Water Amendments. For instance, arsenic. There is a very uncertain scientific evidence of the health effects of arsenic at the levels proposed by EPA. Recently, EPA's own Science Advisory Board expressed concern that EPA's proposal for a maximum contaminant level of 5 ppb may be precipitous action and that a less extreme proposal be made until new studies are complete. Any decisions by EPA to go below the current 50 parts per billion standard would place an enormous cost on small systems without the public health benefits to justify that action.

The unintended consequence of regulating small communities in the absence of public health and cost information can be devastating, causing more harm than benefit to the customers.

In the stakeholder input, we have been disappointed with the consistency in which the Agency dismisses or sets aside input from stakeholders, the scientific community and the public. Numerous local officials have participated at great length on panels and stakeholders groups, only to see EPA unilaterally make all policy decisions. Ultimately, stakeholders are having little impact on the final rule. Work groups to provide background information, are pressed to provide incomplete or not-peer-reviewed data and submitted at the last possible moment.

Finally, flexibility as a remedy for this bureaucracy. The question has been asked, is it possible for EPA to ever choose a flexible approach. We have concluded that based upon our observations, that it is not possible for EPA to utilize that flexibility. But they cannot be faulted for this, because EPA is first and foremost a regulatory agency. They are only liable politically and legally when they don't fully enforce any of the regulatory measures to its fullest extent.

However, due to its mission incentives and culture, EPA at every opportunity has chosen to use its discretion in the Safe Drinking Water Act to increase the bureaucracy of its regulations. Here are some examples of our concern. Capacity development, that act provides for States to develop a program for assuring that it is sufficient for technical, managerial and financial capacity for all water systems and water systems applying for State revolving fund assistance.

National Rural Water Association recommended that States, not EPA, develop the capacity development strategies for meeting these specific areas written into the statute. This would provide States full flexibility to address small systems capacity development. Contrary to this input, EPA has written formal guidelines for these capacity development strategies, despite the fact that there is no statutory authority for EPA to write such a guidance. Our contention is that States should have ultimate flexibility in this process and that every State is presently operating a form of capacity development strategy simply in its regulatory compliance and technical assistance programs

EPA says that writing these guidelines was supported by the majority of stakeholders in a stakeholder process. However, this was not a stakeholder idea. It was a proposal initiated by EPA and pushed rigorously thorough that process.

Radon. EPA has proposed a radon maximum contaminant level of 300 picocuries per liter. Under the Act, a community can comply with the outdoor air equivalent, if its State initiates a multi-media mitigation program. However, EPA appears to be requiring an overly prescriptive mitigation program, rather than an education technical assistance approach. If the States do not adopt workable multi-media programs then small communities will be required to comply with the 300 picocuries per liter, which is an unreasonably stringent standard. Small systems should not be penalized for States' inaction or EPA's overly complex MMM program demands.

In closing, improving drinking water for small communities is more of a resource problem than a regulatory problem. Every community wants to provide safe water and meet all drinking water standards. After all, all local water systems are operated by people whose families drink the water every day, who are locally elected

by their community, and who know first-hand how much their communities can afford.

I want to again thank the committee for this hearing and ask for your assistance in clarity of the intent and the meaning of the provisions of the 1996 SDWA amendments and your resistance to call from special interest groups represent more and more ever stringent Federal unfunded mandates upon communities.

Thank you.

Senator CRAPO. Thank you very much, Mr. Van Dyke.

And to the whole panel, your testimony, both written and oral, has been very helpful to the committee. And we encourage you to continue to advise the committee of concerns.

I want to start out by approaching the issue of what possible solutions or support we can provide at the Congressional level at this point in time. And in that context, a number of you have made recommendations of legislative action that could be very helpful.

And I'd like to go over several of those recommendations that I think might be able to be worked into hopefully a noncontroversial bill. And just ask the panel if any of you have disagreements with any of these legislative proposals, and if so, to state the basis of your disagreement.

The first one, which has been mentioned by several of you, is to extend the current statutory deadlines for the EPA's action by, say, 6 months, so that a little more time can be put into place for the EPA to work with the stakeholders on some of the disputes about what the applicable science tells us. Is there any objection by members of the panel to legislation giving a 6-month extension of the deadlines? Mr. Olson?

Mr. OLSON. Yes. I assume that what you're talking about, are you talking about the arsenic standard?

Senator CRAPO. I would be assuming the arsenic standard and I think the radon, there were a couple of them that were mentioned by folks here. I can go back through my list. I know arsenic was one of them. Why don't you talk about arsenic, and I'll look at my list here.

Mr. OLSON. Senator, I guess I would urge that we take an historical perspective, for example, on the arsenic standard. EPA was originally required to review the 1942 standard for arsenic in 1974. EPA never completed and update the standard back in 1974, saying more research and time was necessary. Congress again ordered EPA to do it in 1986. EPA was put under court order. EPA missed the original deadlines, asked for extensions and said more time was necessary under the 1986 Act.

Now, in 1996, EPA again was ordered to do this by Congress, and given an extended period of time. It was given the research of the National Academy of Sciences, which told EPA and the Nation that the standard should be reduced as promptly as possible.

We believe that at this point, EPA has had ample opportunity and time to review its standard. We have agreed on numerous occasions to extensions of time for this process. We believe that the time has come for the Agency to make this difficult decision and to bite the bullet. I think we would oppose the 6-month extension, simply because we think that the Agency has had plenty of time to do it. It has the science and we don't believe that an extension

of time is necessary. In fact, we're concerned that it would lead to additional extensions in perpetuity to review this 58-year-old standard.

Senator CRAPO. Mr. Kosnett, and I'd ask each of you to be very brief, because we're running out of time. I just want to know your reactions. Mr. Kosnett?

Mr. KOSNETT. Senator, our committee stated specifically in its conclusions that the standard should be lowered as promptly as possible. We felt that the state of the science today was such that, based on sound scientific principles and scientific consensus, we could conclude that the current level was not protective of public health.

Senator CRAPO. Before we go to the others, I want to divert to that point very quickly. Did the study that you were a part of support the 5 part per billion level versus the 10 part per billion level, or whatever, or just recommend reduction?

Mr. KOSNETT. We were not asked to recommend a specific level. And we did not recommend a specific level. We were cognizant of the fact that the setting of a specific level involves not just health issues, but other concerns as well.

Senator CRAPO. Understood.

Mr. KOSNETT. And so we did not provide a number to EPA. But we did feel that the current consensus was that it should be lowered as quickly as possible.

Senator CRAPO. Mr. Grunenfelder and then Mr. Paris.

Mr. GRUNENFELDER. And my perspective is broader. And it depends on what you want to achieve. If it's to get rules adopted that's one thing. If you want to see rules implemented, that's another. To implement them, I don't think 6 months across the board will adequately address the need to prioritize that we're trying to achieve with public health protection and make sure that we can actually roll these things out and get them implemented.

So I think some of the higher public health rules, we should be working on them. We should move those forward. Some of the lower ones I think 6 months is not nearly enough. And I'll just quickly make an example of radon, where EPA's assessment of risk, the risk from drinking water to the radon problem, is 3 percent of the risk for radon. So is that a high drinking water priority which we should divert resources to when there are other, I think more important public health priorities.

Senator CRAPO. Thank you. Mr. Paris, and then I'll have to turn to the Chairman.

Mr. PARIS. Senator, thank you. We would support the 6-month extension in particular for arsenic. The rationale behind that right now is that that rule is just released. It is to be finalized in January of 2001, as by statute. Our fear is that even though we will have a comment period, it will be shortened insofar as EPA's ability to respond to the comments in this particular rule. We feel they need more time than they will be allocated. So we certainly would support that for those reasons.

The filter backwash rule is another example of a rule that we are extraordinarily concerned with. It was put out by statutory deadline. We find tremendous problems with that rule. We think that a statutory extension on that is also reasonable.

And I'll make one other point, and that's the coordination of the rules that impact the same utilities. We have a couple of rules that deal with arsenic and radon that have every potential to impact exactly the same utilities, the utilities that are smallest and least able to handle those rules. I'm not asking here that those be delayed, but I am asking that they be coordinated so that the same utility that has to deal with both rules can have the opportunity to do it once and do it finally and not have to incrementally take steps that may damage previous steps.

Thank you.

Senator CRAPO. All right, thank you. I'll pursue this line in a little bit. But the Chairman has his turn to ask questions now.

Senator SMITH. Thank you very much, Chairman Crapo. And thank you for holding these hearings.

I have a statement for the record. I would ask unanimous consent that that be entered into the record.

Senator CRAPO. Without objection.

[The prepared statement of Senator Smith follows:]

STATEMENT OF HON. BOB SMITH, U.S. SENATOR FROM THE STATE OF NEW HAMPSHIRE

Good morning. I would like to first thank Senator Crapo for his leadership on the Fisheries, Wildlife and Water Subcommittee and for holding this oversight hearing on the Safe Drinking Water Act and recently proposed national primary drinking water standards.

It has been over 3 years since Congress overwhelmingly passed the Safe Drinking Water Act Amendments of 1996. This Act is an excellent example of what can be achieved when we work together on a bipartisan basis.

When we were drafting the 1996 Amendments to the Safe Drinking Water Act, the committee worked closely with the Administration, state and local governments, and stakeholders to ensure that all Americans receive clean and safe drinking water. Today's hearing is an important step in carrying out the goals of these Amendments.

With several new regulations proposed in the past year, including the radon and arsenic rules, cooperation between Congress, the Environmental Protection Agency (EPA), and the drinking water community is necessary to protect public health while continuing to address the costs to our economy and small systems as a result of new drinking water standards.

I have been working on the issue of improving our drinking water supply for many years. I have worked on the radon issue since 1991 when EPA proposed a rule to limit radon in drinking water. I took an interest in this issue because of its importance to New Hampshire. At that time, it was estimated that cities and towns in New Hampshire would have to sepnd as much as $12 billion to comply with the EPA's proposed limit. Even more importantly, the proposed rule would have achieved very little environmental or health benefit since it would have reduced indoor air levels by only 2–5 percent—the real source of risk. I was convinced that the very limited risk reduction did not justify the costs of the new rule.

However, the cost factor was not what caused me the greatest concern. I believed that EPA's proposed rule was not based on sound science. Even EPA's own Science Advisory Board criticized the proposed standard as very costly with minimum health benefits. I agreed with the Board's assessment that controlling radon from all sources was necessary. I also believe resources should be directed toward the greatest health risk, which is from airborne emissions, not drinking water.

In the 1996 Safe Drinking Water Act Amendments, we greatly improved the process by requiring that sound, peer-reviewed science and cost-benefit analyses be used when the Environmental Protection Agency conducts risk assessments for all drinking water standards. I supported a provision that required the National Academy of Sciences (NAS) to conduct a full risk assessment of radon in an effort to produce a more scientifically based standard for radon in drinking water.

The NAS report on radon, released in 1998, concluded that, "the increased level of indoor radon that is caused by using water in the home is generally small compared with the level of indoor radon that originated in the soil beneath the home." Radon is an air problem, not a water problem. The report also found that the risk

from radon is higher among smokers because the combination of radon and smoking increases cancer risks.

Today, EPA is in the process of finalizing the proposed rule on radon. The radon rule sets a Maximum Contaminant Level (MCL) for radon in drinking water at 300 picoCuries per Liter (pCi/L) and an Alternative Maximum Contaminant Level (AMCL) for radon at 4,000 pCi/L. While the NAS report supports the approach taken in the new proposed AMCL for radon, I continue to have serious concerns about the science underlying the specific radon standards, the costs associated with compliance with the new standards, and the burdens placed on small systems to find affordable treatment technologies. Small drinking water systems should not be responsible for addressing an air problem, when they deal with water.

I look forward to hearing from EPA today how it plans to address these issues, and any others that may be raised by stakeholders.

Another major proposed regulation that could have a substantial impact on small systems is the arsenic rule. At EPA's request, the National Research Council, a subset of NAS, reviewed data on the health effects of arsenic in drinking water and recommended revising the MCL for arsenic to a level below 50 parts per billion (ppb). I support lowering the standard. It is clearly warranted to protect public health. But I am concerned that EPA has gone too far.

EPA has recommended 5 ppb as the new MCL for arsenic, a level that the science on arsenic just does not justify. Other levels, such as 10 and 20 ppb, have been proposed by EPA for comment and can be supported by the available science. The 1996 Amendments to the SDWA require the best available, peer-reviewed data when selecting an MCL. I don't believe the data to support an MCL of 5 ppb is available right now.

Proponents of the 5 ppb standard argue that EPA should adopt a lower standard even if the science is not there. I believe the better, and legal, solution is to adopt a scientifically justifiable standard now and then review it in a few years. The SDWA provides for a 6-year review of all drinking water standards. Arsenic would be an ideal candidate for this review. When stronger science is available that can substantiate the 5 ppb level, reduce the level then. As with the radon standard, I also have concerns that economically viable treatment technologies do not exist for small systems to meet such a low standard.

I have a number of questions for the Administration and the water companies and associations represented here today about the Safe Drinking Water Act and the proposed radon and arsenic rules. These issues are very important to me because of the high levels of radon and arsenic in drinking water in New Hampshire.

Another issue of concern to the citizens of my State is the issue of fluoride, and in some cases the addition of fluoride to the water supply. I am pleased that Dr. Hirzy was able to testify on this significant issue on behalf of the National Treasury Employees Union Chapter 280 to express his concerns about fluoride and the fluoridation of public drinking water supplies. I have been contacted by a number of constituents in New Hampshire and across the country who have voiced concerns about negative health effects associated with fluoride in drinking water.

In 1986, EPA set the revised Maximum Contaminant Level and Maximum Contaminant Level Goal for fluoride in drinking water at 4 parts per million (ppm), taking into account the need for an adequate margin of safety. Many public water systems add fluoride—usually at a level of 1 ppm—to prevent the incidence of tooth decay. As I mentioned, I've heard from a number of people across the country who are concerned about this practice. I recognize that the Safe Drinking Water Act prohibits the EPA from requiring the addition of any substance, including fluoride, to drinking water for preventative health care purposes. However, since this subcommittee has jurisdiction over the Safe Drinking Water Act, I believe we have an opportunity to ensure that EPA is on target with assessing the risks of fluoride in drinking water. I hope we can address the fluoride controversy and what the Federal Government's role may be in the debate during today's hearing.

I look forward to hearing from the witnesses this morning. Thank you.

Senator SMITH. And we appreciate your being here, all of you. I echo the comments of Chairman Crapo in the sense that 3 years ago, we passed this bill. We tried to help and I guess the question is, how did we do. It seems as if there still are some problems. And that's why we're glad to have you here.

But in passing that law in 1996, which I think was probably unanimous through the Senate, I don't remember if there were any objections or not, but we tried to work with the stakeholders, folks like yourselves, before drafting and passing that bill. But with all

these new proposed regulations that are coming especially in radon and arsenic and other areas, we want to continue to protect public health and at the same time, not be unreasonable in terms of what you have to face.

Mr. Paris, thank you for coming, welcome from New Hampshire. It's good to have you here.

Can you give us a sense, and perhaps others may wish to comment on it as well, but just in your area of Manchester, the cost ramifications, if we were to go with these proposed rules, no forbearance, if you will? How would this affect your ratepayers? If you can break it down to the individual level.

Mr. PARIS. I'll give it a shot. The system that I represent, first of all I think it's important to understand it's a large system. It reflects probably the greatest ability to pay. And the rules that we're dealing with today to a very large degree are significantly directed toward smaller systems. I think the number and intensity of the rulemaking for small systems is perhaps the key element.

In Manchester, for instance, even though it's not a rule, one of the more significant issues we're going to have to deal with very shortly is MTBE. That falls outside the rulemaking parameters, but it is still one of those issues as public health people and as being responsive to drinking water quality we must be responsive to. I think it's a grand example of the industry taking steps as well as Congress to mitigate a problem that is recognized by the general profession and public health experts as one that needs to have action taken. And that that action is being taken outside the purview of a regulatory mandate. And I applaud that. And I think that that says more about the way these rules can function than anything else.

For Manchester, the microbial disinfection byproducts cluster, if you will, will be the primary focus and impact. We will need to perhaps change the way that we disinfect our water as a result of that. And I would use Manchester as a poor example in that we have made such investment in our system, and I'm very proud of that, that we probably will be able to comply with the actual letter of the law even after these stage two rules are implemented.

But for many utilities, it will mean that they will be adding ozone or ultraviolet irradiation to their systems at significant cost for their customers. It will be done in, I think, a collaborative and a cooperative method to try to get to some of the microbial issues and the microbial risks that are out there.

It's difficult for me to put numbers on it for Manchester, but I would say for the smaller utilities in New Hampshire, these will be considerable hits. And their bills will go along the lines of what the ability to pay constraints are that we discussed earlier.

Senator SMITH. Let me focus on MTBE for a moment, and I'll come back to you, Mr. Paris. We've got representatives across the country here. Can you just, yes or no, is MTBE a problem in your various regions? Mr. Gunter, you're Kansas City, right?

Mr. GUNTER. Currently it's not a problem, not a serious problem.

Mr. GRUNENFELDER. In the Sate of Washington, we don't have widespread contamination, either, that we have found.

Senator SMITH. Who else?

Mr. TOMPKINS. In New Jersey, there is a slight problem in the northwestern part, in Sussex County, from leaking underground tanks. But it's very small and it's contained to that area.

Senator SMITH. The Congress has focused on this, obviously it's a huge issue. I know it's big in New Hampshire, Mr. Paris. Do we have any estimates at this point how many systems are affected in that State?

Mr. PARIS. Yes, I was involved with a recent rulemaking with the State of New Hampshire legislature where the State passed guidance at 13 parts per billion for MTBE in drinking water. During that proceeding, the estimates were that there would be, I think, Dover and perhaps one other community that could be in violation of that standard, but that there were, the number is almost 20 percent, something like that, of the community supplies that either detected MTBE or were in jeopardy of it, due to plume emanation. There was considerable concern.

It's also a concern, not only from leaking underground storage tanks, but as I mentioned before, from power boating and recreational use. As you know, in the beautiful town of Wolfboro, we have tremendous pressure on our resources for recreation.

Senator SMITH. Well, this really gets to the heart of the problem we all face here as Senators, everybody says, well, just ban it. That's easier said than done for a number of reasons that are associated with the Clean Air Act. Of course, the root of the problem is that the underground storage tanks leak. But that's for gasoline. It does not deal with the issue of somebody putting gasoline in a boat and putting the nozzle back and dripping some of that into the water, which then diffuses rapidly through the lake. In the case of Lake Winipesaukee in New Hampshire, which is a huge lake that has a lot of boats, and most States have lakes with boating, so it could become a severe problem in that area as well.

So it is a safe drinking water issue. It's a clean air issue. It's a leaking underground storage tank issue. And it's a very complex one, but one that I would just say to all of you, if you don't have it yet, you're lucky. But it could very well become a problem.

But here again, this goes back, Mr. Chairman, to if we had done good risk assessment and looked at the science, we would have known or should have known that this was going to be a problem if it did get into our groundwater. So we're trying to fix the air problem and in doing that, we created another problem, because we didn't really investigate the science.

Just one more round for Mr. Hirzy before I yield, Mr. chairman. Mr. Hirzy, I know you're an employee of the EPA. And I'm assuming that your views conflict with the Agency on the issue of fluoridation. Is that correct?

Mr. HIRZY. Given the fact that EPA has set the maximum contaminant level, as indicated on the chart, at 4,000 parts per billion, and the so-called optimum level is 1,000 parts per billion, one could assume that. A citizen inquired of Congressman Bob Young to ask EPA about the American Dental Association listing EPA as an endorser of fluoridation. The then Assistant Administrator for Water, Bob Perciasepe, wrote back to Congressman Young and said that EPA has asked ADA to take EPA's name off the list of endorsers of fluoridation.

So it's a wash. EPA I think is playing the good Federal solider and supporting this program that's been a Federal mandate more or less for 50 years. But officially, it's not on the list of endorsers.

Senator SMITH. Has EPA given you any indication, given you or your union any indication that the drinking water standards for fluoride will be reviewed in the near future?

Mr. HIRZY. They haven't talked to me about this issue. We did have a meeting with Cynthia Dougherty and some of her staff members about a year or so ago and laid out our case for such a revision. But we have not had any indication that that was going to happen.

Senator SMITH. You cited several studies which were very interesting. I saw them in your statement. What kind of, are these basically independent studies with no peer review, or has there been sufficient peer review to give these studies credibility or not?

Mr. HIRZY. The ones that are of most concern to us are the peer-reviewed studies that have appeared on *Neurotoxicology and Teratology and Brain Research* in 1995 through 1998. The work of Phyllis Mullinex, for instance, indicated that when rats were dosed, pregnant dams were dosed with fluoride that would result in serum levels in the brain of the pregnant dams that mimics serum levels in human beings drinking water at that maximum contaminant level, the dams gave birth to pups that were hyperactive, born hyperactive and remained hyperactive throughout their life. That was the reference in my testimony to asking for an epidemiology study that looked after that particular end point.

Also in that same journal in 1998, a group of Chinese workers published the results of some research in which they gave basically the same doses that the Mullinex group did, and indicated that there was a depletion of certain critical chemicals in the brain, basically the lipids that constitute the neuronal membrane, that that could explain on a mechanistic basis the outcome of the Mullinex study.

Then in *Brain Research*, in 1998, a group of researchers, which included an EPA scientist, found that one part per million of sodium fluoride resulted in changes in the cerebral vasculature in the test animals and also kidney damage.

Senator SMITH. Well, the current MCL and MCLG or maximum contaminant level and maximum contaminant level goal for fluoride, as you know, from both natural and added, or deliberate addition, sources is four parts per million. If EPA were to revise those standards, which is I think what you're suggesting should be done, what would be your recommendation based on the science of what that standard should be?

Mr. HIRZY. I ran some calculations based on the brain research article. And if one applied EPA's reference dose methodology, as opposed to the methodology that's been used to set MCLGs in the past, the reference dose methodology would indicate a level well below a thousandth of a part per billion of fluoride in the water. The Surgeon General's panel to which I referred in my testimony, folks who were working on that panel made a comment to the effect that we'd have to have rocks in our head if we recommended what at that time was called an RMCL of anything more than about one and a half PPM.

Senator SMITH. Mr. Olson, do you share the concerns expressed by Dr. Hirzy on fluoride?

Mr. OLSON. I don't consider myself an expert on fluoride. But we certainly think that, first of all, you should know that we sued over the original fluoride standard over 10 years ago, urging that the standard be dropped. We thought that a standard more in the neighborhood of one or below was more appropriate, because EPA admits that there are dental fluorosis spots that occur on children's teeth when you get up to the four part per million level.

There is a lot of science, as Dr. Hirzy suggests, that's come out since then. So I guess our view is that certainly there is a need for a careful peer review of all these new data, and there are significant concerns that have been raised over the last 5 years from some of the studies. We don't have a position right now on what the standard should be. But we think that a careful peer review and an open process to look at that new science is definitely called for.

Senator SMITH. And just a final statement, and I'll yield back to the Chairman.

The problem we face here at the Federal level is that each community makes the determinations, it's my understanding, whether they put fluoride in their water. This is not a mandate from EPA. So have other regions of the country experienced, I don't know if you all have fluoride, but have other regions in the country experienced the same thing? I'm getting a lot of complaints about the issue of fluoride from New Hampshire, the citizens. Does anybody else have similar experience?

Mr. HIRZY. If I may, it's my understanding that the State of California has set a health protection goal for less than a part per million, based on a review of the data there. I could stand corrected on that, but that's my understanding, that the actions that have taken place in California.

Senator SMITH. So you're asking that the standard be what? What are you asking? What do you think it should be?

Mr. HIRZY. Half a part per million at most. That would allow for the feasibility to not impose, I think, unreasonable burdens on many water companies. I think, however, I'm going to reiterate my statement that based on the science, and especially this brain research article, the so-called reference dose methodology that EPA uses would require, the dose being something like .000007 milligrams per kg per day, which would bring the MCLG down approaching zero.

Senator SMITH. Thank you.

Senator CRAPO. All right, thank you. Let me get back to the questions I had started out with, with regard to possible legislation. Mr. Gunter had recommended as another approach that we require that the cost benefit analysis or the cost risk analysis be published with the rules, so that we can see what that analysis was. Is there any objection to that approach, to requiring the EPA to do that, here on the panel?

Mr. OLSON. I just want to add one thing. EPA does publish them, and they release them publicly. I guess the concern is that they're not in the Federal Register.

Senator CRAPO. Right, at the time of the publication of the rules, is that the issue, Mr. Gunter?

Mr. GUNTER. That was the issue.

Senator CRAPO. So apparently they do publish them, but not at the same time. So we can't evaluate them in the context of the rule itself. Any objection to a requirement in a statute that would clarify that at the same time we analyze the rule, we have the cost benefit analysis data available? Mr. Van Dyke?

Mr. VAN DYKE. Mr. chairman, I'm not sure how many scientific studies on arsenic were looked at the by the Science Advisory Board. But they did suggest that that was an extreme proposal that EPA was coming up with 5 micrograms per liter. I just want to point out that there are five significant new studies that are now underway. You might want to take a look at when those studies would be available in light of the timeframe extension. That could be significant in terms of what Mr. Fox was talking about before, regarding affordability and compounding effects of some of these regulations.

A community was mentioned with radon and with arsenic. And during an extended timeframe, we could look at compounding effects of some of these regulations. There was a suggestion by Mr. Fox that EPA does not consider an exceedance of three times the affordability of median household income. I'm not aware of a rule or any variance to that effect, and I would appreciate if the committee could look into that. If there is such a variance that as reference, or any variance above $750 per household income. Because any one of these single rules could far exceed that in terms of individual and compounding effects, which reiterates what I've heard commonly referred to in a lot of literature as a train wreck for small systems. There are significant impacts.

Senator CRAPO. So if I understand you right, you're saying you're aware of proposed rules that individually exceed the $750 amount of affordability that Mr. Fox was talking about?

Mr. VAN DYKE. Yes. On a compounding effects basis. There is significant costs. Whether you look at it on the $750 or the three times median household income average, there will be extreme costs.

Senator CRAPO. Let me go to the third suggestion by Mr. Gunter, or maybe it was his second, which was an independent National Academy of Sciences review of how well the EPA is incorporating science into its regulatory decisions. We have seen not only in this context but in a number of other contexts some serious questioning of whether the EPA's science is being done well, and whether they're incorporating good science into their decisionmaking. Any objection to a National Academy of Sciences study of this issue?

Mr. OLSON. Senator, could I respond both to the previous question and this one? I don't think we would have any objection to legislation that would say that in the future, EPA should publish a cost benefit analysis with its, or the HRRCA, as it's called, with the rule. I'm not sure there's a big problem with that. I would be concerned if it would cause delays in upcoming rulemakings.

Senator CRAPO. Understood.

Mr. OLSON. You should know that there always is a cost benefit analysis included in every EPA proposed rule and final EPA rule.

It's just this HRRCA, which is generally a massive document that's much more detailed that comes out, in some cases a little later.

With respect to the National Academy of Sciences review, I don't think we would have any objection to a National Academy of Sciences review. It's always good to have sound science.

Senator CRAPO. All right, thank you. I know there were a number of other legislative proposals brought up by members of the panel. But because of, in the interest of time, I want to move on to another aspect of this. And it is the question of the affordability of the regulations, which was raised with the first panel.

As you heard in the testimony given by the EPA, they're using a 2 and a half percent of median family income nationwide standard, which as they testified was $750. As came out in that testimony, that would be higher than 2 and a half percent for half the families in the country and lower than 2 and a half percent for half the families in the country.

But it was about three times what the current cost per family is. And I would just like your input on that general standard at this point. It seems to me that affordability is a very big issue. And particularly that is the case for smaller facilities and communities that have less resources to apply to the remediation.

The question I have is, although Mr. Fox testified that they hadn't yet reached that $750 level, Mr. Van Dyke indicates, depending on how you look at it, in a cumulative effect, it has been reached or will be with a number of these new proposed new rules. And it seems to me that what we are looking at is tripling the average family's cost of this across the country. Am I understanding that correctly, and do any of you have any comments on this issue in general? Mr. Van Dyke.

Mr. VAN DYKE. The rural water system that I manage, our current average cost without any of these proposed rules in effect is in excess, for the average household usage, of over $500 now, before any of these rules take effect.

Senator CRAPO. So you're at about $500 now, for your system, above it?

Mr. VAN DYKE. Yes, sir. The other issue is, the feasibility analyses that are based on the rulemaking that was described by Mr. Fox, was for large systems, rather than on small systems.

Senator CRAPO. That's right.

Mr. VAN DYKE. Our concerns and a problem for us, is in terms of the way EPA uses that information.

Senator CRAPO. But that information is used for small system?

Mr. VAN DYKE. Yes, sir. And microbial rules that are being promulgated are exempt from the affordability issues. They are not considered in the feasibility analysis.

Senator CRAPO. Oh, so not all of the rule's impacts are included in the calculation of affordability?

Mr. VAN DYKE. That's my understanding.

Senator CRAPO. Mr. Grunenfelder.

Mr. GRUNENFELDER. I just wanted to echo the concerns around a small water system. In the State of Washington, we only have 97 water systems that have over 1,000 connections. So that's about 3,000 population. Whereas we have almost 2,000 water systems with less than 100 connections. So about 300 population.

And the cost impacts of implementing these rules on these very, very small communities is dramatically different than, again, the larger communities. It takes a lot more effort and time to work through these issues, as a result. So the State of Washington, I think, ranks either second or third in the country in terms of getting State revolving fund loans out to small communities. But again, this is making a very, very small dent in the overall impact. And the timing it takes to roll these rules out and actually get them going.

Senator CRAPO. Mr. Grunenfelder, just in terms of the system which you are familiar with, if the EPA rules are adopted as proposed in these various areas, will that have an effect of reaching the $750 level per family in terms of the cost that will be imposed? Can you tell whether that's going to hit this target?

Mr. GRUNENFELDER. I have no doubt in my mind that it will. But for example, just looking at how the arsenic rule would affect small systems, it will affect hundreds of small groundwater systems in the State that have naturally occurring arsenic. So again, it's the small water systems that will have to build the same treatment facility that the larger systems will, with again a rate base of maybe 30 customers to spread that cost over, or 40 customers to spread that cost over. And the rates accumulate very, very rapidly.

Senator CRAPO. And what kind of accommodation, if any, does the EPA provide or propose to provide for a community that has to achieve the same objective with 30 users that 3,000 or 30,000 user community would be required to meet?

Mr. GRUNENFELDER. And again, right now it's only the emphasis of trying to target the State revolving loan fund money to these small communities, which we are clearly doing. But for example, the secretary in the State department of health and I got to visit two small communities last Friday. And when you go and sit down with a water board that has a 50 connection water system, so 50 homeowners in their community trying to meet enhanced surface water treatment rule disinfection byproducts that will be coming up, a number of other rules, they are at a total loss of how they will do that. Let alone repay loans which they might be able to get. They have no credit capacity to get loans.

So it just creates a real dilemma. And again, it's taking us a long time to work through that community to look at how State grant programs or other types of funding can be brought to bear on meeting the requirements. Because we do want them to meet the requirements.

Senator CRAPO. By the way, before I let any others who want to answer this get in, I would like to just quickly ask, one of the other legislative proposals that has been made by a number of you is more resources for infrastructure needs. I assume there's no objection on the panel is we would try to provide more resources for the infrastructure needs.

Anybody else want to comment on any of these issues? Mr. Olson.

Mr. OLSON. Yes, I'd like to speak just for a moment about the affordability issue. I think it's important first of all to recognize that water is an incredible bargain in the United States. Most peo-

ple spend less on their tap water than they do on cable TV, on gas, on bottled water, on electricity, on phone systems.

And everyone, I brought with me this report that was done by the water utilities themselves that suggests that over the next 20 years we're going to have in the neighborhood of $5 billion that has to be spent to upgrade these systems. So the cost of water is going to go up. And they say most of it is not from EPA regulations, it's from other issues that are going on.

The other important issue is that 90 percent of the U.S. population gets its water from these larger systems. Nine out of ten Americans gets their water from these large systems. So for example, the arsenic rule is going to cost about $5 a month for those systems affected for the large systems, $5 to $10 a month. The cost is very reasonable, generally, for any of these regulations, for nine out of ten people.

The issue becomes these small systems. And we have a proliferation of them. And I think all this revolution we've heard about is going to force many small systems either to package technology that basically comes in on a skid and they have to install it or at a point of use which is basically a filter you put on your tap or point of entry where you put it in your house, or to consolidation and regionalization of many of these small systems.

The last thing I think is important is that in 1996, I don't know if you're aware of this, but Congress did put a special provision about small systems in the Act that deals with this very high cost for some small systems. Basically it's a three-pronged approach.

First, they can get out of some of the requirements through variance and exemption provisions that the States administer. Second, there's targeted money through the State revolving fund for small systems, and third, there's a special requirement for special technology for small systems that would be available when they issue a new standard.

So I think a lot of these issues will be dealt with. It's going to be a wrenching, difficult time for many small systems over the next 5 to 10 years.

Senator CRAPO. Thank you. Mr. Tompkins.

Mr. TOMPKINS. Senator, I'd just like to comment on the affordability issue, that from the National Association of Water Companies standpoint, if there are consumers who have an affordability problem, the social agency would make available some form of supplement to their utility bill. And this could be done from Congress right on down, so that you're not making the water utility the social agency.

Senator CRAPO. Thank you. Quickly, before I go on, Mr. Grunenfelder, how often do you get variances from the EPA, as you try to help these small systems?

Mr. GRUNENFELDER. On things like monitoring waivers, we've done some pretty comprehensive assessment throughout the State to see where certain areas of the State simply don't have certain types of VOC or volatile organic chemical, synthetic organic chemical contaminants. And we have granted waivers in those areas.

Things like mailing consumer confidence reports to customers. We have not pursued a waiver in that area, thinking that consumers should know about their water. So it varies with the re-

quirement and how we see it fitting with our objective in the State, which is to get information to the public and protect their health.

Senator CRAPO. All right, thank you. I apologize to the panel, I've got pages of questions here that I'd like to go through and we are already out of time. But I would like to, and I probably will submit some written questions to you and ask you to respond to them.

But I would like to spend just a few minutes here, I'll go late to my next meeting, and just have a brief discussion of the general issue that I was discussing with the first panel, which is this question of whether we have the right level of default protection in our system and whether we are hitting that right point in terms of the amount of resource that we are directing toward certain recovery when the cost gets higher and higher as we get to the incremental increases.

And the first part of that is, as I understood what we talked about with the first panel, we tend to have a tradition or a standard that we follow in the industry or in the regulatory community of identifying where the risk level is and trying to get somewhere between 10 to 4, 10 to 6 levels, 10 to the minus 4, 10 to the minus 6 levels below that in terms of the risk that will be acceptable. Now, if I've stated that right—have I stated it right? Mr. Olson, do you want to say it the right way?

Mr. OLSON. Well, I think there are two different issues and they tend to be confused very often. One is the level at which you regulate a carcinogen, where EPA traditionally has tried to target a goal of no more than 1 in 10,000 people drinking the water for a lifetime would get cancer from that carcinogen. That's for carcinogens, and actually, they try to make it stricter than that if possible or feasible.

The other issue is for something to cause a certain acute effect, you know, a chemical that will cause you to get sick almost instantly. In that case, they will establish safety factors, so they'll do animal tests or they'll base it on human epidemiological evidence. And then they'll try in some cases to put a safety factor on it.

For nitrate, for example, there is virtually no safety factor. There are human studies that show children, babies get sick when they drink water containing nitrate at above around 10 parts per million, and the standard is 10 parts per million. They just figured there was no feasible way to get below it.

Senator CRAPO. Anybody else want to clarify this issue for me? Mr. Paris.

Mr. PARIS. If I may, I fully concur with Mr. Olson's interpretation. One of the comments you'll see in our written testimony has to do with how, when you take that interpretation for risk and you apply it to a small system, it literally takes hundreds of years before any incidence of illness or cancer, in this particular case, would occur in that particular community, taking 1 in 10,000 for 70 years and saying your community has 300 people in it, it takes many, many years, hundreds of years, before it impacts to that type of regulation and that type of risk evaluation has an impact on that community.

It's one of those pragmatic issue, if you will, it reflects in our thinking on why some of these rules, as applied to larger populations, fall down in the practical line of thinking when you apply

them to smaller systems. So I would reflect that in our written testimony as part of our argument.

Senator CRAPO. Any other comments on just what that standard is and how it's used? Mr. Van Dyke.

Mr. VAN DYKE. Mr. Paris has a strong point here. Radon is an example of that. If there's a potential chance of a risk of cancer from radon attributable by water, if you try to mitigate that, a community might be mitigating an unknown or less than zero possible health risk benefit. Feasibility assessments that were described by Mr. Fox, again, use large system analysis. But 94 percent of all public water supplies are below 10,000 population, about 65,000 public water supplies are small.

So the criteria that we're using to judge this risk benefit analysis doesn't work really well in that model when you get down to the smaller systems. It just breaks down.

A more appropriate way, would be to look at cumulative risks of a given population in their area, including water, medical needs, and other things, rather than solely water.

Senator CRAPO. Mr. Kosnett.

Mr. KOSNETT. I just wanted to address an issue regarding that. The risk to any one given person is no different in a small town than in a large town. The statistical power for you to detect it in a small town is limited by virtue of the fact that it's a small town.

But the risk is the same to people, regardless of whether they live in a small town or a big town.

Senator CRAPO. Let me ask you a question to clarify the concern that I have in that context. I am assuming, and let's assume for the purpose of this question that this is true, that the median income of the small town is going to be lower than the median income in the large town. Well, first of all, let me ask, would that be a safe assumption generally? Anybody disagree with that assumption?

Mr. TOMPKINS. Well, in the case of some of these resort communities, I don't think so.

Senator CRAPO. You're right. In a community, say a resort community, it would not be correct.

Well, let me just say it this way. I'm assuming that in rural America, that the income levels on a median basis are lower than they are in urban America. Is that a fair assumption? I see members of the panel shaking their head yes. Let's assume that for the time being, and assume that in a general case, you're looking at people with lower levels of income, and lower numbers of people to provide for the funding of the technology that is needed to solve the problem.

Recognizing that the risk to them is the same in the small community versus the large community, on an individual basis, if the cost to that community on an individual basis is extremely higher than it is in an urban area, isn't that generating another element of risk to that individual because of the loss of income? Dr. Kosnett, do you have an opinion on that?

Mr. KOSNETT. I don't want to opine on the risk associated with economic changes in a person's status, because that's not my area of expertise. So I would defer to other people on that.

Senator CRAPO. Do you know, Doctor, are there experts in that area?

Mr. KOSNETT. About the risk of having a lower income?

Senator CRAPO. Yes. The health risks of having a lower income.

Mr. KOSNETT. I'm certain that there are some associations between health status and income. However, that is an area of specialization in public health, and I think the committee could get input from those individuals.

Senator CRAPO. OK, thank you. Mr. Van Dyke?

Mr. VAN DYKE. Mr. Chairman, in my written testimony, I quote an expert in this area, Scott Rubin:

> "Public health protection isn't free, whether it's medical care, sewage treatment, clean drinking water, AIDS prevention, prescription medicine, food, heat, or shelter. Costs are real. We don't have enough money to go around."
>
> "So yes, if we're setting public health policy, and that's what drinking water regulation is, we'd better make sure that we're getting our money's worth. Because if we're not buying meaningful public health protection, all we've done is take money away from people who need to put food on the table, pay the doctor or keep a house warm.
>
> "The point is simple. Whenever you do anything to increase the price of water, we are forcing millions of families to make another tradeoff which will directly affect their health. At the same time, we take a family that is barely squeaking by and we push them over the edge."

Senator CRAPO. I guess that's the question that I want to get at. Maybe we'll have to have a hearing on just that issue and get some experts in here on that issue.

But the point has been made to me a number of times over the years that when you get to families who are already maxed out on their disposable income in terms of food, health, shelter, the costs of clean drinking water and safe drinking water and the many other things, medicine, prescription drugs, whatever it is that they need, and you decide to reallocate that spending for them through a Federal or a State action, there is a cost. Or there is an impact, I guess is the point.

And somehow I think we've got to bring that impact into the mix of the discussion. Because it may be that the points that have been raised earlier about needing more Federal resources and State resources for these communities that don't have the numbers of population to be able to bring in the technology is a big part of the answer.

But we've got to, in my opinion, identify the full impact here. Because that's what resonates in the political climate. And it's not just that people want to use these dollars for non-discretionary items, for luxury items or a new Corvette or whatever that may be. The question is whether people need it for their prescription drugs or for other non-discretionary items of their budgets.

To me, that aspect of the cost benefit analysis needs to be brought to the forefront and identified. I think that may be what Mr. Gunter was talking about in terms of getting that analysis in terms of the cost benefit brought forward and made a part of the rule proposal itself.

I'm pretty much capped out on time. But if any of you would like to make one last quick comment, I would certainly welcome it.

Mr. OLSON. I think this issue has been debated by this committee since the Safe Drinking Water Act passed, the small community versus large community issue. I just think it's important to focus on the fact that the committee has always tried to avoid creating one standard for people in cities where they get safe drinking water and a different standard for people in small communities that get water that is not safe.

So that tension has always existed. We don't want to create second class citizens across the United States in rural communities where they get less safe water.

The way that we think you deal with that, and I think the 1996 amendments included important provisions that tend to allow more flexibility for small systems and there is quite a bit of additional resources and flexibility in the 1996 amendments that I think largely deal with a lot of those issues.

Senator CRAPO. Thank you, and I certainly agree. Yes, Mr. Hirzy.

Mr. HIRZY. May I please, Senator. There is one and only one substance that the Federal Government has been mandating and promoting that every American citizen consume via their drinking water systems, and that's fluoride. It's been 23 years since there's been a national hearing in the Congress on the science and the social impacts of that particular substance that the Federal Government is pushing. I would like to reiterate my call for a national Congressional hearing on fluoridation, so that the latest science can be brought to bear on that issue.

Senator CRAPO. Dr. Hirzy, your call has been heard, and I will check with and coordinate with the chairman of the full committee, Senator Smith. The comments and suggestions of all of you that may not have even been able to be talked about here today are certainly welcome. I was just reminded, I'm going to leave the record open for 2 weeks so if you'd like to supplement the record with any further thoughts or comments, you're welcome to do so.

I agree with the points that have been made, the risk is the same at an individual level across the country. And we don't want to have citizens who get a different benefit from the law depending on where they live. I just think it's very complex. Because if we do that analysis in the context of only one thing, like arsenic, or fluoride or whatever, and don't realize that we're dealing with populations that may have very high costs associated with what we are providing to them in terms of this standard that they get to pay for, that we could be making them second class citizens in terms of the heating that they have in their home or the health benefits they get through their health care that they can provide to the family or the quality of the food that they eat and so forth.

So it's just a very complex analysis. And I do think that one area of strong consensus that I'm sensing here in the panel and that I'm agreeing with is that it's very possible that the solution is that when we look at the communities that are small enough that they don't have a resource or a population base to solve these problems in an affordable way that doesn't have these large impacts on other aspects of their health, and their quality of life, then that's an area

where, if we want to have a Federal standard, then we'd better have some Federal support for achieving that standard.

So I'll let you have the last word, Mr. Van Dyke, and then I'm going to have to wrap it up.

Mr. VAN DYKE. Mr. Chairman, Mr. Olson talked about the issues that were discussed in the Safe Drinking Water Act on small versus large and some of the tools that were put in the 1996 Act. I won't take up the time of the committee, but ask that you turn to my testimony. For a number of different reasons notwithstanding, what Mr. Grunenfelder said that State primacy agencies are allowing some variances on monitoring, EPA has not granted other variances, or used any of the tools that Mr. Olson described. I refer again to my testimony for examples. There are several reasons why that hasn't occurred, but in the shortness of time, I just ask that you address this issue in the future.

And maybe the committee might look into why this is occurring—those tools are not being put into place.

Senator CRAPO. That's a very good point, in terms of using tools, providing resources is one. But the variances and the other tools, if they're not being utilized, need to be utilized, and I appreciate that comment.

Again, I wish we could go on more. This is a very important issue and I believe we've had a good discussion of it today. However, we are always caught by time issues here. And I appreciate your time that you've given us today. We will be paying very close attention to this, and if we can, find some consensus and some common ground on which we can move forward with legislation to help improve this, we will.

We will continue to use our oversight function here to assure that we achieve some of these objectives that can be achieved without legislation. And I ask you to continue your valiant efforts in keeping us informed of what we need to be focused on.

And with that, this hearing is adjourned.

[Whereupon, at 12:47 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[Additional statements submitted for the record follow:]

STATEMENT OF HON. BARBARA BOXER, U.S. SENATOR FROM THE STATE OF CALIFORNIA

Thank you, Mr. Chairman.

When the Safe Drinking Water Act was passed in 1974 many Americans took the purity of their drinking water for granted. Today, reports of radon, arsenic, MTBE and other contaminants fouling our water undermine the public trust in that water.

In California, where water is scarce, the loss of a drinking water supply to contamination can be devastating to local communities. The City of Santa Monica now pays to import water from the Colorado River after losing its main drinking water wells to MTBE contamination. Lake Tahoe, known for its one-a-kind lake, has lost about half of its drinking water wells to the same fate.

I am pleased that EPA is moving forward to control some of these drinking water threats. Earlier in the year, EPA finally announced that it would begin the regulatory process of banning MTBE. I hope that we move forward in the full committee to ban MTBE faster than EPA's timetable, but I am pleased to see EPA finally moving on this issue.

In response to a 1999 National Academy of Science report, EPA also recently took action to control arsenic in drinking water. Arsenic has turned up in drinking water supplies around the nation. It can cause cancer, cardiovascular problems, skin lesions, reproductive problems and harm to the nervous system. In its report, the

NAS found that the existing drinking water standard—which was set in 1942—does not protect public health.

It found that this outdated standard "could easily" result in a total cancer risk of 1 in 100. This is about 100 time greater risk than EPA allows under other drinking water rules.

I applaud EPA for moving forward to regulate arsenic in drinking water, and I look forward to learning more about this issue today.

Finally, the NAS also recently concluded that radon in drinking water should be controlled. The NAS found that radon can be present in drinking water at levels high enough to cause substantial cancer risks. It also found that the presence of radon in indoor air—where it seeps in from soil—is an even more significant threat.

I understand that EPA does not have the authority to regulate indoor air, and so can't control radon in this way. EPA's proposed rule creatively tries to lessen the impact of regulating radon in drinking water by encouraging states to regulate radon in the air. If a State does, it can meet a less stringent drinking water standard for radon. I am interested in learning more about this approach today. Thank you, Mr. Chairman.

JOINT TESTIMONY OF J. CHARLES FOX, ASSISTANT ADMINISTRATOR, OFFICE OF WATER, AND NORINE E. NOONAN, PH.D. ASSISTANT ADMINISTRATOR, OFFICE OF RESEARCH AND DEVELOPMENT, U.S. ENVIRONMENTAL PROTECTION AGENCY

Thank you, Mr. Chairman, for the opportunity to address the Subommittee today. We are pleased to be able to discuss the Environmental Protection Agency's implementation of the Safe Drinking Water Act Amendments of 1996.

We are proud of the many successes achieved to date. Nearly 4 years into implementation, EPA has completed all actions required of us to date by the 1996 Amendments. As a result of the work of EPA, States, water systems, and the public, the United States has one of the safest drinking water supplies in the world. Over 90 percent of Americans served by community water systems receive water with no reported health standard violations.

The 1996 Amendments moved us toward more comprehensive drinking water protection by: improving the way EPA sets drinking water safety standards based on good science and data; providing funding for infrastructure investments for communities; emphasizing prevention through source water assessments, capacity development, and operator certification; addressing some of the most pressing problems of small water systems; expanding public information and involvement; addressing some of the highest public health risks; and, giving us a framework to alleviate emerging risks.

The 1996 Amendments also acknowledge that drinking water protection must be a shared effort across the entire drinking water community. EPA has used this concept to guide its implementation activities. Through an extensive stakeholder process, the drinking water community has come together to work through a number of issues. We have greatly expanded consultation with the National Drinking Water Advisory Council, established in the statute, through a series of working groups on concerns ranging from small system needs to a new approach to benefits assessment, and currently for our 6-year review of existing contaminant standards. We and our stakeholders convened a day-long forum on December 16, 1999, which was the 25th anniversary of the enactment of the Safe Drinking Water Act, to plan for future protection needs as well as ways to begin to meet those needs. Nineteen organizations within the drinking water community agreed to several goals for drinking water protection, including: decisions based on sound science and risk to health; integrated, comprehensive water supply management; effective source water protection; well-managed and -operated water systems; and, strong public information and outreach. All participants should be commended for their efforts.

SUCCESSES IN MEETING THE STATUTORY MANDATES AND IN IMPLEMENTING PROGRAMS

Funding

The Drinking Water State Revolving Fund (DWSRF) has been extremely successful in less than 4 years of operation. EPA has given out nearly $2.5 billion in grants to all 50 States, Puerto Rico, the District of Columbia, and the territories. States have made over 1,000 loans totaling over $2 billion to water systems to address the most significant public health needs. States are also taking advantage of the set-asides in the DWSRF to conduct the source water assessments and buildup State programs. Small water systems have been a focus of the DWSRF. Nearly 3/4ths of all DWSRF loans awarded have gone to systems serving fewer than 10,000 persons.

Right-to-Know/Consumer Awareness

Drinking water systems have also made outstanding progress in implementing the right-to-know provisions in SDWA. Activities such as the consumer confidence reports give customers of drinking water systems the information they need to make their own health decisions. Today, approximately 253 million Americans have access to their first annual consumer confidence report. Over 100 million Americans are able to read their water quality report online. These reports provide information the public is demanding. In 1999 EPA's Safe Drinking Water Hotline received over 10,000 calls from consumers about their water quality, most coming near the October deadline for the first consumer confidence report. EPA's Local Drinking Water Information website is accessed over 5,000 times per month. I expect this interest to continue as the second reports come out by July 1, 2000.

The public needs immediate information about health threats so they can protect themselves and their children. EPA recently completed revisions to the Public Notification Rule, which now requires faster notice in emergencies, specifically within 24 hours. While providing for faster and clearer communication to consumers, the rule will also reduce burden to water systems by requiring fewer notices overall and enabling water systems to better target notices to the seriousness of the risk.

Preventing Contamination of Drinking Water (Source Water Protection, Capacity Development & Operator Certification)

The 1996 Amendments recognized that a prevention program is necessary to stay ahead of future problems. Effective drinking water protection has to start with an understanding of the threats to the water source, and States are making significant steps forward on their source water assessments. Forty-nine States/Territories have approved Source Water Assessment and Prevention Program, and are conducting assessments for the water supplies within their State.

Providing safe drinking water will continue to increase in complexity. Water systems must have the financial, technical, and managerial ability to meet new challenges and continue to provide safe drinking water to their consumers. EPA has developed guidance to States on both capacity development programs and programs to ensure that all water systems have access to a fully qualified operator. All States are developing their capacity development and operator certification programs.

Regulating High-Risk Contaminants

Additionally, I would like to talk about the success we've had addressing contaminants of highest risk to human health. In the past 2 years, we have proposed, or finalized, a series of new rules that would extend coverage against microbial and other high risk contaminants. We have done this with extensive research, which will be described later in this testimony, and stakeholder involvement, including special emphasis on the needs of small water systems and their consumers.

The Administration and Congress agreed that the most significant threat to public health was microbial contamination, such as E.coli and Cryptosporidium. Adverse health effects from exposure to microbial pathogens in drinking water are well documented. As we have seen in Milwaukee and New York—and most recently in our neighbor, Ontario, Canada—these health effects can include severe infections that can last several weeks and may result in death.

This spring EPA proposed the Ground Water Rule and the Long Term/Enhanced Surface Water Treatment Rule to address the needs of consumers of ground water systems and small water systems, respectively. When promulgated, these rules will complete a cycle of microbial protection with the Interim Enhanced Surface Water Treatment Rule, issued in 1998. Together these rules will cover all consumers of public water systems and reduce threats to human health from microbial disease.

Disinfection of drinking water to protect from microbial contamination is one of the major public health advances in the 20th century. However, the disinfectants themselves can react with naturally occurring materials in the water to form unintended byproducts that may pose health risks. EPA's Disinfectants/Disinfection Byproducts Rule, released with the Interim Enhanced Surface Water Treatment Rule in 1998, addresses the potential health threats that may be related to the disinfection process itself. It strengthens standards for trihalomethanes, establishes new drinking water standards for seven disinfectant byproducts and three disinfectants, and requires treatment techniques to further reduce exposure to disinfection byproducts.

The risk-risk tradeoff between disinfectants and their byproducts is difficult. However, the extensive stakeholder process that EPA used to develop these complex rules gives us better supported and understood rules that strengthen human health protection. We are now concluding a new round of discussions on the second phase of these rules, which will incorporate the results of the microbial and disinfection byproducts research that is currently ongoing.

In November 1999, EPA proposed the Radon Rule, which will have an important impact on reducing the human health risk from radon in drinking water as well as in indoor air from soil. Because of the multimedia nature of radon risk, the SDWA Amendments created a unique multimedia mitigation program to address both risks. Radon in indoor air is the second leading cause of lung cancer in the United States. Although the risk posed by radon from drinking water is much smaller than that from indoor air, the 1999 report from the National Academy of Sciences confirmed that radon in drinking water causes cancer. I believe that our approach of an alternative maximum contaminant level and multimedia mitigation program accurately and fully reflects the 1996 SDWA Amendments' provisions to protect public health and will result in a reduction of cancer cases from both indoor air and drinking water.

Recently EPA proposed to lower the maximum contaminant level for arsenic, another high-priority drinking water contaminant. Arsenic is a known carcinogen that is also linked to many non-cancer health effects. In a March 1999 report, the National Academy of Sciences' National Research Council found that the current arsenic standard of 50 parts per billion (ppb) does not meet EPA's goal of human health protection, and recommended that EPA lower the MCL as quickly as possible.

Finally, EPA's implementation efforts have given us a sensible and workable regulatory framework for the future. The 1996 SDWA Amendments require EPA to make a regulatory determination on whether to regulate at least five contaminants by 2001. Using recommendations from the public, the scientific community, and a National Drinking Water Advisory Council working group, EPA released its Contaminant Candidate List in 1998 to aid in this determination and to help set priorities for the Agency's drinking water program. In establishing the list, EPA has divided the contaminants among those which are priorities for additional research, those requiring additional occurrence data, and those which are priorities for consideration for rulemaking. To provide sound occurrence data, EPA promulgated the Unregulated Contaminant Monitoring Rule in September 1999, which will provide information on the occurrences in drinking water of specific contaminants. The National Contaminant Occurrence Data base, developed at the same time, holds these and other data to assist regulatory decisions. Finally, EPA is developing its process for reviewing the current drinking water standards as part of the mandated 6-year review.

DRINKING WATER RESEARCH

A vigorous and responsive research program is vital to the establishment of scientifically sound, cost-effective drinking water regulations that protect the health of both the general public and subgroups that may be at greater risk than the general population. To meet this challenge, EPA has demonstrated a commitment to strengthen its drinking water research program, which is one of the highest priority areas of research in the Agency. Funding for drinking water research in the EPA Office of Research and Development (ORD) has more than doubled from $20.8 million in fiscal year 1995 to $48.9 million in the fiscal year 2001 President's Budget request. The fiscal year 2001 request represents a $5 million increase over fiscal year 2000. These increases in funding have enabled EPA to address critical research needs for priority contaminants on the current regulatory agenda (e.g., arsenic, disinfection by-products, Cryptosporidium), as well as to expand into new areas of research for unregulated chemicals and microbial pathogens that may be the subject of future regulatory determination (i.e., those on the Contaminant Candidate List). Health effects research in particular has been increased over this period, with the additional funds being used to support: epidemiology studies on disinfection by-products and arsenic, investigations of the toxic effects and mechanisms of action of chemical contaminants in drinking water, research on the health effects of important microbial pathogens, and waterborne disease occurrence studies. Research has also been increased to address methods for detection and control of microbial pathogens.

EPA is meeting the near-term research needs and requirements of the 1996 SDWA amendments through a targeted program that emphasizes research in the areas of health effects, exposure, risk assessment, and risk management research. EPA drinking water researchers are recognized worldwide for their expertise and scientific contributions in each of these areas. We have also expanded the drinking water research effort nationally by leveraging resources and capabilities with universities, various Federal and State agencies, the water industry, and other public and private research entities across the country. The Agency's extramural research grants program (STAR) has been able to substantially increase the involvement of

the academic community in helping to solve important drinking water risk assessment and risk management problems. EPA researchers are working with scientists from the Centers for Disease Control and Prevention (CDC) and the National Institute of Environmental Health Sciences (NIEHS) on such topics as sensitive subpopulations, disinfection by-products and waterborne pathogens. We are partnering with the American Water Works Association Research Foundation (AWWARF) and other organizations to select and fund many high priority drinking water research projects.

In the testimony that follows, I would like to update you on the status of our research to support the implementation of the 1996 SDWA Amendments. I am also pleased to share with you the progress that we have made over the past year with respect to assessing future drinking water research needs and resource requirements, further strengthening our interactions with drinking water stakeholders, and improving research tracking mechanisms.

Research on Microbial Pathogens/Disinfection By-Products

Research by EPA scientists, collaborators and grantees over the past decade has played a crucial role in establishing the scientific basis for the rules to protect the public against contamination of drinking water with microbial pathogens and disinfection by-products. The Agency has been highly successful in addressing the priority research needs identified in the Research Plan for Microbial Pathogens and Disinfection By-Products in Drinking Water, and we are continuing to conduct research in areas where the greatest uncertainties remain. EPA has provided new information and methods to characterize and control the risks posed by microbial pathogens of public health concern, one of the most important of which is Cryptosporidium. Agency researchers have also been leaders in the development of data and methods to determine the health effects and occurrence of disinfection by-products. In recognition of the special needs of small communities, EPA engineers have evaluated a variety of alternatives to conventional water treatment systems that are effective, simpler, and less expensive to operate and maintain.

Research on Arsenic

The EPA's Research Plan for Arsenic in Drinking Water has been used by EPA and outside research entities as a guide to the planning and implementation of both short- and long-term research on this important drinking water contaminant. EPA has completed each of the high priority, short-term research projects in the research plan. We have also made progress in addressing longer term research needs. Examples of completed research include an initial epidemiology study on health effects in a U.S. population (in Utah), refinement of techniques for the analysis of the different forms of arsenic in water and in biological samples, and laboratory and field tests on arsenic control technologies (including those for small systems). In developing the new proposed arsenic rule, the Agency has considered the results of studies conducted by EPA investigators and scientists worldwide. Research that is currently being conducted to address the more complex, long-term issues (e.g., health effects at low doses) will support the required review and revision, as appropriate, of the arsenic standard subsequent to the establishment of a new rule in 2001.

Research on the Contaminant Candidate List (CCL)

The list of microbial pathogens and chemicals on the CCL includes contaminants that either have sufficient data to support regulatory determinations or that need additional research in the areas of health effects, analytical methods, occurrence and/or treatment. Pursuit of this research has become an increasingly important part of the drinking water research program. The fiscal year 2001 budget request includes $13.3 M for research on CCL contaminants, which represents more than double the CCL budget in fiscal year 2000 when the Congressional earmarks in the fiscal year 2000 enacted budget are excluded. This is enabling EPA to address the highest priority research needs identified in the draft CCL Research Plan, which will be reviewed by the Agency's Science Advisory Board this summer and finalized shortly thereafter. The draft CCL Research Plan has incorporated extensive input from outside scientists, the water industry, and other stakeholders.

Examples of current CCL research include efforts to develop and evaluate analytical detection methods for several CCL pathogens (e.g., microsporidia, Norwalk virus, echovirus and coxsackievirus). Studies are underway to determine the occurrence of various emerging pathogens in source and potable waters. A survey is being conducted to collect information on CCL pathogens from public health laboratories across the country. Research to evaluate the effectiveness of conventional and alternative treatment technologies in removing or inactivating these contaminants is being conducted. For the CCL chemicals, a number of research activities have been initiated in the areas of health effects, analytical methods development, risk assess-

ment and treatment. The results of these studies and those conducted by outside organizations will provide the data needed to support the second round of CCL regulatory determinations in 2006.

Research on Sensitive Subpopulations

EPA has placed considerable emphasis on research to characterize the extent to which individuals in different life stages (fetuses, infants, children, the elderly), those with pre-existing diseases, or other groups of individuals may be more sensitive than the general population to the effects of waterborne pathogens and chemicals. Population-based epidemiology studies are being conducted to identify potentially harmful contaminants, risk factors, and sensitive subpopulations. Studies in laboratory animals are providing hazard identification and dose-response data, and are helping to elucidate how contaminants cause their effects. Standardized toxicity tests, better exposure data, and improved risk assessment methods are being developed to provide an improved scientific basis for characterizing risks to sensitive subpopulations. The status and results of these studies are summarized in a Report to Congress that is in the final stages of preparation and will be submitted later this summer.

Research Planning and Budget

EPA uses a comprehensive, coordinated approach to assess needs and make budgetary decisions for research to support all of the Agency's programs. Research needs for drinking water are evaluated and prioritized by ORD in close partnership with the Office of Water, using peer-reviewed research plans and strategies (including those for microbial pathogens/disinfection by-products and arsenic). Input is also obtained during periodic consultations with scientific advisory groups and stakeholders. Our annual research planning and budget cycle reflects these efforts. In addition, a new multi-year planning effort is underway to link near- and long-term research priorities with annual planning and budgeting. Research priorities to support future regulatory determinations are being guided by the draft CCL Research Plan and by a new Comprehensive Drinking Water Research Strategy that is scheduled for completion in fiscal year 2001.

The Office of Research and Development has been working closely with the Office of Water over the past 6 months to examine research needs, resource requirements, and timeframes for when results must be available to support future regulatory activities. Based on these analyses, we believe that the current level of funding and the resources requested for fiscal year 2001 are sufficient to meet both the near-term regulatory requirements as well as the needs of future regulatory activities.

Stakeholder Involvement and Research Tracking

EPA places a high priority on sharing information with stakeholders to ensure that all groups are fully informed about research activities and can provide input concerning research needs and priorities. An example of a highly successful effort to involve stakeholders early in the research planning process is the Drinking Water Research Needs Workshop, co-sponsored by EPA and AWWARF in September 1999. Participants from the water industry, universities, various government agencies and the private sector worked together to identify and prioritize research needs for unregulated drinking water contaminants and to estimate the resources that would be required to address these needs. The EPA's draft CCL Research Plan was a key focus of discussions at the workshop, and a Research Needs Report that summarized the workshop proceedings has already been used by EPA to develop the next draft of the CCL Research Plan. Another example of stakeholder involvement is a series of meetings that were held throughout the country in 1999 as part of the SDWA 25th Anniversary Futures Forum activities. These meetings, which were co-sponsored by EPA and several partner organizations, focused on drinking water research needs and a variety of other topics such as drinking water treatment technologies, source water quality and quantity, vulnerable subpopulations and small water systems.

To further involve the stakeholders in shaping the future drinking water research agenda, EPA is establishing a new research working group under the National Drinking Water Advisory Council (NDWAC). This working group will assist the Agency in developing the Comprehensive Drinking Water Research Strategy. In addition, research information-sharing meetings are being held with the drinking water community on a regular basis.

With regard to research tracking, over the past year we have been examining ways to improve the availability of information associated with projects listed in the Agency's drinking water research plans. A new prototype tracking system is being tested as a basis for evaluating the feasibility and utility of an expanded version that includes all drinking water research. This internet-based system will allow in-

dividuals from inside and outside the Agency to easily access information on drinking water research projects. The planned improvements to the research tracking system, combined with the opportunities provided by EPA for stakeholders to provide input into the Agency's research agenda, will collectively allow the drinking water community to become more informed about the status, timing, and funding of ORD research activities.

Sound Science to Support SDWA

The need for sound and objective science to improve the efficiency and effectiveness of drinking water regulations is a central issue in the 1996 Amendments to the Safe Drinking Water Act. EPA is meeting this challenge through the efforts of a dedicated work force of scientists and engineers, along with the collaboration of investigators from various agencies, universities, and other research entities throughout the country. An increased level of funding is enabling the Agency to develop scientifically sound approaches and data to characterize risks to human health, and to provide practical, cost-effective approaches for preventing and managing risks associated with exposure to the drinking water contaminants of greatest public health concern.

CHALLENGES

While the Agency is proud of its successes and accomplishments, we are also aware of the many daunting challenges both in the short- and long-term—facing the entire drinking water community. We are certainly aware that the significant number of new requirements in SDWA represents a significant demand on the States' and systems' ability to implement a wide variety of activities. I believe that they are manageable through the framework provided by the Safe Drinking Water Act, but will require concerted effort by all participants in the drinking water community. As EPA has implemented SDWA, we have attempted to ease some of this strain. We have had extensive stakeholder involvement in our actions, including a particular focus on small water systems. This has improved the quality of our rules and provided flexibility to States and water systems. The SDWA Amendments provide the authority to accommodate the needs and concerns of small systems and to emphasize technologies as a cost-effective approach to achieve compliance with our rules. We are working with States and the organizations representing them to address specific issues, like resource needs. We have also given the regulated community advance notice of new requirements, so that they may better prepare. I believe that the Contaminant Candidate List process, when fully implemented, will give us a fair and workable way to address the highest risks to public health. We will also attempt to consolidate rules by type to move away from a contaminant-by-contaminant approach to regulation.

As we develop our rules we have taken into consideration the impacts that other rulemakings will have on the regulated community. We have tailored rules to consider local or regional considerations. We have phased implementation components where possible. We have worked to improve the capacity of water systems to meet these new requirements through early and improved technical assistance, training, outreach, and funding through the DWSRF. And we are working to lessen the pressure on water systems as the last line of defense by promoting all of the tools for watershed and source water protection through such mechanisms as the Clean Water Act and the Food Quality and Protection Act.

The cost of providing safe drinking water—finding a water supply, treating the water, delivering the water, and maintaining the system—will continue to be a challenge. The additional complexity of future public health threats will require an increased level of sophistication in the water industry. EPA's 1997 Drinking Water Needs Survey Report to Congress identified over $138 billion in industry needs with the vast majority of these needs targeted for delivery of water not for meeting regulatory requirements. The drinking water industry has released their own assessment of drinking water infrastructure needs, which you will hear about in their testimony. EPA is committed to working with Congress, the drinking water industry, and consumers to ensure that Americans continue to receive safe, affordable drinking water into the future.

To continue and improve on our current standard of public health protection will require constant vigilance and the ability to look ahead to address emerging issues. Challenges to our drinking water still exist. These include unknown or newly emerging threats to public health, a pace of development that may threaten source water quality if not properly managed, an expanding and aging population that increasingly includes those with special health concerns, a need for additional high-quality research on health effects and treatment technologies, and a need for accurate information on compliance with drinking water standards. Collection of data

that is reliable and accurate and information systems that can serve not only as repositories of data but also as a user-friendly reference for the drinking water community and the general public is a challenge that EPA is addressing at this time.

For the longer term, the Office of Water and the Office of Research and Development will continue to work closely and ensure that the research needed to determine which contaminants from the Contaminant Candidate List are to be regulated is conducted and completed so that we have firm scientific underpinnings for these future rules. The identification of, and decisions on, the contaminants to be regulated and the research to be done on these contaminants are two of the biggest challenges facing EPA over the next several years. The new regulatory framework set forth in the 1996 SDWA Amendments, which allows the drinking water community to assist in the decisionmaking process on the contaminants to be regulated, has not yet been fully realized. We are working toward that approach and believe that EPA and its stakeholders can attain the objectives that Congress intended. I am confident that the Agency will be able to report its successes and accomplishments in implementing the total regulatory framework contained in the 1996 Amendments.

This concludes our presentation. Thank you again for the opportunity to discuss these important issues. We would be happy to address any questions you may have at this time.

RESPONSES BY CHARLES FOX TO ADDITIONAL QUESTIONS FROM SENATOR CRAPO

Question 1. What is the current EPA policy for determining whether a public water system is small or large?

Response. Consistent with section 1412(b)(4)(E)(ii) of the Safe Drinking Water Act (SDWA), EPA's policy for determining whether a public water system is small or large is based on the population served by the system. There are three categories of small systems that serve 10,000 or fewer people. Large metropolitan water systems are defined as serving more than 10,000 people.

Question 2. On what basis does the EPA determine whether a proposed drinking water standard and regulation is feasible (i.e., affordable) for public water systems? What size water system do you currently consider "large" when determining whether a standard is feasible?

Response. Section 1412(b)(4)(D) of SDWA, as amended, defines the term feasible to mean ". . . feasible with the use of the best technology, treatment techniques, and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration)." Cost assessments for the treatment technology feasibility determinations have been based upon impacts to regional and large metropolitan water systems. This protocol was established and published in the Congressional Record when SDWA was originally enacted in 1974 and was carried over when the Act was amended in 1986 and 1996. The population size categories that EPA have historically used to make feasibility determinations for regional and large metropolitan water systems has ranged from 50,000—75,000 people to 100,000—500,000 people.

Question 3. On what basis does the EPA determine whether a proposed regulation is affordable for a small system?

Response. Based on section 1412(b)(4)(E)(ii) of SDWA, EPA makes affordable technology determinations for the following small system size categories: a population of 10,000 or fewer but more than 3,300; a population of 3,300 or fewer but more than 500; and a population of 500 or fewer but more than 25. EPA uses its affordability criteria to evaluate the cost of available technologies for these categories in determining whether or not these technologies represent affordable compliance technologies. If no affordable compliance technologies can be identified, EPA would identify variance technologies that could meet a less stringent regulatory level. (More detailed information on affordability is contained in the answer to question 7.)

Question 4. In your 1998 report, Variance Technology Findings for Contaminants Regulated Before 1996, the EPA writes that "[t]he most common population size categories used [to make cost assessments for treatment technology feasibility determinations] were 50,000–75,000 and 100,000–500,000 people." What is the estimated percent and number of public water systems and community water systems these size categories represent? What is the median size of public water systems?

Response. Large systems are currently grouped into the following population-served categories: 10,001—50,000 people, 50,001—100,000 people, 100,001—1,000,000 people and > 1,000,000 people. For community water systems, there are an estimated 779 systems (1.4 percent) that serve more than 50,000 people of which

an estimated 431 systems (0.8 percent of total systems) serve between 50,001 and 100,000 people. These largest of the large systems provide water to over 55 percent percent of the population served by community water systems. The median size for community water systems is in the 101—500 people-served category, which falls into the small system category. All systems in this size category serve about 4 percent of the population.

Question 5. Does the EPA feel legally required to set standards based on what is feasible for systems serving populations greater than 50,000 or 100,000? What does this mean for the affordability of drinking water standards nationwide and the vast majority of systems?

Response. EPA is legally required under SDWA to set standards based on what is feasible for large systems. SDWA also requires EPA to make affordable technology determinations for small systems and to identify technologies that meet these requirements. In EPA's publication, "Variance Technology Findings for Contaminants Regulated Before 1996," feasible technologies such as reverse osmosis, granular activated carbon, and lime softening were not affordable in the 25—500 people-served category. However, centrally managed point-of-use devices were affordable options in this size category, but would not be implementable in large systems. Thus, the structure of SDWA allows EPA to find different solutions for different size systems in order to achieve compliance with drinking water standards.

Question 6. In testimony, you explained that the EPA considers public water systems serving more than 10,000 individuals to be "large" systems. Your statistics indicate that nearly 80 percent of people served by public water systems are served by these large systems. This is consistent with the understanding of this committee as expressed in the Report of the Committee on Environment and Public Works on S. 1316, the Safe Drinking Water Act Amendments of 1995 (S. Rept. 104–169). Specifically the report explains that (P. 31). However, in recent documents the EPA has stated that the "EPA will continue to use feasibility for large systems in setting NPDWRs [serving populations greater than 50,000]." (63 FR 669432, December 16, 1998). What size category of systems has the EPA used to determine feasibility of MCLs for the M/DBP cluster of rules, the proposed arsenic rule, and the proposed radon rule? What percent of the population is served by the system size category(ies) used for these rules?

Response. About 50 percent of the population served by the water systems affected by the M/DBP rule receive water from the system sizes used for the feasibility determinations, i.e., those serving more than 50,000 people. Both non-community and community water systems are covered by the M/DBP rule. About 55 percent of the population served by the water systems affected by the proposed arsenic rule receives water from the system sizes used for the feasibility determinations. Only community water systems are covered under the proposed arsenic rule. About 31 percent of the population served by the water systems affected by the proposed radon rule receive water from the system sizes used for the feasibility determinations. Only community ground water systems are covered by the proposed radon rule.

Question 7. The feasibility of a proposal has great implication on whether the regulation will serve the purpose of promoting public health because if it is too costly and burdensome, it may not be able to be implemented by small systems. The EPA has identified drinking water costs exceeding 1 percent–2 percent of a community's median household income (MHI) to be potentially burdensome (in line with other Federal agencies' guidelines for affordability) (U.S. EPA, Information for States on Developing Affordability Criteria for Drinking Water, EPA 816-R–98–002). In your testimony, you explained that the Agency uses a national level affordability threshold set at 2.5 percent of MHI for determining affordability. If so, it seems that the EPA has set the affordability threshold for small system variance at an usually high level as a policy decision to make variance technologies unavailable to all but "a small subset of small systems" because of the threshold's correlation to economic burden. (U.S. EPA, Variance Technology Findings for Contaminants Regulated Before 1996, p.48). This affordability threshold would seem to impose a greater burden on more small communities than the government typically requires. The EPA's writing on this approach makes it seem that Congress did not intend for small systems variances to be available in a meaningful way. On what do you base this policy? How is this consistent with the strong emphasis Congress placed in 1996 on making regulatory compliance workable for small communities and systems? Using this approach, how many variance technologies has the EPA identified for those existing and pending regulation for which variance technologies are permitted? Does this approach render § 1415(e) on small systems variances meaningless?

Response. EPA believes there are some important distinctions among the affordability criteria that have been used for various purposes. We also believe that our approach to developing affordability criteria to determine whether small system variances may be granted appropriately balances a number of important considerations. Moreover, we think it is important to recognize a number of other key elements of the 1996 SDWA amendments that relate to affordability for small systems and that can be used to address their unique circumstances.

EPA's guidance document, "Information for States on Developing Affordability Criteria for Drinking Water," (1998) recommends an affordability threshold of 2.5 percent of median income. We are aware this criterion is higher than that used by various States, and by some other agencies and organizations (including the Department of Housing and Urban Development, National Consumer Law Center, and earlier guidance from EPA itself), to assess household affordability of drinking water costs for various purposes. EPA notes that the State affordability criteria listed in Appendix F are intended for use in prioritizing systems for assistance from the Drinking Water State Revolving Fund and are not necessarily the same criteria that the State would use to make small system variance determinations. The threshold used for determining whether additional assistance is needed to meet a National Primary Drinking Water Regulation should, in EPA's view, be lower than the threshold used to determine when a system may be allowed to operate at a lesser level of protection than the MCL.

EPA would be concerned about an approach involving the use of what it considered to be an inappropriately low national level affordability criteria since it would not, in our view, be supported by its analysis of comparable household expenditures for other goods and services. We considered the percentage of median household income spent by an average household on such items as housing (28 percent), transportation (16 percent), food (12 percent), energy and fuels (3.3 percent), telephone (1.9 percent), water and other public services (0.7 percent), entertainment (4.4 percent), and alcohol and tobacco (1.5 percent) in identifying an initial range of options for the affordability threshold. (This analysis did not consider comparable expenditures by low-income households.) One of the key factors that EPA used to select an affordability threshold of 2.5 percent of median household income was cost comparisons with other risk reduction activities for drinking water. Section 1412(b)(4)(E)(ii) of the SDWA identifies both Point-of-Entry and Point-of-Use devices as options for compliance technologies. EPA examined the projected costs of these options. We also investigated the costs associated with supplying bottled water for drinking and cooking purposes. The median income percentages associated with these risk reduction activities were: Point-Of-Entry (> 2.5 percent), Point-of-Use (2 percent), and bottled water (> 2.5 percent).

The complete rationale for EPA's selection of 2.5 percent as the affordability threshold is described in "Variance Technology Findings for Contaminants Regulated Before 1996." EPA is concerned that a less restrictive set of criteria could have the net result of a national level finding that this and many future drinking water rulemakings were unaffordable for small systems—thus creating, in effect, a two-tiered approach to national rulemakings and public health protection. A two-tiered approach could be created because large systems would be complying with the MCL while some small systems might be operating at a level above the MCL, though it would still need to be protective of public health. These systems could only receive a small system variance if the State determined that there was no affordable technology and that alternate sources or restructuring were unaffordable.

EPA did not identify any variance technologies for the existing regulations for which variance technologies are permitted (U.S. EPA, "Variance Technology Findings for Contaminants Regulated Before 1996," EPA 815-R–98–003). This document did note that in one instance, the centrally managed, point-of-use device option was the only affordable compliance technology. EPA has not identified variance technologies in any of the proposed rules for which variance technologies are permitted. EPA does not believe that the approach used to make affordable technology determinations renders small system variances meaningless and notes that variance technologies may be available for future regulations.

One important option that Congress authorized in the 1996 SDWA amendments was point-of-use devices as a mechanism for small systems to comply with drinking water regulations (section 1412(b)(4)(E)(ii)). EPA believes that the centrally managed point-of-use device option in SDWA is a lower cost alternative for very small systems to comply with the MCL that reduces the need for variance technologies. Under this option, small systems maintain at-the-tap units inside each customer's home and treat only the water used for consumption and food preparation. This results in treating about 1 percent of the total water used in a household and can significantly reduce treatment costs in very small systems (those serving less than

100 people). Thus, SDWA currently provides a compliance approach that could significantly reduce costs in small systems compared to traditional approaches.

The 1996 SDWA amendments also authorized the Drinking Water State Revolving Fund (DWSRF). As of April 1, 2000, $2.4 billion of the $3.6 billion appropriated for the DWSRF program had been awarded to States. State DWSRF programs have made more than 1,000 loans at a total level of some $2 billion to construct needed infrastructure projects. Of the loans that have been made, 74 percent have gone to small systems serving fewer than 10,000 people. These loans represent 41 percent of the funds available for loans. The affordable technology determinations assume that all treatment costs are borne by the systems and are passed along to customers (a conservative assumption that would tend to project higher small system costs than would actually result). Loans or grants from the DWSRF or the Rural Utility Service of the U.S. Department of Agriculture would lower household impacts in systems receiving these loans. Other mitigating measures that can reduce the impact on households include: rate design, consolidation strategies, and regionalization approaches that are discussed in Appendix F of "National-Level Affordability Under the 1996 Amendments."

Question 8. SDWA is silent with respect to the cumulative costs of rules. If the EPA seeks to implement dozens of rules all individually "affordable," would that cumulative impact be too much for many public water systems and households to bear? How does the EPA take into consideration cumulative costs of rules?

Response. EPA develops the cost impact of each rule separately. (This estimate excludes costs to treat co-occurring contaminants that have already been costed out by other rules.) We also consider the cumulative costs of the rules because this is an extremely important consideration for determining whether a rule individually or in combination with other rules will breach the affordability threshold. We do not believe that any of the soon-to-be promulgated rules, either individually or in combination, will cause the affordability threshold to be exceeded. However, this could be a factor in the future and will be an important consideration as we examine the impact of current rules on the affordability "baseline." The baseline of existing water bills will be adjusted upward to account for treatment costs resulting from rules promulgated after 1996 in two ways. First, an estimate will be made of each rule's impact on the baseline costs. The national median annual household water bill for each size category will be adjusted by averaging the total national costs for the size category over all the systems in the size category. This revised baseline will be subtracted from the affordability threshold (based on 2.5 percent median household income for each population size category) to determine the new available expenditure margin. The affordable technology determinations will be made by comparing the projected costs of treatment against the lower available expenditure margin. Second, actual changes in the baseline will be measured approximately every 5 years by the Community Water System Survey and the national Census. These changes will reflect not only the increased costs resulting from our rules but also any changes resulting from other factors that could affect capital or operating and maintenance costs.

Question 9. What portions of systems are expected to require financial assistance under this approach? Do you feel it would be better public policy for SDWA regulations to be affordable to a greater portion of households? Do you have any recommendations for the Congress on this matter?

Response. Determining if there are affordable compliance technologies under section 1412(b)(4)(E)(ii) is only one of several ways that SDWA provides for the consideration of affordability. (Variance technologies are identified when there are no affordable compliance technologies for a given system size/source water quality combination.) The other three SDWA provisions refer to the affordability criteria established by the State or primacy agent for system-level determinations. The most significant of these system-level affordability criteria is found in section 1452(b) of SDWA, i.e., affordability on a per household basis is one of the three factors used to prioritize systems for assistance from the Drinking Water State Revolving Fund. EPA published information to assist States in the development of their affordability criteria as required by section 1415(e)(7)(B). While EPA has provided information to the States to help them in these efforts, States are responsible for making site-specific decisions about financial assistance. Thus, EPA cannot estimate the number of systems expected to require financial assistance.

When determining if there are affordable compliance technologies under section 1412(b)(4)(E)(ii), Congress specifically instructed EPA to consider the three smallest size categories of water systems. Section 1412(b)(15)(A) requires EPA to identify variance technologies if, given the quality of the source water to be treated, there are no affordable compliance technologies for that system size category. The critical

factor is source water quality conditions that can affect treatment costs rather than system-level financial considerations. As each category contains thousands of systems, EPA has chosen to define affordability based on the median system within each size category. As noted in the response to question #7, basing affordability determinations on the most financially troubled systems would undercut compliance technologies and set a double standard for health protection: one for economically disadvantaged systems and one for everyone else. Conversely, basing affordability decisions on what the better-off systems can afford would place variance technologies beyond all practical application. Thus, we have designed our affordability criterion (for purposes of a national affordability determination) to apply to the median case and have established this criterion after considering a number of important factors, as described in the response to question #7.

Finally, although some individual systems are in financially poor condition, EPA also considers affordability to be a problem that has a user level dimension. Even within larger, better-off water systems, there are users with very low incomes for whom even current water charges might be burdensome. If EPA were to define affordability for new treatment technologies such that even these groups could afford the cost, there would be no new technologies found to be affordable and, consequently, there would be no additional level of public health protection. Fortunately, there are "lifeline rates," i.e., declining block rates and other tools available to the individual systems that allow them to tailor financial relief to the needs of the individual user.

We believe it would be premature at this point to offer recommendations to Congress, as we are just now beginning to see, in real terms, how the affordability aspects of the 1996 amendments will impact the process. We should have a better sense of how this will work after the tools have been in place for some time.

Question 10. Does the EPA plan to go back and compare estimated compliance costs with actual compliance costs of rules for purposes of reassessing affordability? How will the EPA use the information gained from such a review to apply for future rulemakings?

Response. Yes. EPA plans to compare estimated compliance costs with actual costs of rules for purposes of reassessing affordability. In fact, one such analysis was presented in the preamble to the proposed radon rule, where treatment costs from the cost models were compared with costs at sites with aeration treatment. It was found that EPA's cost estimates tended to overestimate costs for small systems. EPA's approach to reassessing affordability is to use the Community Water System Survey and national Census data to measure changes in annual household water bills in small systems. This approach captures not only the increased costs resulting from implementation of drinking water regulations, but also any changes resulting from other factors that could affect annual water bills. It is important to recognize that any cost projections associated with a particular rule are estimates. Actual costs will depend upon thousands of individual decisions made by utilities as they seek to find the lowest cost compliance solutions. This more accurate information is important in understanding the affordability of our rules and the impact of this information on the "baseline" (discussed in question/answer #8) and on future rulemakings.

Question 11. In separate provisions of the 1996 SDWA amendments, Congress directed the EPA to promulgate regulations on enhanced surface water treatment and control of the recycling of filter backwash in the treatment process. In April, the EPA jointly proposed an enhanced surface water treatment rule for small systems and the filter backwash rule (LT1/FBR) and co-mingled the cost-benefit analyses for these two provisions. Why did the EPA merge the two and jointly assess the Health Risk Reduction and Cost Analyses (HRRCA) for these quite different rules?

Response. The Long Term/Enhanced Surface Water Treatment Rule (LT/ESWTR) and Filter Backwash Recycling Rule (FBRR) were published as separate components in a single Notice of Proposed Rulemaking published in the Federal Register on April 10, 2000 for several reasons. First, the 1996 SDWA amendments acknowledge the interrelationship of the FBRR and the Enhanced Surface Water Treatment rule. Section 1412(b)(14) of the amendments states:

[T]he Administrator shall promulgate a regulation to govern the recycling of filter backwash water within the treatment process of a public water system. The Administrator shall promulgate such regulation not later than 4 years after the date of the enactment of the Safe Drinking Water Act Amendments of 1996 unless such recycling has been addressed by the Administrator's Enhanced Surface Water Treatment Rule prior to such date (emphasis added).

Second, the primary goal of both rules is the same, i.e, to ensure that drinking water systems are providing at least 2-log removal of the infectious pathogen

Cryptosporidium. Third, the entities most affected by both rules are small drinking water systems serving fewer than 10,000 people. The LT1ESWTR affects only small drinking water systems; almost 75 percent of the systems affected by the FBRR are small systems. Publishing the proposed rules in the same Federal Register notice provided small systems the ability to understand, review, evaluate, and comment on both rules simultaneously, thereby reducing the amount of burden necessary to review. EPA believes that publishing the two rules in the same Federal Register notice increased the audience who might otherwise have only commented on one of the rules. Finally, both rules address the performance of filtration and treatment at drinking water systems. Because the rules are interrelated, systems could be expected to make changes to address one rule that would, in turn, affect compliance with the other. Combining the rules at proposal allowed stakeholders and small systems to simultaneously evaluate how best to address both rules, which are intended to become effective at nearly the same time.

With respect to the co-mingling issue, the Health Risk Reduction and Cost Analyses (HRRCA) supporting the LT1/FBR proposal was discussed in a single Regulatory Impact Analysis (RIA) document. However, the RIA clearly indicated the results of the risk, benefit, and cost analyses for the LT1 component separately, the FBR component separately, as well as analyzing the combined impact of the two rules. In response to comments received and concerns expressed in other forums, EPA will promulgate the rules separately with separate and distinct RIAs.

Question 12. Is it the EPA's view that you have the authority to mix diverse rules together and jointly evaluate their costs and benefits when public water systems must take very different steps to meet each of the requirements?

Response. The Agency has indicated that these rules are interrelated, i.e., 1) they have the same goal of providing at least 2-log removal of the infectious pathogen Cryptosporidium, 2) they affect primarily the same universe of small drinking water systems, and 3) they deal with the same issues of drinking water treatment plant performance. The costs and benefits described in the Notice of Proposed Rulemaking were evaluated separately for the LT1ESWTR and FBRR as well as in combination. EPA is publishing the final rules separately and will evaluate only the costs and benefits of each specific rule. Although systems may, in fact, take different steps to address the LT1ESTR and FBRR, a significant number of small systems will make decisions and take action that address both rules simultaneously, thereby achieving cost-effective solutions that save a system's valuable resources. The Agency continues to believe that States and systems should be given every opportunity to maintain flexibility in addressing regulations, while at the same time reducing costs. Proposing both rules in a single Federal Register notice allowed stakeholders to focus attention on both rules and prioritize sound strategies and solutions for dealing with the requirements.

Question 13. Has the Agency prepared an assessment of the costs and benefits of the proposed LT1/FBR rules individually?

Response. Yes. The proposed rule contained separate cost and benefit analyses for the LT1ESWTR and the FBRR, as well as a combined analysis. This was carried out so stakeholders could evaluate the costs and benefits of each rule independently as well as the combined effect of the two similar rules.

Question 14. What level of uncertainty do these proposed rules involve in terms of estimated occurrence of microbial contaminants and benefits of the proposed regulatory approach without the ICR data? Given the potential impact of the rule on small systems, would it be better policy to delay promulgation to allow the data to be incorporated into the rule?

Response. Examination of the ICR occurrence data analysis and new Cryptosporidium infectivity data indicates that benefits will remain similar to the benefits calculated under the current analysis for the LT1ESWTR. However, the final LT1ESWTR rule and supporting documentation will include a sensitivity analysis that describes the new data and the effects the data will have on benefits. Using either the ICR or non-ICR data, the quantified and non-quantified benefits justify the costs of the LT1ESWTR. EPA was not able to quantify the benefits of the proposed FBRR because of data limitations; nevertheless, the Agency believes there are considerable unquantified benefits, in terms of minimizing the adverse impacts of microbial contamination, that provide an adequate justification for this rulemaking. Specifically, the ICR data do not address filter backwash impacts therefore, the new data would not remedy the data limitation problems. As allowed under the 1996 SDWA Amendments, the Agency has determined that the non-quantified benefits justify the costs of the FBRR. The Agency does not believe that it is in the interest of public health protection to delay these rules until final analysis, including scientific peer review, of the new occurrence data is completed. As indicated,

both benefit analyses (non-ICR and ICR) firmly justify the promulgation of the LT1ESWTR rule. (As discussed above, the FBRR is not directly affected by the ICR data.) Delaying the LT1ESWTR rule would result in vastly unequal levels of health protection from the highly infectious pathogen, Cryptosporidium, for people drinking water in small communities as compared to those in larger communities. Delay would also result in small systems not addressing risks associated with microbes under the LT1ESWTR at the same time they are addressing risks from disinfection byproducts under the Stage 1 Disinfection Byproduct Rule promulgated in 1998. The importance of addressing both risks simultaneously was a foundation of the 1997 Federal Advisory Committee's Agreement in Principle as well as the 1996 SDWA amendments. Delaying the LT1ESWTR could result in microbial disease outbreaks in small communities throughout the country in 2004 as systems change disinfection to reduce disinfection byproducts and unknowingly increase risks associated with microbial pathogens such as Giardia and Cryptosporidium.

Question 15. How much more time would the EPA require to incorporate the available ICR data into the proposed regulations? Will the regulations be sufficiently sound if you proceed without the use of the data?

Response. The Agency is in the process of completing its analysis of the ICR data, including scientific peer review. However, EPA will be including a sensitivity analysis in the final rule and rule documentation, which includes the new ICR and Cryptosporidium infectivity data. The sensitivity analysis will be incorporated into the HRRCA analysis supporting the final LT1ESWTR. The HRRCA analyses supporting both the LTIESWTR and FBRR are sound. New analysis using the ICR and new Cryptosporidium infectivity data indicates that risks and benefits associated with the LT1ESWTR are similar to risks and benefits associated with the data used to support the Interim Enhanced Surface Water Treatment Rule (IESWTR) less than 2 years ago. Both analyses yield the same conclusion, i.e., the benefits justify the costs of the rule.

Question 16. What is the status of, and schedule for completing, research supporting the arsenic rule? Please comment specifically on the status of research Congress has called for and supported in recent years.

Response. Research conducted by EPA to support the arsenic rule has been guided by the Agency's peer-reviewed Research Plan for Arsenic in Drinking Water. This plan emphasizes research to reduce uncertainties in assessing and controlling health risks associated with exposure to low levels of arsenic in drinking water, as required by the 1996 SDWA Amendments. EPA has completed all of the high-priority, short-term research projects described in the plan. Many of these studies directly support the current arsenic rule, while others represent significant progress in addressing longer term research needs.

Specific projects that have been completed include: 1) an initial epidemiology study on important health endpoints in an arsenic-exposed population in Utah; 2) collaborations with investigators conducting epidemiology studies in other countries; 3) studies on the metabolism and mode of action of arsenic; 4) an evaluation of analytical techniques for speciation of the different forms of arsenic in water and in biological samples; 5) the development of a national data base on arsenic concentrations in water; 6) the synthesis of existing and new data to support the risk assessment for arsenic; 7) laboratory and field tests on arsenic control technologies; and 8) studies on the management of arsenic residuals generated by water treatment processes.

Question 17. Could you review the science supporting an arsenic standard of 5 parts per billion (ppb) compared to 10 ppb and explain how the Agency considered cost, benefits, and uncertainties in developing the new standard?

Response. The key elements of the Agency's review of health effects, uncertainties, costs, and benefits as well as its evaluation of other possible MCL choices are thoroughly discussed in the preamble to the proposed rule (relevant section attached). In brief, EPA examined the various health effects attributable to arsenic in drinking water at various levels with a particular focus on the National Academy of Sciences' report. In so doing, we identified a number of quantifiable adverse health effects, mainly due to bladder cancer as well as a number of currently unquantified or partially quantified health effects, e.g., lung cancer, cardiovascular effects, skin cancer, etc. We then sought to monetize these benefits, where possible. We also developed the costs associated with various possible arsenic levels based on the projected costs, including those for treatment, monitoring, and administration. For developing both costs and benefits, we identified a number of uncertainties and summarized these in the preamble to the proposed rule. In weighing the various regulatory options, we considered the costs and benefits, both monetizable and non-monetizable and the associated uncertainties. As described in the preamble, the Agency proposed to exer-

cise the discretionary authorities of section 1412(b)(6) of the Safe Drinking Water Act (SDWA) to move away from the "feasible" level of 3 parts per billion or ppb, a level based on consideration of costs to large systems and the capability of analytical methods. We further proposed that 5 ppb best reconciled the various factors under consideration, but we also solicited comment on regulatory options of 3 ppb, 10 ppb, and 20 ppb, in recognition of the uncertainties associated with this decision and the possibility of weighing these decision criteria differently. As noted in the discussion, MCL options of 10 or 20 ppb provide less certainty that the MCL would be protective of human health. Of particular concern was the (then) unquantified effects of lung cancer. NAS suggested that excess lung cancer deaths from arsenic could be two to fivefold greater than the excess bladder cancer deaths. Since the publication of the proposal, more specific information about arsenic's ability to cause lung cancer has become available and we apprized the public of this information in a Notice of Data Availability (NODA).

Question 18. The EPA is required to review and, if necessary, revise each drinking water standard every 6 years. The law requires the revised standard to maintain or provide greater protection for public health. When testifying before the subcommittee and asked whether the EPA could relax a 5 pbb arsenic standard to reflect research results that showed a less stringent standard would provide the intended level of protection, you replied, "Yes." Is this the EPA's interpretation of its authorities under § 1412(b)(9)?

Response. Yes. We believe it is possible that a standard of 5 ppb, if promulgated, could be relaxed in subsequent years using the authority of § 1412(b)(9) if review of available information at the time supported such a decision. In particular, the Agency would conduct an extensive examination of the data and information about the Maximum Contaminant Level Goal (MCLG) for arsenic as well as information about an associated possible revised Maximum Contaminant Level (MCL). In evaluating the MCLG/MCL, EPA must continue to meet the requirements of § 1412(b)(4). Of particular interest, in the case of arsenic, would be a determination of whether or not the dose-response curve for arsenic was non-linear (i.e., whether a certain threshold of exposure existed before adverse effects attributable to arsenic were observed). Such a finding would operate to raise the MCLG from the level of zero that has been proposed and hence, make it more likely that the MCL could also be raised without violating the statutory requirements of § 1412(b)(9).

Question 19. Given the delay in proposing the arsenic rule, will the EPA be able to respond meaningfully to the public comments and still finalize the rule by January?

Response. EPA will finalize the arsenic rule after we carefully review, consider, and respond adequately to public comments. We will strive to complete the rulemaking process as close as possible to the1996 SDWA amendments' statutory deadline for this rule.

Question 20. What percent of MCL exceedances for radon and arsenic are projected to occur among the system category used to determine feasibility for these proposed contaminant standards?

Response. For community water systems, there are an estimated 779 systems (1.4 percent) in the three size categories that serve more than 50,000 people. These systems provide water to over 55 percent percent of the population served by community water systems. For arsenic, just over 1.1 percent of the proposed MCL of 5 ug/L exceedances occur in systems serving more than 50,000 people. For radon, 0.5 percent of the proposed MCL of 300 pCi/L exceedances occur in systems serving more than 50,000 people. For the radon rule, the percentage is lower because the rule only applies to ground water systems. Many larger systems rely solely on surface water.

Question 21. In estimating household costs for complying with the proposed arsenic rule, has the EPA made any assumptions about systems receiving variances and exemptions?

Response. As required by section 1412(b)(4)E of SDWA, as amended, we examined available treatment technologies for small systems (those serving less than 10,000 people) and were able to identify affordable technologies for all small system size categories. Thus, we would not expect to issue a national finding that any particular size category was unaffordable and warranted variance technologies and identification of an associated regulatory level less stringent than the MCL. States have authority to provide exemptions to particular facilities to allow more time to comply with an MCL. For small systems, States may provide up to 9 additional years (beyond the 3 to 5 years for compliance). We also did not attempt to forecast the extent to which States may issue exemptions to any particular facility to allow additional time to comply with the MCL.

Question 22. In 1996, Congress gave the EPA authority to set a standard less stringent than the feasible level when benefits do not justify the costs; the EPA may set the standard at a level that maximizes health risk reduction benefits. Given the reported lack of scientific evidence regarding the existence of adverse health effects of arsenic at very low levels, the preponderance of expected occurrence among small systems, and the expected costs and technical challenges posed by a very low standard, why did the Agency choose not to use this authority in developing the proposed MCL?

Response. In the June 22, 2000 proposed rule, EPA indicated its intention to exercise these authorities to set a standard less stringent than the feasible level, which EPA has proposed to be 3 ppb. The proposed MCL of 5 ppb represents a level other than the feasible level. We also solicited comment on whether or not, based on consideration of the factors noted in your question, we should exercise those authorities to move to a level higher than 5 ppb (i.e., 10 or 20 ppb).

Question 23. Similarly, given the relatively high costs to small communities and low benefits associated with reducing radon exposures from water compared to air, why did the Agency choose not to use this authority under the rule?

Response. EPA did consider the benefits and cost authority provided to the Administrator through the1996 SDWA amendments and made a determination that the benefits justify the costs for the proposed MCL. The 1998 Health Risk Reduction and Cost Analysis shows that the benefit-cost ratios were very similar across the wide range of regulatory levels considered. The legislative history of this cost-benefit provision indicates that the Administrator is not required to demonstrate that the dollar value of the benefits are equal or greater than the costs (Senate Report 104–169 at S. 1316, p. 33)

Question 24. The EPA's radon Health Risk Reduction and Cost Analysis states that 85 percent of cancer cases from water exposures to radon will occur among smokers. How was this risk incorporated into the cost benefit analysis? What is the cost-benefit ratio of the proposed standard excluding smoking-related illnesses?

Response. Regarding risks to smokers, the National Academy of Sciences (NAS) Radon in Drinking Water Committee, as part of their assessment of the risks of radon in drinking water, considered whether groups within the general population, including smokers, may be at increased risk. The NAS found that current and former smokers (those who have smoked at least 100 cigarettes over a lifetime) were at increased risk from exposure to radon, but did not identify smokers or any other group as a sensitive subpopulation (i.e., a subpopulation that warrants protection at levels more stringent than those applicable to the general population). The proposed maximum contaminant level (MCL) of 300 pCi/L was not selected to target protection to smokers. Rather, EPA's proposed MCL is based on risks to the general population, including current and former smokers. The risk assessment for radon in air is based on an average member of the population, which includes smokers, former smokers, and people who have never smoked. The projected cancer deaths in smokers and former smokers would not have occurred but for the added exposure to smokers caused by drinking water with radon levels above the proposed maximum contaminant level (MCL). EPA determined that 85 percent of the risk accrues to current and former smokers by combining the risks to current, former, and never smokers, using a national estimate of current and former smokers of 58 percent for males and 42 percent for females. The benefit-cost ratio for the general population is 0.89 at the proposed MCL. For current and former smokers the ratio is 0.71. For people who have never smoked the ratio is 0.17.

Question 25. A number of communities have expressed concern that the feasibility of complying with the radon Alternative MCL instead of the MCL will depend on the details of the EPA's guidelines for State MMM programs. However, the guidelines were not available for comment with the proposed rule. What is the status of the MMM program guidelines and has the Agency received comment on them?

Response. As part of the proposed regulation, EPA published four criteria that the Agency proposes to use to approve States' MMM program plans. It is these four criteria that a State's MMM plan must meet. In addition, EPA explicitly requested public comment on various aspects of the criteria. The proposed criteria for MMM program plans provide and ensure extensive flexibility for States in the design, development, and implementation of MMM. The proposed MMM criteria identify certain information that is required to be developed and then described in an MMM program plan in order to be approved by EPA. EPA expects States' MMM plans to vary in the specifics of their responses to each of the criteria. The Agency will also be providing a handbook of ideas, suggestions, recommendations, options, resources, and other information to help States and others to develop and design their MMM plans. However, the information in the handbook is for consideration only and is not

required to be included in a MMM plan to receive approval. The handbook will be available with the final rule.

Question 26. In the other chamber, a bipartisan effort is underway to provide better public health protection than the proposed radon in drinking water rule. The legislation, for which the EPA has provided technical advice, would focus on indoor air radon reduction efforts and have water suppliers comply strictly with EPA's proposed alternative radon standard of 4,000pCi/l. Does the EPA believe this type of legislation would provide better public health protection than the proposed radon regulation?

Response. There are health risks for radon in both water and indoor air. EPA agrees that the risks from radon in indoor air are greater. In the proposed radon regulation, States are provided the flexibility to select either the MCL or the MMM/Alternative MCL option in order to target their efforts on the risks most important to each State. However, EPA encourages States to seriously consider adopting the MMM option as the most cost-effective approach to reducing public health risks from radon.

EPA has not yet formally received proposed legislation from either the House or the Senate. However, the Agency is aware of interest in proposing legislation on indoor radon that would facilitate State's implementation of MMM programs that would provide the accompanying flexibility for community water system compliance with the Alternative MCL. EPA also understands that such legislation would not affect the timeline for promulgation of the final radon regulation. EPA intends to fulfill its obligation under the bipartisan SDWA amendments of 1996 to develop protective standards for radon in drinking water, which the NAS has confirmed poses a cancer risk. EPA is committed to protecting public health, while providing States with statutorily authorized flexibility to use a multimedia approach in limiting the public's exposure to radon.

Question 27. The EPA has stated that it will adopt the radon regulation by the statutory deadline of August 2000. Does the EPA still plan to keep to this timeline? Given the lateness of the initial activities by the EPA and the wide public interest in the rule, does the EPA need more time to fully accommodate public comments and concerns?

Response. The Agency has received extensive and detailed public comment on the proposed rule and plans to take adequate time in order to be fully responsive to the issues and concerns raised by our stakeholders and the general public.

Question 28. You are no doubt familiar with the Water Infrastructure Network report on unmet infrastructure needs, which suggests an approximately $20 billion per year shortage of infrastructure funding? What does the EPA expect its upcoming infrastructure "gap analysis" to detail? If the report outlines unmet needs, what recommendations does the EPA have for addressing that gap?

Response. In 1995, EPA conducted the first Drinking Water Infrastructure Needs Survey to estimate the capital investment needs of community water systems. The survey, which was published as the "Drinking Water Infrastructure Needs Survey: First Report to Congress, February 1997," showed that the national drinking water need is large—$138.4 billion (in 1995 dollars) for the next 20 years. Of this total, approximately $76.8 billion is for current infrastructure improvements to protect public health. (These "current needs" are projects to treat for contaminants with acute and chronic health effects and to prevent contamination of water supplies. A portion of these needs are for SDWA compliance.) The installation and refurbishment of transmission and distribution lines accounted for over 50 percent of the total need, followed by treatment, storage, and source needs. EPA has been conducting the second Infrastructure Needs Survey and will release the results in February 2001.

Both the WIN report and the EPA study agree that there is a critical need for continued capital investment in our Nation's aging water infrastructure to ensure that Americans continue to receive clean, safe water.

During 1999 and 2000, EPA had preliminary discussions to inquire whether a funding gap exists between the national need for infrastructure investment and the national spending on drinking water infrastructure. The drinking water and wastewater programs will be entering into a closer analysis of this issue during the coming year. EPA has taken steps to investigate how to help systems operate more efficiently to reduce their overall costs. For example, EPA offers training sessions to assist smaller systems with operating and managing their assets with the aim of prolonging the life of their infrastructure while minimizing the costs of maintenance or replacement.

Over the past several decades, the Nation has invested over a trillion dollars to build and upgrade sewage treatment plants, minimize industrial discharges, and

protect our drinking water. As a result, millions of pounds of pollution have been removed from our waterways, the number of waterbodies safe for fishing and swimming has more than doubled, and 90 percent of Americans drink tap water that meets Federal health standards. However, the continued provision of clean and safe water will require EPA and state and community partners to work together to make the needed investments.

RESPONSES BY CHARLES FOX TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1. The EPA asked the National Academy of Science/National Research Council (NAS/NRC) to review EPA's characterization of potential human health risks from ingestion of inorganic arsenic in drinking water, review available data on metabolism and health effects and identify further research if needed. Except for hazard identification at higher doses, NRC identified more research in order to improve our understanding of risks from low-dose exposure to arsenic and the best course of action. Nevertheless, the NRC concluded that "upon assessing the available evidence,. . . the current EPA MCL for arsenic in drinking water of 50 ug/l does not achieve EPA's goal for public health protection and therefore requires downward revision as promptly as possible."

a) Is the NRC referring to the 10–4–10–6 risk range as the EPA's goal for public health protection for arsenic in drinking water?

Response. In its executive summary excerpt of the document, "Arsenic in Drinking Water" (March 1999), NRC does not explicitly refer to the 10–4–10–6 risk range that has been used by EPA in establishing drinking water MCLs for carcinogens. However, we believe the NRC was well aware of this range and note that its recommendation that the current level of 50 ppb is not sufficiently protective was made after the report observes that 50 ppb is associated with a risk of approximately 10–3—outside of EPA's target risk range.

Question 1(b). For risk management purposes, can a final MCL fall outside that range because of feasibility and cost-benefit analyses and still achieve the EPA's goal for public health protection?

Response. EPA ordinarily seeks to establish MCLs whose risk are within the target risk range of 10–4 to 10–6. However, an MCL can be promulgated consistent with SDWA requirements and still be outside the traditional risk range. This could happen, for example, if feasibility were a problem and the resulting MCL had to be set quite high relative to the Maximum Contaminant Level Goal (MCLG), or if the Agency determined that the benefits of an MCL within the target risk range did not justify the costs.

Question 2. The NRC stated that ". . . no human studies of sufficient statistical power or scope have examined whether consumption of arsenic in drinking water at the current MCL ([50 ppb or] approximately 0.001 mg/kg per day) results in an increased incidence of cancer or non-cancer effects." It further stated that ". . . It is not uncommon for several hypothesized models to fit observed data about equally well but to produce substantially different risk estimates at low-dose exposure."

Since the scientific community has known for years that there are important gaps in our understanding of the modes of action of arsenic, why were there no studies designed to shed more light on the low-dose response in the 3–50 ppb range, as stipulated in the 1996 statutory requirement?

Response. Studies to address the issue of low-dose effects of arsenic have been and continue to be a key component of EPA's drinking water research program. These long-term studies, as described in the Research Plan for Arsenic in Drinking Water, have been designed to address the highly complex scientific issue of the shape of the dose-response curve in the low dose region. Difficulties encountered in conducting these studies have included: 1) the limited power of epidemiology studies to detect effects in this low dose range for the types of illnesses reported to be associated with exposure to arsenic; and 2) the lack of a suitable animal model for observing arsenic-induced effects.

Research conducted or supported by EPA is making important contributions to our understanding of the low dose effects of arsenic. EPA investigators completed a pilot epidemiology study on a population in Utah that was exposed to a range of arsenic concentrations in drinking water. In addition to studying various health effects for their possible association with exposure to arsenic, the researchers were able to examine and compare the patterns of metabolism of arsenic in the study participants. Other opportunities for studying human populations, with a particular focus on issues relating to the metabolism of arsenic, are being considered for fund-

ing in 2001. Studies in animals on the metabolism and mode of action of arsenic are also providing important insights that will guide future research on the effects of arsenic at low doses. EPA has also worked in partnership with the American Water Works Association Research Foundation and the Association of California Water Agencies to support research to address this issue, and jointly sponsored a grant solicitation in 1996. Through that activity EPA is supporting research in the academic community on the interactions between arsenic and glutathione and the resulting impacts on arsenic toxicity and arsenic-induced health effects; and a dose-response study evaluating the susceptibility of skin keratoses from ingestion of low levels of arsenic in drinking water.

Question 3. For dose-response assessment, the studies are not conclusive in the low-dose range. NRC stated that "additional epidemiological evaluations are needed to characterize the dose-response relationship for arsenic-associated cancer and non-cancer end points, especially at low doses. Such studies are of critical importance for improving the scientific validity of risk assessment." The NRC also stated that "the most accepted explanation for the mode of action for arsenic carcinogenicity is that it induces chromosomal abnormalities without interacting directly with DNA. These markers of tumor response would lead to a dose-response curve that exhibits sublinear characteristics at some undetermined region in the low-dose range, although linearity cannot be ruled out." [emphasis added].

(a) Congress recognized the importance of health effects research in regulating arsenic, as demonstrated by the 1996 statutory requirement to develop a research plan to reduce the uncertainties in assessing health risk associated with exposure to low levels of arsenic. EPA's research has not adequately reduced those uncertainties so far. What research is planned to improve our understanding of the low dose-response?

Response. As described in the previous response, EPA is conducting or supporting long-term research in human populations and in laboratory animals to improve our understanding of the shape of the dose-response curve in the low dose region. EPA has been working with the States to identify new opportunities for conducting epidemiology studies in areas of the country, such as the pilot study conducted by EPA in Utah, that could provide information on potential cancer and noncancer effects at low doses. Studies are being conducted in laboratory animals and human populations to identify possible biological indicators of exposure and effect, which may be helpful in describing the dose-response curve in future studies in human populations. This includes work to characterize the relationship between metabolism and toxicity, to determine the variability of metabolites as a function of sex, age, volume of water ingested, and to examine the role of diet as a source of exposure to arsenic. Efforts are being made to improve risk assessments in the low-dose range by developing a physiologically based model of the kinetic and dynamic behavior of arsenic. Research using animals is evaluating events that occur at the molecular and cellular level to evaluate the mechanism(s) by which arsenic causes its effects. In addition, research is being conducted on the various factors that may modify human susceptibility to arsenic at low exposure levels.

Question 3(b). Is such research underway and will the results be available in time for finalization of the proposed rule?

Response. With the exception of the Utah pilot study, all of the efforts described above are long-term research activities that are underway. The results of these studies will not be available in time for finalization of the proposed rule. The risk assessment for the proposed rule is based on the large body of peer-reviewed scientific literature that has already been published, and will consider any new results from the Utah pilot study that are available in time.

Question 4. For exposure assessment, the EPA analysis has several limitations that need to be pursued further. For example, EPA's assessment is primarily based on the Taiwanese study which used "ecological data" instead of individual exposure. The NRC cautioned interpretation of any risk assessment based on ecological data alone because of the inherent uncertainties in them. That study also grouped exposure concentrations into broad exposure categories. The NRC also found that practice to add considerable uncertainty about exposure concentrations in the Taiwanese data because of the considerable variability in the arsenic concentrations in multiple wells within some of the villages. Another factor that affects exposure in the Taiwanese study was arsenic intake from food which apparently was not adequately accounted for, thereby introducing even more uncertainty.

Please discuss and characterize, in some detail, each of these and other sources of uncertainty of the Taiwanese study including how they affect risk assessment in the low dose-response range (i.e., overestimation or underestimation of risk).

Response. As stated in the preface to your question, there are several sources of uncertainty in the Taiwan studies (Tseng and Chen). These include not only ecological design but also the fact that arsenic from food intake was not examined. In addition, there were other chemicals in the well water including humic acids, and the methodology for analyzing arsenic was a colorimetric one.

While it is preferable to have individual exposure data, there are none for arsenic, so EPA used the available ecological, grouped data. The Executive Summary of the NRC report noted that the ecological Taiwan studies provide "the best available empirical human data for assessing the risks of arsenic-induced cancer." The NRC report referred to the older Tseng study data as grouped into "three broad exposure groups." However, NRC's risk analyses used Taiwanese data published by Chen, which grouped people's exposure by village into 42 categories. NRC mentioned that Poisson model results were less affected by grouping Chen's data than the model EPA used in its 1988 risk assessment. Results in other populations (e.g., Mexico, Chile) are consistent with the results from Taiwan.

Because arsenic is naturally occurring, people can be exposed to low levels of arsenic primarily from food and water. Various foods contain organic and inorganic arsenic. In general, the inorganic forms of arsenic are the ones of most toxicological concern. The most common forms found in most fish and shellfish are arsenobetaine and arsenocholine. Available evidence indicates that these two organic arsenicals are not toxic to humans, so levels of arsenic from fish consumption are of little toxicological significance. The levels of inorganic arsenic in foods could be of concern, but we do not have sufficient information to understand at what level the inorganic arsenic in food is of concern. For EPA's risk assessment, however, the important question is whether the food from Taiwan had more inorganic arsenic than food from the United States or other countries, such as Chile and Argentina. There are a few suggestions in the scientific literature that the food in Taiwan may have had more inorganic arsenic than the comparable food in the U.S., but the data base for both countries is limited. In the proposed arsenic rule, the Agency noted on page 38949 that not accounting for sources of arsenic intake in Taiwan other than drinking water (i.e., from food) would overestimate risk in the U.S.

It is possible that other substances in the water, such as humic acids, could have affected the cancer incidence in Taiwan. If this were so, one would have expected to see lower risks from arsenic exposures in Chile and Argentina (rather than comparable risks) because the water in these countries did not have humic acids. It has also been suggested that selenium deficiency in the diet of the study population may have increased its susceptibility to arsenic relative to the general U.S. population. It is plausible but not proved that poor diet substantially exacerbates the toxicity of arsenic. Much more work is needed to draw any definitive conclusions about the role of specific dietary components in the manifestations of arsenic toxicity.

NRC notes that the colorimetric assays used to make arsenic measurements in Taiwan can accurately measure to 40 g/L. Only five of the 42 Taiwanese villages had less than 40 g/L, so risks were not significantly affected by the analytical limitations.

Question 5. Risk characterization: To characterize the arsenic risk in drinking water in the US, EPA relied principally on the extrapolation of the Taiwanese study to the United States. There are some concerns about that extrapolation. The NRC identified several factors in this regard that it stated it could not assess quantitatively. These are poor nutrition and low selenium concentrations in Taiwan, genetic and cultural characteristics, and arsenic intake from food. For example, NRC found that arsenic intake from food in Taiwan is higher than in the US, resulting in an overestimation of risk from drinking water. The NRC noted that selenium should be considered as a moderator of arsenic toxicity and should be taken into account. According to NRC, not accounting for the fact that the Taiwanese have less selenium intake than US population could result in overestimation of the benefits of arsenic reduction in the US. Another factor that tend to overestimate risk is the measure of total arsenic in drinking water, while the risk calculations are based on inorganic arsenic, the hazardous form of arsenic. The justification given in the proposed rule for the use of total arsenic appears to be based on very limited data of arsenic occurrence in drinking water in US. In some cases, the proposed rule acknowledges these limitations but stops short of performing at least a qualitative assessment.

Please discuss how EPA treated these overestimations of arsenic risk in applying the Taiwanese study to conditions in the US, particularly in the proposed MCL range.

Response. In the arsenic risk assessment, there are several risk factors that cannot be quantitatively assessed, which add to the uncertainty surrounding the risk of arsenic exposure. Each must be considered to see if it could make a major impact

on the calculated risk. If selenium and/or poor nutrition were major factors, it could be expected that the risks of bladder and lung cancers in Chile and Argentina two countries with apparently adequate nutrition would be quantitatively lower than those found in Taiwan. However, the NRC Panel found that the risks of bladder and lung cancer after arsenic exposure were similar in the three countries. Likewise, the genetic and cultural differences in the three populations were not reflected in the magnitude of risks.

We discussed the effect of arsenic content in the diet on risks in the previous question. The proposed arsenic rule provides the worldwide bladder cancer mortality ranges known to EPA on page 38942 and EPA requests comment (page 38950) on whether we have properly weighed the uncertainties that overestimate and underestimate risks.

The reasons for proposing a total arsenic MCL are discussed in the proposed arsenic rule under the heading, "Why is EPA proposing a total arsenic MCL?", on page 38952. As a general rule, the vast majority of arsenic found in U.S. drinking water sources is inorganic, and this also appeared to be the case in Taiwan. Accordingly, it does not appear that using total arsenic is an overestimation of exposure and proposing the rule as total arsenic does not appear to be a problem.

Section 1412(b)(4)(B) of the Safe Drinking Water Act requires EPA to set an MCL as close to the MCLG as is feasible, unless it would increase the risk from other contaminants (§ 1412(B)(5)) or if EPA proposes that the benefits would not justify the costs (§ 1412(B)(6)). Within this framework, EPA proposed an MCL of 5 g/L and asked for comment on a level of 3 g/L, as well as on levels of 10 g/L, and 20 g/L (pages 38950–38952 of the preamble). Prior to that, EPA discussed the sources of uncertainty: mode of action, population differences, diet, selenium, model choice for analyzing data, grouped data, and ethnic differences on pages 38949–38950.

Question 6. The EPA's estimate of arsenic in drinking water in the US is based on limited data, extensive generalizations, and other assumptions. It appears that those estimates are therefore subject to large uncertainties. Do the large uncertainties associated with risk assessment in the low dose-response range make the EPA's estimate of the occurrence of arsenic in drinking water more or less important with respect to risk management? Please explain. Please include how uncertainties in the estimate of arsenic occurrence affects the cost-benefit analysis.

Response. The estimate of occurrence is central to our analysis of both costs and benefits, since occurrence establishes "the baseline" (i.e., determines how many public water systems would have to comply with a particular regulatory level and, correspondingly, how many people would receive the health benefits associated with a particular regulatory level). We believe that an accurate occurrence estimate is an extremely important component of our overall risk management analysis for this rulemaking (as it is for any major contaminant rulemaking). While we acknowledge that there are uncertainties associated with the data and information on occurrence used for the development of the proposed arsenic in drinking water regulation, we respectfully disagree with the characterization that it is based on "limited data, extensive generalizations, and other assumptions." We believe the 25,000+ data points examined have led to a reliable and reasonable estimate of the level of occurrence of arsenic in public water systems. Our occurrence estimate compares closely with those of the American Water Works Association and the U.S. Geological Survey.

Question 7. Do the large uncertainties associated with risk assessment in the low-dose range and the large uncertainties in the estimation of arsenic occurrence in US drinking water make an accurate estimate of cost of available technology more or less important with respect to risk management? Please explain.

Response. An accurate estimate of the cost of available technology (and other costs associated with compliance with the proposed rule) is central to our analysis of the costs and benefits of the rule as is an accurate understanding of the occurrence. EPA attempts to reduce uncertainties and gain the best possible understanding of every component of our risk assessment, characterization, and management processes.

Question 8. The cost-benefit analysis used in the EPA's decisionmaking does not appear to be conducted with the same level of rigor as the risk assessment.

a) Please explain why such a difference if both components carry significant weight in the decisionmaking.

Response. The benefits analysis is derived substantially from the risk assessment. For example, the risk of excess cancer deaths at any particular arsenic level derived from the risk assessment is used, in part, to monetize the benefits by multiplying the number of projected deaths by the value of a statistical life (VSL). Thus, we do not agree with the premise of the question that a different level of rigor was em-

ployed in the various analyses. We believe that the cost-benefit analysis was performed as rigorously as possible, given the available data and information.

Question 8(b). Since the Administrator used the cost-benefit analysis to depart from the feasible MCL, could her decision have been subjected to an unknown degree of uncertainty introduced by the cost-benefit analysis?

Response. As with any scientific undertaking, there is a measure of uncertainty associated with the calculation of the costs and benefits of the proposed rule. However, these uncertainties were clearly identified and are discussed in the preamble to the proposed rule. Greater or lesser weight given to the various uncertainties could influence the selection of the MCL option and is one of the principal reasons the Agency is soliciting comment on a range of MCL options.

Question 8(c). Has the cost-benefit analysis used in the proposed rule been peer reviewed? If so, by whom and what were some of the recommendations for improvement? Are there peer-reviewed guidelines that EPA uses for its cost-benefit analysis?

Response. The component elements of the cost-benefit analysis were peer reviewed or reviewed by independent third parties. However, the overall risk management decisions based upon that analysis involved the exercise of the Agency's discretionary authorities. There are a set of peer-reviewed (by the Science Advisory Board) guidelines that provide an overall framework for the Agency's cost-benefits analyses. In addition, the elements of EPA's approach to cost-benefit analysis for this proposed rule that were reviewed, either by peers or independent parties, and some of the principal recommendations in each case are as follows.

Risk Assessment: NAS' National Research Council provided recommendations on the strength and limitations of various national and international health effects research that serve as a basis for risk assessment.

Occurrence Estimates: Informal discussions with water industry experts, internal peer review by the Agency's statisticians, consultation with the U.S. Geological Survey provided: 1) an approach for dealing with "censored data," i.e., results of analyses below detection levels but known to be greater than zero; 2) a geographic approach to developing state-wide estimates for states with only limited arsenic data available; and 3) recommendations relative to how much historic data to accept and still be considered representative of current conditions.

Benefits Analysis (overall): National Drinking Water Advisory Council provided specific recommendations on how to treat both qualitative and quantitative data in the cost-benefit analysis.

Benefits Analysis (latency and value of a statistical life): EPA's Science Advisory Board recommended that the Value of a Statistical Life is the best available metric to value lives saved as a result of cancer cases avoided; and, recommended that the Agency consider, as a part of its final regulatory impact analysis, discounting benefits based upon a latency period prior to the onset of cancer and increasing benefits to account for rising income over the course of a life time.

Cost Analysis (general): Blue Ribbon Panel of industry experts provided specific recommendations concerning baseline assumptions to be used in costing of equipment projected to comply with drinking water rules and other related issues.

Cost Analysis (arsenic): EPA's Science Advisory Board provided critical evaluation of the Agency's treatment technology costing decision tree and other analyses performed to develop national cost projections for proposed arsenic rule; recommended that the Agency further investigate issues related to disposal of water treatment utility waste residues generated as a result of treating for arsenic.

Question 8(d). Did the EPA analysis of Community Water Systems (CWS) and the best available technology (BAT) consider the cost of such technology when optimized for arsenic removal?

Response. Yes, our analysis specifically examined the optimal use of various technologies and the associated costs.

Question 8(e). What biases are introduced as a result of data averaging on the estimated cost of smaller CWS?

Response. EPA's approach to estimating unit treatment costs is very conservative. In our view, it more than compensates for any biases introduced as a result of relying on some data averaging. For example, the performance of ion exchange for arsenic removal is affected by sulfate. EPA has developed two sets of equations based on sulfate concentrations of less than 25 mg/L and in the range of 25—90 mg/L. The unit costs are based on the highest sulfate concentration in the range. For a system with 30 mg/L sulfate, the operating and maintenance costs are overestimated by a factor of 3 because the costs are based on 90 mg/L sulfate. Thus, EPA believes that the use of conservative assumptions in the unit costs would account for any bias introduced by data averaging on the estimated cost of compliance in smaller CWS.

EPA has compared estimated compliance costs with actual costs of rules for purposes of validating its cost models. One such analysis was presented in the preamble to the proposed radon rule, where treatment costs from the cost models were compared with costs at sites with aeration treatment. It was found that EPA's cost estimates tended to overestimate costs for small systems.

Question 9. Why hasn't the proposed rule been reviewed by the Science Advisory Board (SAB) before its publication for general comment, particularly those portions that address the use of data to determine occurrence of Arsenic in drinking water, the effectiveness of BAT, and the economics? (b) Will there be enough time for EPA to consider and revise those portions of the proposed rule, especially in light of the weight given to the cost justification of the proposed MCL by the Administrator's invocation of her new authority?

Response. The Agency began working with representatives of the SAB in early Fall of 1999 to arrange a time to accomplish the SAB's review of the proposed rule. Unfortunately, the earliest time that such a review could be scheduled was March 2000. Nevertheless, we believe there will be sufficient time to consider the comments of the SAB on the proposed rule, particularly those comments dealing with costs of the proposed rule and EPA's proposed decisions regarding BAT. (The SAB was not specifically asked to review the Agency's occurrence estimates nor did it ask to do so.)

Question 10. EPA stated in the proposed rule that this is the first time that the Administrator has invoked her authority to set a MCL less stringent than the feasible level because of cost benefit considerations. In that context, please describe the rationale for not proposing a MCL of 10 or 20?

Response. The key elements of the Agency's review of health effects, uncertainties, costs, and benefits as well as its evaluation of other possible MCL choices are thoroughly discussed in the preamble to the proposed rule (relevant section attached). In brief, EPA examined the various health effects attributable to arsenic in drinking water at various levels with a particular focus on the National Academy of Sciences' report. In so doing, we identified a number of quantifiable adverse health effects, mainly due to bladder cancer, in addition to a number of currently unquantified or partially quantified health effects (e.g., lung cancer, cardiovascular effects, skin cancer, etc.). We then sought to monetize these benefits, where possible. We also developed the costs associated with various possible arsenic levels, based on the projected costs including those for treatment, monitoring, and administration. In developing both costs and benefits, we identified a number of uncertainties and summarized these in the preamble to the proposed rule. In weighing the various regulatory options, we considered the costs and benefits (both monetizable and non-monetizable) and the associated uncertainties. As described in the preamble, the Agency elected to exercise the discretionary authorities of section 1412(b)(6) of the Safe Drinking Water Act (SDWA), to move away from the proposed "feasible" level of 3 parts per billion or ppb, a level based on consideration of costs to large systems and the capability of analytical methods. We next determined that 5 ppb best reconciled the various factors under consideration, but we also solicited comment on regulatory options of 3 ppb, 10 ppb, and 20 ppb, in recognition of the uncertainties associated with this decision and the possibility of weighing these decision criteria differently. As noted in the discussion, MCL options of 10 or 20 ppb provide less certainty that the MCL would be protective of human health. Of particular concern, in this regard, was the unquantified effects of lung cancer. NAS suggested that excess lung cancer deaths from arsenic could be two to fivefold greater than the excess bladder cancer deaths. Since the publication of the proposal, more specific information about arsenic's ability to cause lung cancer has become available and we have apprized the public of this information in a Notice of Data Availability (NODA).

Question 11. In view of where we are in terms of uncertainties in our knowledge of risk assessment of arsenic in drinking water (more than 12 years since the issuance of the Special Report by EPA's Risk Assessment Forum), and uncertainties in knowledge of arsenic occurrence in the nation's CWSs and best available technologies, what lessons has the Agency learned that would improve risk management?

Response. Prior attempts to develop a revised arsenic in drinking water regulation were hampered by a lack of information concerning the effects of arsenic in low doses. While uncertainties still remain, we believe that the research and analysis completed to date has raised significant concerns relative to arsenic in drinking water and supports a new arsenic in drinking water regulation. This finding is strongly echoed by the NAS' National Research Council and is generally accepted by virtually all stakeholders in the drinking water arena, including environmental and public health advocates, state regulators, and industry representatives. In addi-

tion, our overall ability to perform more robust risk management analyses has been strengthened by the Agency's efforts to improve the scope and accuracy of the individual component analyses that comprise risk management (see response to earlier question concerning peer review of the elements of the cost-benefit analysis).

Question 12. Mr. Fox stated in his testimony that ". . . [NAS] said 50 parts per billion was a risk range of about 10–3 . If you do extrapolate the National Academy of Sciences study down, you're probably in the range of 4 to 6 parts per billion,. . . If you end up considering the normal agency risk range, how we've done these things in the past, which is typically 10–4 to 10–6 for a cancer range, your arsenic number would actually be well below three. . about 0.02. The National Academy was pulling this way down, our traditional agency risk range would have even been below three, and the feasibility analysis would have taken us to three. So given this pressure on arsenic, we then took the new language of the of the Safe Drinking Water Act that allows us to consider costs, and it gave us the ability to move off of what was feasible based on a consideration of cost, and that's basically how we ended up at five."

a) Based on that testimony, if 50 ppb represents 10–3 annual risk, then wouldn't 5 ppb represent 10–4 risk, which falls within the EPA's "normal risk range" of 10–4—10–6?

Response. Yes, we agree that 5 ppb, under the terms of the question, would fall within the 10–4—10–6 risk range.

Question 12(b). If 5 ppb is within the EPA's normal risk range, shouldn't the "feasible" MCL be somewhat higher based on the above and the following testimony?

Mr. Fox further stated in his testimony that "Feasible is what can you technologically achieve, what is affordable, and what do our monitoring capabilities allow us to measure down to."

Response. No, the feasible level is based on consideration of cost effectiveness for large systems and the capabilities of analytical methods. For arsenic, removal of arsenic to relatively low levels (down to 3 ppb) is technologically achievable, cost-effective for large systems, and measurable by existing analytical methods.

Question 12(c). Does EPA use the feasibility test to arrive at a risk value that is always constrained to the 10–4–10–6 range or can a "feasible" MCL fall outside this range, i.e., 2x10–4?

Response. The feasible level is determined irrespective of the target risk range and independent of any risk assessment. Thus, it could theoretically fall outside of the target risk range. However, as noted above, the feasible level for arsenic is below (i.e, more stringent than) the proposed MCL.

Question 13. Mr Fox stated in his testimony: "So given this pressure on arsenic, we then took the new language of the Safe Drinking Water Act that allows us to consider costs, and it gave us the ability to move off of what was feasible based on a consideration of cost, and that's basically how we ended up at five."

We assume Mr. Fox is referring to the EPA's authority of moving away from the "feasible" MCL using cost as a basis as given in section 1412 (b)(6).

a) Is EPA finding that while the "feasible" MCL is affordable, the costs of its implementation do not justify the benefits? Please explain.

Response. Yes, EPA is proposing to use the authorities of section 14112(b)(6) to find that the benefits of the feasible level do not justify the costs and is proposing to exercise these authorities to establish the MCL at a higher (i.e., less stringent) level.

Question 13(b). Is EPA departing from the "feasible" MCL solely on the basis of its cost-benefit analysis as testified?

Response. Yes.

Question 14. The EPA, in its proposed rule, lists in addition to cost, the degree of scientific uncertainty regarding the dose-response curve (affected by differences in nutrition and arsenic in food) as basis for departure from the "feasible" MCL.

a) Please explain this apparent conflict with Mr. Fox's testimony referred to above.

Response. In Mr. Fox's testimony, he refers to consideration of costs as a basis for choosing a proposed regulatory level higher than the feasible level. Mr. Fox was implying, but did not explicitly state, that costs were deemed to be too high in comparison with benefits. The apparent conflict to which you refer is the proposed rule's reference to the uncertainties surrounding the scientific basis for the health effects as a basis for moving from the feasible level. These positions are not in conflict because the benefits portion of the cost-benefit analysis relies largely on the health risk assessment. Thus, uncertainties associated with our understanding of the health effects of arsenic at low levels carry over into the benefits analysis and the

resultant cost-benefit comparison. Thus, the preamble and Mr. Fox's testimony are not in conflict.

Question 14(b). Instead of this back-end adjustment that confounds the analysis, why isn't the Agency accounting for the scientific shortcomings in the front-end and arriving at a more acceptable dose-response curve?

Response. The NAS' National Research Council stated that "information on the mode of action of arsenic and other available data that can help to determine the shape of the dose-response curve in the range of extrapolation are inconclusive and do not meet EPA's 1996 stated criteria for departure from the default assumption of linearity. Of the several modes of action that are considered most plausible, a sublinear dose-response curve in the low-dose range is predicted, although linearity cannot be ruled out." In other words, the NAS was not able to identify a "more acceptable" dose-response. The Agency is relying on the NAS' recommendation in this regard.

Arsenic

Question 15. I understand that in the draft proposed rule EPA sent to the Office of Management and Budget (OMB), the Agency suggested a limit of 5 ppb for arsenic and asked for comments on 3 ppb and 10 ppb. At the request of OMB, EPA is now accepting comment on 20 ppb. It would seen that OMB has concerns with the cost-benefit analysis used for the proposed arsenic rule. What are OMB's concerns?

Response. The OMB reviewed all aspects of the proposal and supporting documentation. A summary of changes made to the rule and the preamble as a result of OMB is available in the docket for this rule and is attached for your reference.

Question 16. A group of water associations have found that an MCL of 5 ppb for arsenic would place a significant burden on water utilities. The group estimates public water systems nationwide would have to invest $1.25 billion annually for an MCL of 5 parts per billion (ppb) and $0.5 billion for an MCL of 10 ppb. EPA estimates are $374 million for an MCL of 5ppb and $160 million for an MCL of 10 ppb.

A. Can you explain the discrepancies between EPA's and the water associations' estimates?

Response. The American Water Works Association Research Foundation's (AWWARF) cost estimates are based on 6 case studies of medium and large utilities in the West and Southwest—scaled up to the country as a whole. EPA's estimates are based upon a detailed analysis of a wide array of water utilities of various system sizes and source water characteristics. In addition, the AWWARF study includes an assumption that arsenic waste residuals from water treatment plants will be extremely costly to dispose of. We agree that this will occasionally be the case but do not share AWWARF's view of the magnitude of this problem. We will be meeting with AWWARF representatives in coming weeks to compare assumptions and calculations in an effort to refine our cost estimates, as appropriate.

B. Were increased disposal costs of handling arsenic-contaminated waste and infrastructure needs accounted for in EPA's calculation of the costs of the proposed rule?

Response. Yes, but as noted above, we do not share AWWARF's estimates of the magnitude of these costs.

Question 17. EPA was almost 5 months late in proposing the arsenic rule. Is EPA still expecting to be on target for the January 2001 Safe Drinking Water Act statutory deadline to propose a revised standard? What additional research is necessary before finalization of the arsenic rule can occur?

Response. EPA will finalize the arsenic rule after we carefully review, consider, and respond adequately to public comments. We will strive to complete the rulemaking process as close as possible to the1996 SDWA amendment's statutory deadline for this rule. We will look with interest to the comments received on the proposed rule. However, we also believe we have identified a number of the principal concerns and issues of stakeholders through our attendance of public meetings and conferences and correspondence. Thus, we are currently considering and evaluating an array of opinion and input while we await additional comments in response to the proposed rule. We are not awaiting any additional research to be completed before completion of the arsenic rule. However, we have issued a Notice of Data Availability, which notifies the public of the availability of quantified data on lung cancer as a result of arsenic in drinking water.

Question 18. EPA estimates that 12 percent of community water systems would need to take corrective action to lower arsenic levels to 5 ppb. 94 percent of these systems serve less than 10,000 people per system. EPA has not proposed variance

technologies to assist these systems with coming into compliance with the proposed standards.

a) For what reasons has EPA not proposed variance technologies for small systems?

Response. As required by section 1412(b)(4)(E) of SDWA, we examined available treatment technologies for small systems (those serving less than 10,000 people) and were able to identify affordable technologies for all small system size categories. Thus, we would not expect to issue a national finding that any particular size category was unaffordable and warranted variance technologies and identification of an associated regulatory level less stringent than the MCL. We also did not attempt to forecast the extent to which States may issue exemptions to any particular facility to allow additional time to comply with the MCL.

Question 18(b) and (c). How is EPA addressing the needs of small community water systems?

What guidance will you provide these systems to enable their compliance with the standards?

Response. EPA has taken a number of steps to address the particular concerns of small systems. Chief among these was the convening of a group of small entity representatives (SERs) under the auspices of a small business panel convened pursuant to the Small Business Regulatory Enforcement and Fairness Act. The SERs provided valuable information to the Agency on the particular concerns of small systems. Their concerns are reflected in the panel report, which is available in the docket for this rulemaking. The Agency carefully considered the issues and concerns of small entities in the development of this rule and will be providing specific guidance to small entities to aid in their compliance with this rule shortly after the rule is promulgated. Among the principal concerns of small entities was the importance of identifying affordable, easy-to-operate treatment technologies to comply with a revised arsenic MCL.

Radon

Question 19. The proposed maximum contaminant Level (MCL) for radon is significantly below the average outdoor level for radon in air. How do you justify the MCL of 300 pC/L (picoCuries per Liter) if radon transferred from water to air at 300 pCi/L is substantially less than the natural radon variability outdoors?

Response. In developing the proposed MCL, EPA has followed the framework provided by the Safe Drinking Water Act (SDWA) for setting limits for radon in drinking water, and solicited comments on the MCL proposed. EPA believes the proposed MCL of 300 pCi/L, in combination with the proposed Alternative MCL and MMM approach, accurately and fully reflects the SDWA's provisions. SDWA requires EPA to set the MCL as close as feasible to the maximum contaminant level goal (MCLG), which the Agency proposed as zero, based on extensive documentation that radon is a known carcinogen with no known health effects' threshold. In the case of radon, EPA has proposed a feasible level (as defined by the availability of cost-effective treatment technologies and analytical methods) of 100 picocuries per liter (pCi/L). The Agency used the flexibility under SDWA to take into account the costs of controlling radon from other sources to propose an MCL at 300 pCi/L, which is within the upper end of the Agency's traditional target risk range of one excess cancer death per 10,000 people.

Question 20. Do you agree that the greatest risk to human health posed by radon is from radon found in air? If this is the case, wouldn't it be more beneficial to set a realistic MCL for radon in water that protects human health and direct more resources toward the State Indoor Radon Programs?

Response. EPA believes Congress recognized the multimedia nature of radon risk when it amended the Safe Drinking Water Act (SDWA) in 1996. Radon in indoor air is the second leading cause of lung cancer in the United States, after smoking. However, though the risk posed by radon from drinking water is much smaller, the 1999 report from the National Academy of Sciences (NAS) confirmed that radon in drinking water causes cancer deaths, primarily lung cancer from inhaling radon transferred into indoor air from drinking water.

Under the proposed rule, States have the flexibility to select either the Maximum Contaminant Level (MCL) or the Multimedia Mitigation(MMM)/Alternative MCL option. In the event that a State opted not to develop an MMM program, individual community water systems (CWSs) would have the option of developing local MMM programs. EPA believes, however, that an MMM program at the State level would minimize the burden on community water systems. EPA believes the MMM approach in the radon proposal offers an important and effective opportunity under the SDWA framework to reduce the highest levels of radon in drinking water, while

spending resources most cost effectively to address the more significant public health risk—radon in indoor air. Most states, including New Hampshire, currently have a program to address radon in indoor air under the State Indoor Radon Grant Program that is partially funded by EPA. The MMM program is intended to enhance these existing state radon programs. Although the 1996 SDWA amendments contain no new authorizations for funds to implement the regulation for radon in drinking water, EPA has proposed to make available existing funding sources to implement this regulation. The State Indoor Radon Grant program would be available for a State MMM program.

Question 21. I have concerns with the inclusion of smokers in the risk assessment that was used to set the radon standard? Based on a recent industry assessment, the MCL wold rise to 800 pCi/L if smokers were removed from the assessment. How does EPA justify the inclusion of smokers in the risk assessment?

Response. Regarding risks to smokers, the National Academy of Sciences' (NAS) Radon in Drinking Water Committee, as part of its assessment of the risks of radon in drinking water, considered whether groups within the general population, including smokers, may be at increased risk. The NAS found that current and former smokers (those who have smoked at least 100 cigarettes over a lifetime) were at increased risk from exposure to radon, but did not identify smokers or any other group as a sensitive subpopulation (i.e., a subpopulation that warrants protection at levels more stringent than those applicable to the general population). The proposed maximum contaminant level (MCL) of 300 pCi/L was not selected to target protection to smokers. Rather, EPA's proposed MCL is based on risks to the general population, including current and former smokers. The risk assessment for radon in air is based on an average member of the population, which includes smokers, former smokers, and people who have never smoked. Based upon available information and models, the projected cancer deaths in smokers and former smokers, modeled as an excess risk, would not have occurred but for the added exposure to smokers caused by drinking water with radon levels above the proposed maximum contaminant level (MCL).

Question 22. How will EPA determine what constitutes an acceptable Multi-Media Mitigation Program?

Response. EPA published the proposed criteria for determining what constitutes an acceptable MMM Program in the proposed rule. We would use those four criteria. The proposed MMM criteria require certain information to be developed and then described in an MMM program plan in order to be approved by EPA. We will approve the plan if that information is included. As required by SDWA, EPA will evaluate MMM programs every 5 years, and is proposing to work with States to improve MMM program plans as needed as a result of that evaluation.

Question 23. A number of water utilities have expressed liability concerns if they decide to implement a Multi-Media Mitigation Program to meet the Alternative MCL level, but their respective state selects to establish the MCL level. What is EPA doing to address these liability concerns?

Response. It is EPA's understanding that, in California, private and some publicly owned utilities are concerned about tort liability for residual risk when meeting the Alternative MCL, because of the perception of a dual standard and the availability of a more protective MCL. Private utilities have been sued on the basis of residual risk, even when meeting existing standards for drinking water. The California Supreme Court has agreed to hear these cases, likely this Fall. If California and other States adopt the Alternative MCL and MMM program as expected, then there will be only one standard in the State (the Alternative MCL), not a dual standard. The Agency intends to provide States and CWSs with information that will be useful in communicating the relative risks of radon in drinking water and radon in indoor air. A single standard at the State level may help to address tort liability concerns to some extent.

MTBE

Question 22. What regulatory decisions has EPA made that are relative to MTBE contamination of drinking water?

Response. EPA has decided to proceed with proposal of a secondary standard for MTBE. The secondary standard would provide EPA's recommendation to States of an appropriate level for MTBE in finished water supplies from the standpoint of taste and odor. Also, at the same time, we are moving forward to gather additional information about the health effects and extent of occurrence of MTBE (at levels associated with health effects) in order to determine whether or not to proceed with a health-based primary standard for MTBE.

Question 23. What are EPA's current plans for determining the potential health effects of MTBE contamination of drinking water?

Response. Current plans for determining the health effects of MTBE contamination of drinking water will be based on two sources of information. First, using current toxicological data and recently developed information that characterizes the pharmacokinetic behavior of the chemical, EPA will develop:1) an estimate of the level of exposure likely to be without an appreciable risk of adverse non-cancer effects during a lifetime (oral reference dose [RfD]) and, 2) an estimate of excess lifetime cancer risk that may result from continuous exposure to the agent (cancer unit risk). These estimates will be used to aid in the characterization of the hazard and risk of MTBE and for comparison with other fuel additives. EPA intends that this assessment information will be placed on its publicly accessible Integrated Risk Information System (IRIS). The Agency anticipates that these draft IRIS assessment documents for MTBE will be submitted for external peer review and will be publicly available in Spring 2001. EPA's second source of information will include an analysis of health effects testing of baseline gasoline and gasoline with MTBE, TAME, ETBE, or ethanol, as this data becomes available. It is likely that this analysis will take place after the development of the MTBE RfD and cancer unit risk, which may necessitate a future review of the MTBE RfD and cancer unit risk assessments.

Fluoride

Question 24. As you know, Dr. William Hirzy testified at the hearing against fluoride and the fluoridation of public water supplies. What is EPA's official policy on the fluoridation of drinking water?

Response. On July, 25, 1997, Robert Perciasepe, then Assistant Administrator of the Office of Water (OW), wrote to the American Dental Association and addressed the Agency's position on fluoridation. He stated:

As you no doubt are aware, the Safe Drinking Water Act prohibits EPA from requiring or supporting the addition of any substance (including fluoride) to drinking water for preventive health care purposes. Those decisions are made on a State or local basis and do not directly involve EPA. . . . .State or local fluoridation practices typically result in a total fluoride concentration of 1.2 mg/L or less, well below the EPA Maximum Contaminant Level Goal (MCLG) for fluoride of 4 mg/L.

Thus, the law does not prevent fluoridation and EPA does not expect any adverse health effects will occur from the practice. A copy of Mr. Perciasepe's letter is attached.

Question 25. When was the last time EPA reviewed the health effects data and current MCL and MCLG for fluoride in drinking water? How is EPA addressing the concerns of the anti-fluoride community with respect to the MCL for fluoride in drinking water?

Response. The last EPA-sponsored review of fluoride was done by the National Research Council (NRC) of the National Academy of Sciences (NAS). Their assessment was published by National Academy Press in the book, Health Effects of Ingested Fluoride, in August 1993. The NRC concluded that the current 4 mg/L standard is appropriate as an interim standard to protect the public health.

The Institute of Medicine at NAS completed a review of fluoride as a dietary constituent in 1997. NAS established Adequate Intake (AI) Values for prevention of dental cavities by life-stage group and Tolerable Upper Intake Levels (UL) by life-stage group. The UL values for infants and children through age 8 (0.7 to 2.2 mg/day) protect against dental fluorosis and the values for older children and adults (10 mg/day) protect against skeletal fluorosis. This review did not involve EPA.

EPA responds to letters, E-mails, and telephone calls it receives from the anti-fluoride community. The EPA responses provide information on the Maximum Contaminant Level (MCL)/MCLG that protects against skeletal fluorosis and the Secondary MCL which protects against dental fluorosis. A Regulatory Background summary is included with the EPA letters. The Regulatory Background summary provides information on fluoridation and fluoridation additives as well as on the EPA MCL/MCLG and SMCL. (The Regulatory Background summary is attached.)

Question 26. Does EPA plan to review fluoride during the 6-year review of national primary drinking water standards to begin this August?

Response. Yes, EPA will re-examine the health effects of fluoride in the context of our reevaluation of all drinking water regulations as required under Section 1412(b)(9) of the Safe Drinking Water Act amendments of 1996.

Question 27. What health effects data exist on the safety of fluosilicate additives in drinking water? What are the Agency's future plans for conducting research on the safety of these additives?

Response. The fluosilicate additives dissociate at the concentrations used in fluoridation releasing fluoride ions. Accordingly, the extensive toxicological data available for sodium fluoride are believed to apply to the fluosilicate products, and the risk assessment for fluoride ion in drinking water applies to the fluosilicates used for fluoridation.

EPA has found one report on the toxicology of fluosilicate additives. Data on hydrofluosilicic acid are included in a report submitted to EPA under TSCA Section 8(e) by Rhone-Poulenc in 1992. The report includes data on skin irritation, eye irritation and an acute oral LD–50 in rodents The results of these studies provide minimal information on the toxicological properties of hydrofluosilicic acid and are suitable only for identification of hazard and not for risk assessment. A copy of the report is attached.

The EPA has no present plans for conducting research on the safety of fluosilicate additives. Fluosilicate additives are certified for use in the treatment of potable water under ANSI/NSF Standard 60: Drinking Water Treatment Chemicals—Health Effects. Standard 60 allows the agencies that certify additives against the Standard to request specific toxicological data to support certification. The need for toxicological studies should be appraised by the agencies that certify products against the Standard, and, if there are data needs, they should be requested from the manufacturers as part of the certification process. The enclosed Regulatory Background summary provides information on the additives certification program and provides contact information for two programs that have certified fluosilicate products: NSF International and Underwriter's Laboratories.

Responses by Norine Noonan to Additional Questions from Senator Crapo

Question 1. What steps has the EPA taken in response to the recommendations of the September GAO report criticizing Agency prioritization of SDWA research funding and planning?

Response. The Agency has made considerable progress in responding to the recommendations of the September GAO report regarding prioritization of research funding and planning. Working closely with the Office of Water, the Office of Research and Development has conducted an evaluation of research needs, resource requirements and timeframes for when the results of research must be available to support near- and long-term regulatory requirements. EPA has also engaged outside stakeholders, including the American Water Works Association (AWWA), the AWWA Research Foundation (AWWARF), other governmental agencies, universities and other public and private sector groups to address important scientific issues associated with drinking water.

EPA's yearly request for resources for drinking water research is a multi-faceted approach. The first step involves ORD's Water Research Coordination Team's (WRCT) evaluation of that fiscal year's drinking water research needs and the resources needed to achieve them. The WRCT's recommendation for funding drinking water research is based on risk-based prioritizations of research needs, is consistent with the peer-reviewed and published drinking water research plans, considers evolving drinking water research needs in developing research plans/strategies, and uses information collected from Stakeholder and FACA drinking water meetings. The planned yearly research is intended not only to meet the immediate regulatory needs of EPA, but also to meet future drinking water needs and other Sound Science research needs of the Agency. The WRCT's recommendations are reviewed by ORD senior management and subsequently by the EPA Research Coordination Council, which is comprised of senior representatives from ORD and each of the EPA's Program Offices. The Agency's budget planning process seeks to ensure balance across the Agency's research resource needs.

The fiscal year 2001 President's Budget request for drinking water research has grown from $20.8 million in fiscal year 1995 to $48.9 million in fiscal year 2001. These research activities address high priority research areas associated with disinfection by-products, arsenic and microbial contaminants. Since 1996, the external research community has received over $19 million to support drinking water research activities in grants awarded through EPA's Science to Achieve Results (STAR) program.

EPA places a high priority on sharing information with stakeholders regarding the status and plans for research on drinking water contaminants. The drinking water community will continue to have many opportunities to provide input into drinking water research planning and funding through stakeholder meetings and a new National Drinking Water Advisory Committee (NDWAC) research working

group that is being established. Below are examples of ongoing efforts in specific research areas:

Microbial Pathogens/Disinfection By-products (M/DBP) Research—EPA's research activities on microbial pathogens and disinfection by-products (DBPs) in drinking water are consistent with the highest priorities identified in the Research Plan for Microbial Pathogens and Disinfection By-Products in Drinking Water. This research has supported informed risk management decisions for the Stage 1 and Stage 2 DBP rules and the new microbial rules that apply to surface water and ground water.

Arsenic Research—As required by SDWA, a comprehensive research plan for arsenic (the Research Plan for Arsenic in Drinking Water) has been developed. The Plan focuses on reducing the uncertainty in assessing health risks associated with exposure to low levels of arsenic. Other areas of research included in the plan are the evaluation of cost-effective treatment technologies for small water systems and improved analytical methods.

Contaminant Candidate List (CCL)—The draft CCL Research Plan, developed with considerable stakeholder input, was peer reviewed by the EPA Science Advisory Board on August 8–9, 2000. An internal CCL research implementation workgroup will ensure that the actual timeframes and sequencing of research are appropriately established and periodically reviewed.

Comprehensive Drinking Water Research Strategy—Finally, a comprehensive evaluation of research needed to support the full range of drinking water decisions facing the Agency over the next 5 years is currently being undertaken. The Comprehensive Drinking Water Research Strategy will describe near- and long-term research needs for M/DBPs, arsenic, CCL contaminants, the additional data needs to aid in the required review of existing standards, and other emerging issues such as preserving water quality in distribution systems. The Strategy, which will be completed in FY2001, will be used to guide discussions within the EPA and with stakeholders concerning research needs and resource requirements for the entire drinking water research program.

Question 2. Has the EPA developed a long-term plan for research?

Response. As mentioned in the response to Question #1, EPA has developed a draft Contaminant Candidate List (CCL) Research Plan that was reviewed by the EPA's Science Advisory Board in August, 2000. This plan describes a process for determining the future research agenda for unregulated drinking water contaminants, and establishes priorities for research on specific waterborne pathogens and chemicals on the first CCL. EPA is also developing a Comprehensive Drinking Water Research Strategy that frames the important scientific questions and identifies research needs and priorities associated with SDWA rulemaking activities over the next 5 to 10 years. The strategy describes critical research issues for chemical and microbiological contaminants in the areas of health effects, exposure, risk assessment and risk management (i.e., prevention or control of risks). Specific topic areas include, for example, disinfection by-products, arsenic, and CCL contaminants, as well as cross-cutting issues such as sensitive subpopulations and water reuse. EPA will work closely with the water community to ensure stakeholder input during the development of the strategy, and to promote coordination of research with outside organizations.

Question 3. How would you characterize the scientific soundness of the Taiwan study on arsenic? Do you believe this represents a firm foundation for the proposed EPA standard with regard to dose-response modeling? How heavily did the EPA rely on the Taiwan study in developing its proposed standard?

Response. An important consideration in assessing the health effects of arsenic is that humans are much more sensitive to arsenic than are animals. We do not currently have a reliable animal model to study the health effects of arsenic. Therefore, we rely, to a considerable extent, on human studies from locations where sizable populations have been exposed to relatively high levels of arsenic (e.g., hundreds of parts per billion) and where adverse health effects attributable to arsenic are clearly demonstrable. In establishing a regulatory level in the U.S., we then seek to extrapolate to a "safe" level one with a significantly smaller risk of adverse health effects.

The Taiwan study (Tseng and Chen) was based on populations of 40,000 individuals who were exposed to high levels of arsenic over many years. There are several sources of uncertainty in the Taiwan study. These include the overall design of the studies as well as the fact that arsenic from food intake was not specifically examined. In addition, the methodology for analyzing arsenic in water was not as precise as some of the methodologies available today. There was also uncertainty associated with tying the concentrations of arsenic in wells to individuals in the villages con-

suming water from those wells. Finally, there may be differences between the study population and the general U.S. population that could affect susceptibility to arsenic in drinking water (e.g. selenium or other nutritional deficiencies).

EPA asked the National Academy of Sciences (NAS) to assess all appropriate studies and information in order to provide us with their advice on the health effects of arsenic. The NAS considered the Taiwan study as well as other available studies, particularly those in Chile and Argentina. The NAS provided examples of quantitative estimates of the dose-response in humans associated with arsenic in drinking water to the Agency, and stated that the current MCL is not sufficiently protective and needs to be revised to be made more stringent as soon as possible. The Executive Summary of the NRC report noted that the Taiwan studies provide "the best available empirical human data for assessing the risks of arsenic-induced cancer." The Agency relied heavily on this recommendation in developing a proposed MCL. However, it should be recognized that we proposed setting a level higher than the feasible level after consideration of benefits and costs. We also clearly pointed out the uncertainties associated with the underlying studies and request comment on higher, alternative MCL options.

Question 4. What plans has your office made to prepare for the upcoming review of existing standards required every 6 years?

Response. EPA has undertaken a comprehensive initiative to prepare for the once every 6 year review of existing standards. We have been examining occurrence and health effects information on these existing contaminants to determine whether or not this information warranted a revision of the maximum contaminant levels. In addition, we have been examining the various implementation histories (e.g., monitoring provisions) to determine whether or not the rules warranted revisions from this standpoint. In particular, we have asked for the advice of the National Drinking Water Advisory Council to guide how we conduct the review and expect the Council's recommendations by this Fall. In addition, we have held one nationally advertised stakeholder meeting and plan to hold others.

Question 5. What are the five new contaminants that the EPA intends to review in 2001 in accordance with the requirement of SDWA? What resources has the EPA devoted to the purpose?

Response. EPA published a Contaminant Candidate List (CCL) in March 1998 that included 60 contaminants which may be candidates for future regulation. Of these 60, we believe 48 contaminants require additional research related to health effects, occurrence, treatment technologies, analytical methods, or health effects in order to make a determination of whether or not they should be regulated by August 6, 2001 (as required by the SDWA). For the remaining 12, we believe we currently have sufficient information to make this determination. Outcomes of this determination could be to regulate no contaminants, all 12 contaminants, or some lesser number of contaminants. However, we need to have considered at least five contaminants as a part of this process. The 12 contaminants under consideration are Acanthamoeba, sulfate, sodium, manganese, boron, 1,3-dichloropropene, naphthalene, metolachor, metribuzin, aldrin, dieldrin, and hexachlorobutadiene. It is also possible that decisions could be made on additional contaminants, such as perchlorate and MTBE, if sufficient and timely information becomes available. Moreover, in response to our request, the National Drinking Water Advisory Council recommended in June 2000 a protocol for making regulatory determinations. In addition, we held one nationally announced stakeholder meeting and expect to hold others as we work toward decisions by August 2001.

To date, the total resources devoted to this determination process are approximately $1.2 million and include about four (4) EPA full time equivalents (staff), who have examined voluminous available data and information, and $800,000 to support the work of contractors in assisting EPA staff in this evaluation. We asked for advice from the National Drinking Water Advisory Council to help us establish a protocol for making regulatory determinations. We received the Council's recommendations this past June.

Question 6. Given the heightened interest in fluoride in drinking water in several communities around the country, has the EPA moved the review of this potential contaminant forward in the review process?

Response. The 1996 amendments to the Safe Drinking Water Act request that EPA review the maximum contaminant level (MCL) values for regulated chemicals every 6 years and revise them as appropriate. EPA has initiated this process for the chemicals (including fluoride) regulated before 1996. The Agency is presently working with the National Drinking Water Advisory Committee to develop the protocol for the review process. The review will consider new health effects data along with improvements in analytical methods and treatment technologies. An Advanced

Notice of Proposed Rule Making (ANPRM) is planned for the Summer of 2001. The ANPRM will seek public comment on EPA's preliminary decision whether to revise, or not revise, the standard for each of these chemicals. EPA plans to publish in the Federal Register its final revise/not revise decisions in the Summer of 2002. If the Agency decides to revise the fluoride standard, the rulemaking schedule for that revision will also be published in the 2002 notice.

Question 7. Given the interest in MTBE among the states, what research is the EPA undertaking to move the evaluation of this potential contaminant forward in the regulatory determination process?

Response. EPA is conducting a number of research activities to address key uncertainties in the assessment and control of risks associated with exposure to MTBE. Many of the projects being carried out by researchers at EPA, as well as by scientists at other government organizations, industry, and academic institutions, can be found in Appendix 2 of the EPA's "Oxygenates in Water: Critical Information and Research Needs" (1998). A description of EPA research on MTBE can also be found at the following website address: http://www.epa.gov/mtbe/research.htm

A brief description of EPA research on MTBE is provided below:

1. Health effects of MTBE. EPA scientists are conducting an experimental evaluation of the pharmacokinetics (i.e., uptake, metabolism and elimination) of MTBE by inhalation, oral, and dermal routes of exposure. One of the primary goals of this study is to provide data for the development of route-to-route extrapolation models, which will enable risk assessors to make better use of all of the available health effects data on MTBE.

2. MTBE toxicological reviews. Agency scientists are compiling and reviewing toxicological information as part of the process of developing an MTBE oral reference dose (RfD) and cancer risk estimate for use in MTBE risk assessments.

3. Monitored natural attenuation of MTBE under varying geological conditions. This project addresses the question of the extent and rate of the natural biodegradation of MTBE under several different geochemical conditions. The results will be of use in characterizing the potential for exposure to MTBE, and will assist in developing guidance on the extent to which monitored natural attenuation can be incorporated into the remedial actions taken at leaking underground storage tanks where MTBE is present.

4. Cost-effectiveness of MTBE treatment methods. Research is being conducted to evaluate the cost-effectiveness of different treatment options for ground water or drinking water that is contaminated with MTBE. One project involves an analysis of the use of granular activated carbon (GAC) that has been treated with iron to adsorb MTBE from contaminated ground water, after which hydrogen peroxide is added to regenerate the GAC and oxidize the adsorbed MTBE. Another project is exploring the conditions necessary to air strip MTBE from drinking water supplies and the advanced oxidation technologies necessary to destroy released MTBE. Different techniques for biodegrading MTBE using membrane reactors are being evaluated, and a field study of various technologies for removing MTBE from drinking water is being conducted in California.

Question 8. The National Research Council recommended that the EPA establish a deputy administrator position for science and technology to coordinate and oversee research. What is the Agency's view of this recommendation? How has the EPA responded to this recommendation?

Response. In a letter sent to several Members of Congress, W. Michael McCabe, Acting Deputy Administrator, stated:

The National Research Council's report contains a variety of recommendations for strengthening scientific practices within EPA and EPA's Office of Research and Development (ORD). While the Agency is continuing to examine the report's individual recommendations, in general we believe the Agency's mission to protect human health and the natural environment would be well-served if the report's recommendations were adopted. Perhaps most significantly, we agree with the recommendation that a new position be created for a deputy administrator for science and technology and that there be a statutory term appointment for the Assistant Administrator (AA) for ORD. A top science official with the authority to coordinate and oversee scientific activities throughout the Agency would help coordinate among EPA's diverse programs and help strengthen EPA's overall scientific performance. We also agree that a longer fixed term for the AA/ORD would help strengthen the scientific and managerial leadership of that organization and enhance the continuity of that leadership.

Question 9. How much is the EPA relying on outside research to develop pending rules?

Response. A considerable amount of outside research was considered, along with the contributions of EPA scientists and collaborators, in the development of the arsenic rule and the Microbial/Disinfection By-Products (M/DBP) Stage 2 rules. The radon rule was based primarily on research conducted by outside organizations. The health effects portions of the preambles of the radon (11/2/1999) and arsenic (6/22/00) proposed rules provide more detailed information about the outside research utilized. The preamble to the Spring 2001 M/DBP Stage 2 rule will provide similar information.

STATEMENT OF GREGG L. GRUNENFELDER, SAFE DRINKING WATER ACT IMPLEMENTATION THE STATE PERSPECTIVE, ON BEHALF OF THE ASSOCIATION OF STATE DRINKING WATER ADMINISTRATORS

The Association of State Drinking Water Administrators (ASDWA) is pleased to provide written testimony on implementation of the Safe Drinking Water Act (SDWA) of 1996 to the Senate Committee on Environment and Public Works Subcommittee on Fisheries, Wildlife, and Drinking Water. ASDWA represents the state drinking water administrators in the 50 states and six territories who have responsibility for implementing the many provisions of the SDWA and ensuring the provision of safe drinking water. State drinking water programs are committed to providing safe drinking water and improved public health protection to the citizens of this nation. ASDWA's testimony will focus on the many successes that the states have achieved over the last 4 years as well as many of the disturbing trends that are emerging, and the challenges that remain.

States have been protecting drinking water for more than 25 years, in some cases going back decades to the early U.S. Public Health Service standards. Since 1974, states have adopted and been implementing standards for 20 inorganic chemicals including lead and nitrate; 56 organic chemicals including pesticides, herbicides, and volatile chemicals; total trihalomethanes; total and fecal coliform; as well as implementing treatment requirements for surface water systems for turbidity, Giardia, and viruses. In addition, states have developed technical assistance programs, conducted sanitary surveys, and addressed operator certification, training, enforcement, emergency response, and review of water utilities plans and specifications.

The 1996 reauthorization of the Safe Drinking Water Act contained numerous new requirements to continue to ensure safe drinking water in this country. These new requirements include: consumer confidence reports; revisions to the lead/copper rule; Stage 1 D/DBP rule; interim enhanced surface water treatment rule; source water assessments and delineations for all public water systems; unregulated contaminant monitoring requirements; a revised public notification rule; a long-term enhanced surface water treatment rule; a filter backwash rule; a radon rule; a rule to protect ground water; an arsenic rule; a radionuclides rule; Stage 2 disinfection by-products rule; long-term 2 enhanced surface water treatment rule; water system capacity development programs; and operator certification program revisions. In addition, the U.S. Environmental Protection Agency (EPA) is required to obtain data to make determinations on whether to regulate an additional five more contaminants every 6 years.

The states were willing players and partners in the discussions leading up to reauthorization in 1996 with the specific understanding that a significant new mandate such as this law, which encompasses sweeping new reforms and activities outside of the traditional drinking water program, must be accompanied by significant new resources and staff. While critical, resources alone are simply not enough. In addition, states need a reasonable regulatory schedule and the flexibility to allow states to shift staff and resources to new programs in a calculated and manageable fashion. Unfortunately, almost 4 years into implementation, the states are seeing disturbing trends emerge from EPA that are preventing the states from achieving full implementation of the law. In fact, these trends are resulting in a dilution of public health protection efforts and the forced prioritization of state program activities. These trends include:

- Inadequate Funding and Unwillingness to Address Cumulative Costs and Program Integration
- Early Implementation
- Changing State Roles and Expectations
- Increasing Record Keeping and Reporting Burden

Each of these topics is discussed in more detail below.

Inadequate Funding and Unwillingness to Address Cumulative Costs and Program Integration

On average, states have historically provided 65 percent of the total funding for the drinking water program while EPA has provided only 35 percent, even though the SDWA authorizes EPA to fund up to 75 percent of the full costs of the program. Currently, about $271 million in state and Federal dollars is available to the state drinking water program. A Resource Needs Model, recently developed by the states and EPA, projects that state drinking water programs face a $100 million resource shortfall and a shortfall of almost 2,000 FTEs for FY–01. These shortfalls almost double through 2005 based on anticipated state workloads for the plethora of new regulations and programs being promulgated (see page 7).

To further compound the problem, EPA has not requested any increase in state PWSS program grants (current funding level is $90 million), that provides the reliable, sustainable base for state operations, since FY–96. In fact, the Agency has not even requested the full amount of $100 million as authorized in the SDWA. Although the Agency often looks to the drinking water SRF as a new source of funding for states, they do not fully recognize that states cannot hire permanent staff using a funding source that changes annually and the authority for which expires in 2003; that requires a 100 percent match of new state dollars; and that puts states in direct competition for the same pool of funding with water systems that have overwhelming infrastructure needs to improve public health protection.

The practical outcome of failing to provide any new PWSS funds is that state funding bases have been eroded over the years due to inflation and indirect and direct cost increases. In addition, the growing economy has made hiring and retaining staff more difficult as state salary levels become less competitive in the marketplace. The state drinking water programs have never been fully and adequately funded and are now challenged to meet enormous new mandates without the significant new money and staff needed to ensure full and effective implementation of the new programs as well as maintenance of the existing core programs.

The situation is further exacerbated by EPA's unwillingness or inability to fully address the cumulative costs to states for each of the very complex and comprehensive new programs and regulations being developed. There appears to be no acknowledgement that state program funding is finite and, in fact, already inadequate, nor a willingness to simplify and streamline regulations and provide adequate flexibility to reduce state implementation burdens. This attitude forces states to prioritize their activities based on available staff and resources and ensures that full implementation will likely not be realized. The states were committed in 1996 to take on the new mandates of the SDWA with the understanding that resources, staff, and needed tools would be available to ensure full and effective implementation of the new program as well as maintenance of the existing program. States are still committed to the improved public health protection opportunities envisioned in the law but are growing increasingly frustrated and angry that barriers are being erected to preclude their achievement of these goals.

Recommendations: 1) EPA should work with the states to confirm the current staff and resources needed to fully implement the program; 2) EPA should work with the states and Congress to close the documented resource gap and ensure that adequate funding will be available in future years based on the individual and cumulative costs of new regulations and programs; 3) EPA must also work with states to streamline and simplify new regulations and programs to reduce increased burden to the greatest extent possible; and 4) in the event that the gaps cannot be closed, EPA must be willing to engage the states in discussions on how to prioritize and manage the new mandates with existing or inadequate resources.

Early Implementation

The situation referenced above is further exacerbated by the Agency's continued insistence on early implementation of rule requirements prior to states adopting their own rules within the statutory framework of 2 years from the date of rule promulgation. This is especially troublesome with respect to the overwhelming number of rules EPA currently has out for review and the difficulty states and water systems will have complying with all of these new rules simultaneously. States need their rules in place in order to establish basic regulatory and enforcement authorities; to train operators and water system owners on Federal as well as state requirements; reprogram data management systems to accept new data reporting requirements, track compliance, and report to EPA; and ensure adequate laboratory capacity. Forty-nine of the 50 states have primacy and have the mechanisms in place to work with utilities within their state to achieve and maintain compliance. Inserting EPA Regions into the process, who are not onsite and do not have the resources, experience, and mechanisms in place to do much more than send letters and issue

orders, greatly complicates the process and leaves the program in great disarray at the point when states must assume responsibility. This is a disservice to the states, the utilities, and the public across this country and brings into question the concept of primacy and state authority.

Recommendations: 1) The Agency's use of Memoranda of Understanding (MOU) prior to state rule adoption is not acceptable and the Agency must immediately cease all activities directed at forcing states to implement requirements before state rules are adopted; 2) EPA should forego all attempts to require EPA Regions to assume interim implementation activities.

Changing State Roles and Expectations

Of significant concern to ASDWA and the states is the expanding expectation of scale and scope being promoted by EPA that dramatically changes the state role from regulatory oversight to implementer of SDWA regulations. States have historically assured safe drinking water by conducting basic oversight and surveillance of water utilities and measuring utility compliance through performance measures such as compliance with public health standards of finished water. While some states have the capacity to be more involved in operations issues, for the most part, the daily operations and maintenance of utilities have primarily been left to the utility—using certified operators, licensed consulting engineers, and technical assistance from the states and other providers when needed. This has historically been the case because of resource and technical capacity limitations at the state level and liability issues associated with making process control decisions for the utilities that are regulated by the states.

This direction represents a significant change from the majority of current state practices and must involve a meaningful dialog with state drinking water administrators, environmental commissioners, public health agency directors, Governors, Congress, and legislative bodies. The majority of state drinking water programs currently do not have the resources or sufficient staff with the technical expertise to work with individual utilities on a one-to-one basis to help make decisions on operating practices. If the Agency wants to make this change, then the states, including appropriate legislative bodies, must have buy-in to this process and there must be assurance that adequate numbers of trained state staff and resources will be made available to meet these new expectations.

At a time when most citizens want government out of daily decisionmaking, EPA is establishing a structure to position government regulators to assume operational responsibility of our drinking water infrastructure. The Agency is not being honest with itself, Congress, and the public if it believes that state drinking water programs are currently in any position to fully implement these new provisions, even with a minimal oversight role, much less be able to assume a significant new role in water plant treatment, operations, and management decisionmaking.

Recommendations: 1) Congress needs to consider the fundamental role for government regulators to play; and 2) EPA needs to recognize that they are promoting a significant change in scale and scope of the program with expectations that states need to increase their day-to-day management role of water utilities. This shift needs to be more fully explored by the states and EPA, and additional funding made available to support this expansion of state responsibility and staff technical capacity if this change is accepted.

Increasing Record Keeping and Reporting Burden

Although ASDWA recognizes EPA's need to ensure, on the Federal level, that a rule is being implemented properly, EPA must recognize the increasing burden that is being placed on state data management programs with consideration for the number of upcoming rules. States, which should be EPA's partners in ensuring safe drinking water, are willing to submit necessary data elements to EPA to meet this need, but do not have the staff or resources to report extraneous data elements that are not necessary, and based on past experience, are typically not even used by the Agency. Therefore, prior to proposing a final rule, EPA must enter into a dialog with state drinking water program staff to evaluate what data must be collected by the water systems, what data must be reported to states, and the minimum data elements that must be reported to the Agency, and determine the impact these requirements will have on states and water systems. The cumulative costs and impacts of these continual data requests must also be evaluated to ascertain if collectively they are providing states and EPA with meaningful data linking rules to real public health improvements.

Successes

In spite of the many roadblocks, hurdles, and challenges that state drinking water programs have faced over the last 4 years, and indeed 25 years, states have attained

a significant amount of success in implementing the provisions of the SDWA. For example, States have made significant progress in working with utilities using surface water supplies to install new treatment facilities to assure a much higher level of public health protection. Sources of lead from drinking water have been significantly reduced; the data and information about water system quality and compliance is now more readily available to the public through Consumer Confidence Reports, state compliance reports, the Envirofacts data base, and state web sites; the quality of water plant operators and water system capacity is being significantly improved; and an important source of funding for infrastructure improvements has been established in all states and loans are now being made to water systems to improve both their infrastructure and their ability to provide safe water to their consumers. States are also now beginning a very comprehensive and resource intensive effort to delineate and assess the quality of all source water being used for drinking water to ensure that local communities have the tools and information they need to protect their drinking water sources.

States intend to do all they can to meet their existing and new commitments, however, the road blocks and barriers being placed before and upon states are beginning to take their toll. More and more states are vocalizing their frustrations with the excessive, and in many cases unrealistic, expectations that are appearing in new regulations; the unrealistic expectations that EPA has for early implementation of the rules; and most critically, the lack of sufficient funding and staff to fully and effectively meet their own expectations as well as those of EPA, Congress, and the public.

The states are not interested in continuing to be the victims of GAO reports and IG investigations that find deficiencies in state programs when the staff, resources, and tools have not been made available for states to succeed. While quietly prioritizing and addressing implementation activities at the state and local level may meet the states' short-term needs, it is doubtful that ultimately it will meet the expectations of the public and Congress. States do not want to see the gains that have been made over the last 25 years eroded as focus and attention shifts from base, core public health activities to complex, new, and in many cases unimplementable regulations. The fundamental principles of the SDWA Amendments of 1996 are sound and, if correctly administered, have the potential to provide meaningful new public health protections. The states want the chance to succeed and they want the opportunity to help craft, as EPA's partners, the future direction of programs that will ensure the provision of safe drinking water in this country.

Upcoming Rulemaking Schedule

- 11/99 Proposed Radon Rule
- 4/00 Proposed Long Term/Enhanced Surface Water Treatment Rule
- 4/00 Proposed Filter Backwash Rule
- 4/00 Radionuclides NODA
- 4/00 Proposed Minor Changes to Stage 1 M/DBP Rule
- 5/00 Proposed Ground Water Rule
- 5/00 Proposed Secondary Standard for MTBE
- 5/00 Final Public Notification Rule
- 6/00 Proposed Arsenic Rule
- 8/00 Final Radon Rule
- 8/00 Final Filter Backwash Rule
- 11/00 Final LT
- 11/00 Final Ground Water Rule
- 11/00 Final Radionuclides Rule
- 12/00 Final Secondary Standard for MTBE
- 1/01 Final Arsenic Rule

July 29, 2000.

The HONORABLE MIKE CRAPO and BARBARA BOXER,
U.S. Senate,
Committee on Environment and Public Works,
Subcommittee on Fisheries, Wildlife, and Water,
Washington, DC 20510–6175

DEAR SENATORS CRAPO AND BOXER: Enclosed please find my response on behalf of the Association of State Drinking Water Administrators (ASDWA) with regard to questions provided by Senators Crapo and Smith as followup to the June 29 Senate hearing on implementation of the Safe Drinking Water Act (SDWA). I am pleased

to provide this response and look forward to working with you and the members of the subcommittee to address these issues.

I would like to re-iterate the States' commitment to ensuring public health protection and reaching the challenging goals set under the new SDWA. To accomplish this large undertaking, States need to know that there will be a reasonable, rationale implementation schedule that will allow them to be effective players in the process; that the necessary tools such as staff, resources, data systems, laboratory capacity, etc. will be available in a timely manner; and that regulations will be developed in a manner that is implementable for States as well as water systems.

On behalf of ASDWA, we appreciate the opportunity to share some of the state concerns with you and look forward to working with you in the future.

Sincerely,

GREGG L. GRUNENFELDER,
Director, Washington Drinking Water Divisionand ASDWA President-Elect.

RESPONSES OF GREGG GRUNENFELDER TO ADDITIONAL QUESTIONS FROM SENATOR CRAPO

Question 1. Under the radon rule, much is predicated on States adopting a multi-media mitigation program to provide water systems with an alternative MCL. What do you expect state costs to administer such a system to be? How many States do you anticipate will adopt a multi-media program?

Response. The current approach to the proposed radon rule allows water systems to comply with an alternative standard of 4000 pCi/L but only after the state has developed a multi-media mitigation (MMM) approach to address radon in air (or the water system has developed its own program). EPA's own documentation shows that the primary health concern associated with radon is inhalation of radon from soil gases (98 percent) and a minor, secondary impact is through drinking water (2 percent). The primary concern that States have with the radon rule and the multi-media approach is that it holds the state drinking water programs responsible for ensuring the implementation of an air program. In some States, the air program does not even reside in the Agency responsible for implementing the SDWA. Even those States that have both programs in one Agency most commonly have the program in a different part of the Agency—not the drinking water program.

Management within EPA's OGWDW has indicated on several occasions that they do not intend to request additional funding through the water program to implement the MMM approach. They contend that any increased funding should come through requests from the air program within EPA. To date, we have no indication that the air program is seeking any additional funding to ensure implementation. This puts the drinking water programs in a position of having to redirect limited, and in fact, inadequate resources from high priority drinking water needs to fund the development and implementation of an air program.

States are in agreement that radon in air is a health issue but feel strongly that the implementation of that program should reside with the air program. State drinking water programs believe that from a public health and cost benefit perspective is that the drinking water standard should be set at 4000 pCi/L and that the drinking water programs assume responsibility for ensuring that all water systems meet this standard. In addition, EPA's air program should work with States to enhance indoor air programs to address the real health risks associated with radon. This approach will have a meaningful impact in bringing down the levels in those water systems that have high radon levels, and provide greater health protection by ensuring that strengthened air radon programs reach those consumers exposed to high levels in air.

The current approach sends a mixed message to the public that two standards for radon in drinking water—4000 pCi/L and 300 pCi/L are both protective of public health. The further irony is that there is no clear linkage between water and air actions. A water system could comply with 4000 pCi/L or 300 pCi/L but none of their customers benefit from a reduction of radon in air. The best case scenario is that all water systems comply with the 4000pCi/L standard and all consumers benefit from a strengthened air program.

At this point in time, 10 state drinking water programs have indicated that they currently do not plan to implement a MMM program. The primary reason is that they do not currently have a radon in drinking water problem. In their view, it is counter to the needs of the drinking water program to redirect inadequate resources to an air issue when there is not a problem in drinking water. Ten States have not yet made a decision and will likely not do so until they see the final rule and understand the cost and transactional issues for the state. Ten States have indicated a

qualified yes to a MMM program but again the final decision will rest on the complexity and implementability of the final rule and the support of their upper management and Governors to commit the resources needed to implement the program. Twelve States have indicated that they will likely implement an MMM program but the majority are doing so primarily because they believe it is irresponsible to hold their water systems "hostage" to a 300 pCi/L standard in drinking water. The remaining eight States have not indicated a response.

At this time, it is not possible to fully evaluate state costs for implementing an MMM approach. Until the final rule is promulgated and States understand how the program will be implemented which includes the monitoring, reporting and documentation involving MMM aspects of the rule and evaluation can not be made. It is, however, a major concern that neither the drinking water or air program at EPA has indicated any interest in providing additional resources for this effort.

Question 2. How should EPA address the cumulative cost of drinking water regulations?

Response. EPA needs to more clearly and fully evaluate the cumulative costs of current as well as future regulations on both water systems and state drinking water programs. The new SDWA law did not negate or lessen the responsibility that States have to ensure that the pre-1996 regulations are fully implemented. This requires continued monitoring, reporting, and enforcement activities on the part of the States and water industry. As EPA develops new regulations, they do attempt to quantify water system and state costs, but at least on the part of the States do not evaluate whether current state resources are adequate or where new resources will be obtained to implement the new requirements.

For water systems, EPA does attempt to put together cost impacts, broken out by system size and classification, but does not take the next step in evaluating the cumulative impacts of all the rules and the impacts that this cost has on overall water system affordability. EPA should be directed to aggregate the costs, per household, for various system sizes and evaluate if the costs still meet the affordability criteria they have established such as the percent of median household income. The clear need is for EPA to take a comprehensive, integrated look at the cumulative costs of all rules, not just whether one rule or another by itself meets their affordability criteria. This will be especially critical for many of the upcoming regulations, which will have a disproportionate impact on small ground water systems.

Question 3. What is ASDWA's view of the EPA's current approach to assessing the feasibility of drinking water standards?

Response. The constant dilemma is how to ensure that regulations and standards that are designed to be feasible for large systems under the law are also in fact feasible for small systems. The law provides a number of approaches that the Agency can take such as evaluating the availability of cost effective technology for various systems sizes, including a large number of small system categories. This is an important step in every rulemaking and one that is designed to evaluate whether affordable technologies are available that would allow small systems to obtain compliance. EPA appears to be taking this responsibility seriously and has provided this information under new rulemakings. EPA has also attempted to stagger small system compliance deadlines and simplify monitoring requirements to make rules more implementable for small water systems while still ensuring compliance. These approaches should continue to be used in the future.

Occasionally, however, this analysis is not productive such as under the radon rule where the Agency's own analysis shows that a standard of 300 pCi/L is not affordable for small systems. This also only takes into account this one rule, not the cumulative cost of past and future rules. A number of stakeholders have stated that we should not be creating "second class citizens" meaning that the same level of protection should be afforded to everyone. The dilemma is how to avoid this situation recognizing that 96 percent of the water systems that are regulated are small and may not have the economies of scale to meet new regulations in a cost effective manner.

Question 4. What do you anticipate will be the principle conclusions of the next needs assessment from States? Do you anticipate there to be changing trends not evident in the current needs assessment?

Response. With regard to the infrastructure funding needs for water systems, members of the State Revolving Fund (SRF)work group have already been informed that the assessment identified at least three times as many eligible/documented projects as the 1995 assessment, although this will not necessarily translate into triple the national need. Several large cost filtration projects were included in the 1995 needs report but not in the 1999 report since they were already under construction. The identified costs for SDWA compliance will likely shift as compliance with old

rules is achieved and new rules are promulgated affecting more systems. The needs report will also likely underestimate the actual need because it did not allow for identification of costs for rules that have not yet been promulgated by EPA such as the radon and arsenic rules for which there are potentially large capital costs.

Certain capital costs are almost certainly understated because they are difficult to identify. These include consolidation of water systems and creation of new systems as two examples. Other capital costs have simply been excluded by EPA because they are not eligible for SRF funding, but which could be major capital needs. Examples include the cost of acquiring water rights or building surface reservoirs for unfinished water storage. The costs of complying with the Endangered Species Act may require a major capital investment, particularly for cities in the West.

Question 5. Your testimony criticizes the EPA for underfunding the state PWSS program grants. What level is necessary to meet state needs to hire staff and provide for state operations?

Response. Historically, States have provided 65 percent of the funding and EPA only 35 percent of the funding made available to implement the SDWA. This is in sharp contrast to the language in the statute that authorizes EPA to fund up to 75 percent of the full cost of implementing the law.

In 1999, ASDWA, in partnership with EPA, revised and updated a resource needs model that evaluated state program implementation needs at the national level for small, medium, and large systems through FY–05. This national model determined that state program resource needs will rise from $353 million in FY–99 to $459 million in FY–05. State staffing needs will rise from 5,025 full time equivalents (FTEs) in FY–99 to 5,838 FTEs in FY–05.

Based on ASDWA's interpretation of the data, acknowledging what States are currently taking from the SRF set-asides, we estimate a resource shortfall of $83 million in FY–99 rising to $207 million in FY–05 with an FTE shortfall of 1627 FTEs in FY–99 rising to 2,670 FTEs in FY–05.

States recognize that there are two primary sources of Federal funding now available to the States under the new SDWA. These include the PWSS grants and set-asides from the SRF. The PWSS program grants, however, have historically provided the basic foundation from which States could hire full-time, permanent staff. The level of funding for PWSS grants to States (not tribes) has not increased since FY–96. It is also funded at only $90 million, not the full $100 million as authorized in the statute. The SRF provides new set-aside authority that theoretically can provide up to 10 percent of the funds for program implementation. Unfortunately, the theoretical availability of the funds through the SRF has not translated into actual state use of the full amount.

The reasons that more of the set-aside is not being used are many. They include: the perceived transient nature of the SRF—both in the availability of consistent level of funding from year-to-year and the fact that the funding is set to expire in FY–03; the lack of state overmatch funds; the set-asides that EPA is taking off the top at the National level which may vary from year-to-year and which ultimately reduces the available funding to the States; and the various threats of funding withholding for failure to meet EPA expectations on capacity development and operator certification programs. All of these "unknowns" translate into a valid question on the part of the States as to the reliability of this funding in the short and long term, particularly since the use of these funds are set on an annual basis based on Intended Use Plans that are subject to public involvement and stakeholder comment. In addition, in many States the SRF funds are viewed primarily as a resource for capital projects to address significant infrastructure improvement needs. In these States there is a policy direction to focus use of these funds on infrastructure improvement projects, and not enhancement of state program implementation efforts. In this regard, state drinking water programs find themselves competing for money to further "grow" state government with the dollars designated by Congress through the statute to be used for much needed drinking water infrastructure improvements to protect public health. This is a difficult battle to fight and in some States is politically infeasible.

The States would like to work with Congress and EPA to further evaluate the barriers associated with the use of the SRF set-asides and determine how adequate funding can be made available to the States in a manner that offers a permanent source of funding and with a funding vehicle that is readily available and useable to the States.

Question 6. Where will States turn to meet their funding shortfalls in staffing and operational needs?

Response. State drinking water programs have historically been underfunded even though many have increased their use of state general fund revenue and insti-

tuted various types of fee-based programs over the years. In fact, many States are providing significantly higher levels of funding than the Federal Government to implement this Federal mandate. And although a number of States are in very good economic condition due to the growing economy, Governors are remaining fiscally conservative and reluctant to increase the size of ongoing programs. Therefore, as in the past, and likely for the future, States to prioritize their activities at the state and local level based on the most important public health issues in each state. Frankly, this means that not all aspects of all the rules are likely to be fully implemented, at least not within the timeframe expected by EPA.

The States believe there needs to be a dual approach to closing the resource gap. First, increased levels of Federal funding must be provided to the States in a manner that allows them to fully and efficiently use the new funding. States must also evaluate their own contributions and determine whether additional resources can also be made available at the state level. Second, EPA and Congress need to more fully understand the resource and staffing issues at the state level that provide barriers to full and effective implementation and steps must be taken to streamline and simplify current as well as future regulations. Transactional costs need to be minimized to the maximum extent, States need to have the full 2 years authorized under the statute to adopt their regulations, and States, as well as water systems need a reasonable, rationale approach to implementation with a schedule and timeframe that allows States to develop the internal infrastructure they need to track, report, and ensure compliance.

Until such time as the States are fully funded and staffed to meet the new requirements of the SDWA, many will continue to try to patch together their program using contractors and leveraging the services of technical assistance providers and others to assist in implementation. A number will set implementation priorities and the timeframe for implementation may be extended. Finally, some States may have to resort to requesting the additional 2-year extension for rule adoption to try and better schedule their workload.

Question 7. Early implementation by the EPA of rule requirements under the SDWA presents state regulatory agencies with compounded resource demands and other complications. How can the EPA better work with the States to address their concerns?

Response. States are very concerned with, and fundamentally disagree with, EPA's interpretation of the statute that all water systems must be in compliance with new regulations within 3 years of rule promulgation. This reading of the law does not allow the States the statutorily mandated 2 years to adopt their own regulations and obtain legislative authority if needed. States are concerned that EPA's approach is not honoring the state primacy process and appears to be making the state role superfluous to the drinking water implementation process. This has the potential to provide a significant barrier to state flexibility if States are not given the opportunity to craft flexible regulations that meet state-specific needs because EPA has already started implementing regulations at the national level on the date of rule promulgation.

States need time to address their own administrative process and involve their citizens in the rule development process. The 2-year period for adoption and the third year before the rule becomes effective is critical for States to train their staff and utility operators, certify laboratories and ensure laboratory capacity, revise data management systems, notify systems of their monitoring and compliance responsibilities based on state-adopted regulations, and ensuring enforcement authority. It is crucial that States be able to develop the infrastructure they need to manage implementation.

EPA needs to fully understand the barriers and constraints that the States are under in the rule development process; better appreciate the infrastructure that must be developed at the state level to ensure compliance with regulations; honor the 2-year state adoption process; and allow States the opportunity to use the flexibility Congress gave them to craft state regulations. EPA also has to understand the potential impacts on state fee programs when EPA assumes responsibility for early implementation.

EPA also needs to acknowledge States as full partners in developing new programs and regulations under the SDWA, not just another stakeholder. EPA could be directed to go to a state association such as ASDWA for review of their proposed rules and initiatives for administrative/implementation issues much like they now go to the Science Advisory Board to address scientific aspects of their proposed rules. EPA should also be charged with assessing state implementation costs during the 6-year review process and use that information to modify its current methodologies for estimating these costs. EPA also needs to improve its process for developing implementation plans/guidance for the States, allowing States full involvement in

the process and ensuring that all new activities and data management flow charts are available at the time of rule promulgation.

At the hearing on June 29, Senator Crapo asked if there were any legislative fixes that should be addressed to improve the law. ASDWA would ask the Senator and this subcommittee to review the law in the area of effective and compliance dates and evaluate whether a modification is needed to allow States as well as water systems the opportunity to adopt and implement regulations and achieve compliance.

Question 8. What recommendations do state administrators have for the EPA in providing technical assistance and developing a data collection and management system that reflects the increasing complexity of implementing new regulations?

Response. State data management programs are currently struggling to keep up with the volume of data they must manage. One of the biggest problems they face is rule complexity and a disconnect between what EPA wants to know and what it needs to know for rule implementation. EPA needs to consider data management and data needs as an integral part of rule/program development. They need to put together data implementation plans for each new rule/program, ensuring that the changes and flow charts are made available to the States at time of rule promulgation so that States can make the necessary changes to their data bases in a timely manner. Rule managers also need to be cognizant of how state data systems operate, the types of data and timeframe that data is currently gathered, and work to ensure that new data elements fit within that data construct. EPA should also be strongly encouraged to maintain and continue supporting the development of SDWIS/State—a data management system designed to assist States in managing their data needs and reporting to EPA.

States and EPA also need to work together to develop data reporting elements that track outcomes rather than process. In its rule proposals, the Agency should be required to articulate exactly what question(s) it is trying to answer by requesting a particular piece of data and how that data will be used by the Agency. The cumulative cost of reporting burdens across rules should also be evaluated.

In the area of technical assistance, the States urge EPA to continue to conduct training sessions on new rules at time of rule promulgation and also at time of rule implementation. To make these training sessions most effective, implementation manuals and guidance documents should be provided to States with several weeks lead time to allow them to review the materials and seek additional input and comments from others on their staff. A schedule of training opportunities also needs to be made available at least a year ahead of time to afford States the opportunity to plan their travel budgets. Detailed information about locations and agendas for specific training should be made available at least 2 months in advance to allow States to process their out-of-state travel orders.

RESPONSES BY GREGG GRUNENFELDER TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1. In your statement, you address significant funding gaps in the public water system supervision grants and other grant programs. What are your recommendations for addressing these shortfalls?

Response. The States and EPA need to open a dialog on state funding issues and evaluate how the documented resource gap can be closed. States and EPA need to develop an understanding of the barriers that currently exist to States fully using the SRF set-aside funds and understand the technical and staff barriers that may prevent States from significantly increasing their funding and staffing levels. Once understood, we should work toward a resolution to make SRF funds more accessible; recognize the cumulative cost of the regulatory burden on States; and acknowledge this through the development of more easily implemented regulations. At a minimum, the EPA should request the full authorization for both the PWSS grant program and the SRF and Congress could consider allocating some of the existing budget surplus to increase PWSS grant funds.

EPA needs to better understand the cumulative cost impacts on the States and may need to work with States to develop implementation priorities based on the highest priority public health issues should full staffing and funding not be made available. EPA should also evaluate the DWSRF with an eye to potentially reducing or eliminating some of the numerous cross cutter issues that make providing funds to small systems more difficult.

Question 2. What additional flexibility is necessary for States to implement the arsenic, radon, and other proposed rules to be finalized over the next year?

Response. A very important flexibility is for EPA to allow States the 2 years authorized in the statute to develop their state regulations. A number of the new rules tend to be treatment technique rules that require States to take a larger role in decisionmaking and evaluating compliance and treatment options using a toolbox of options. This flexibility can not be realized if EPA starts implementing the Federal rule before States have evaluated their various options and adopted their rules.

Under the radon rule, States do not believe that EPA is allowing them the opportunity to use their full flexibility in deciding whether or not to develop a multimedia mitigation (MMM) program and whether it makes more sense to require the lower drinking water standard. A recent letter from EPA to the Nation's Governors urging them to adopt the multi-media approach had to undergo several major iterations before the Agency agreed to even mention that the rule allowed another implementation option.

Another concern of the States is the perceived tendency on the part of the Agency to micro-manage rule implementation. It seems like the Agency tries to manage every possible scenario which makes the rules very complex and cumbersome. The States would argue that the best approach would be to establish the outcome measures for each rule and let the States decide how the outcome should be achieved.

With the barrage of new rules hitting States and water systems simultaneously, the high degree of complexity of the rules, and the lack of consistency among rules, States will need to be able to prioritize their workload, make judgments on the occurrence of contaminants within their States and be able to issue state-wide or area wide waivers, and may need the flexibility to extend implementation schedules for lower priority activities.

STATEMENT OF GURNIE GUNTER, DIRECTOR, KANSAS CITY WATER SERVICES DEPARTMENT, KANSAS CITY, MISSOURI, ON BEHALF OF THE METROPOLITAN WATER AGENCIES

Introduction

Good morning, Chairman Crapo, Chairman Smith, and members of the subcommittee. I'm Gurnie Gunter, Director of the Kansas City, Missouri, Water Services Department. On behalf of the nation's largest municipal drinking water agencies, thank you for holding this hearing. We appreciate the priority status you have given oversight of the implementation of the Safe Drinking Water Act.

The Kansas City Water Services Department is responsible for water, wastewater, industrial waste and stormwater. We produce and deliver high-quality drinking water that surpasses Federal and state standards; we collect and treat discharged wastewater and by-products from residents as well as businesses; and we operate and maintain a stormwater system to collect, transport and dispose of precipitation that falls in the area. The Kansas City Water Services Department delivers drinking water to about 650,000 people every day.

In addition, I am a board member of the Association of Metropolitan Water Agencies (AMWA), and my testimony today is on the Association's behalf. AMWA represents the largest municipal drinking water agencies in the United States. Together, AMWA member agencies serve clean, safe drinking water to over 110 million people.

History

Since late 1996, when the Amendments to the Safe Drinking Water Act were enacted, the Environmental Protection Agency has developed a number of new rules and programs. These include a source water assessment program, a rule requiring annual water quality reports for consumers, an updated program for water systems to inform consumers of violations of drinking water regulations, and a loan program for drinking water systems.

One of the most important fundamental changes brought about by these Amendments is Congress' directive to the Agency to rely on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices."

To meet the requirements of the 1996 Amendments, EPA is at work on a number of new rules. These include rules governing filter backwash, ground water disinfection, radon, other radionuclides and, most recently, arsenic. Also, EPA, water suppliers and environmental organizations are engaged in negotiations over the second phase of a rule to control microbes and the chemical byproducts of disinfection. And finally, EPA with the help of the National Drinking Water Advisory Council is establishing a process to determine other contaminants to regulate from the Contaminant Candidate List.

Support for EPA and the States

The last time AMWA testified on implementation of the Safe Drinking Water Act was before any major, new regulations had been issued under the 1996 revisions. The Act set out a demanding regulatory schedule, and AMWA commends EPA's Office of Ground Water and Drinking Water for its hard work. Also in previous testimony, AMWA strongly supported adequate funding for EPA's drinking water program as key to attaining the promise of the new Act. Today, we reiterate that support and call your attention to several areas of funding need.

AMWA's major concern, given the requirements of the Act for the use of sound science, is adequate drinking water research funding. Research is critical to ensuring that drinking water regulations address contaminants that actually occur in drinking water and that occur at levels of public health concern. This is important so that the limited resources at all levels of government—Federal, state, and local—are directed at high-priority risks. It is also critical for the public, who must ultimately bear the increased costs of drinking water driven by new regulations, to receive true value for what they are being asked to spend. This year, EPA has requested nearly $49 million in drinking water research funding. AMWA believes that this is the minimum needed, and we urge you and your colleagues in the Senate to support this request.

AMWA also would like to express its support for our state regulators. The Safe Drinking Water Act authorizes Federal funding for up to 75 percent of state implementation costs. At present, state program funding hovers at just over 35 percent, while the list of regulations that states must implement becomes larger and more demanding each year. Recognizing this deficiency and seeking to ensure the Safe Drinking Water Act is implemented as per Congress' intent, AWMA recommends that state primacy programs be funded at more appropriate levels.

Lastly, we encourage Congress to support the authorized level of $1 billion per year for the Drinking Water State Revolving Fund. This program assists water systems throughout the country in building facilities to meet the new requirements of the Act.

Areas Where Implementation Can Be Improved

We have already noted the remarkable amount of effort EPA has put into implementing the 1996 Amendments, but we would also like to express a number of concerns and to offer recommended actions. The Agency is already aware of these recommendations, as they appeared in AMWA's official comments on various proposed rules.

Source Water Protection. First and foremost, AMWA looks to EPA to better coordinate its various programs to prevent pollution of the nation's drinking water sources. It is more effective and more equitable to prevent pollution in the first place rather than rely on drinking water suppliers to install ever more complex and costly treatment to remove that pollution from the public's water. It is more effective for two reasons. First, no treatment technology removes all contaminants 100 percent of the time. Second, prevention at the source for many contaminants reduces threats to recreational use of water sources as well as the aquatic environment. It is more equitable, since preventing pollution at its source ensures that those responsible for it bear the costs of removal, rather than transferring those costs to drinking water system customers.

The case of MTBE, the gasoline additive approved by EPA under the Clean Air Act, provides an example of why coordination is needed. At the time MTBE was approved for use, EPA's scientists warned that, because of its characteristics, pollution of drinking water supplies was likely. The additive was nevertheless approved, and now we have extensive MTBE contamination of drinking water supplies. Consideration of drinking water concerns in the initial decision would have led to better results.

Indeed, the Clean Water Act and Safe Drinking Water Act offer many opportunities for coordination to protect drinking water sources.

The Use of Sound Science. The revised Safe Drinking Water Act stresses the use of sound science in developing and making regulatory decisions. As previously noted, AMWA has strongly supported increased research funding for drinking water to meet this purpose. Unfortunately, recent events have given all of us reason for concern. As you may know, EPA recently finalized a maximum contaminant level goal (MCLG) for chloroform at zero, despite noting in the final rule that the best available, peer-reviewed science indicated a non-zero value was more appropriate. EPA has now vacated the chloroform standard after a court ruling that the Agency failed to use the best-available science.

More recently, EPA proposed a Filter Backwash Rule while acknowledging that they lack sufficient scientific information to know what risks might be involved, the

effectiveness of current treatment, or the benefits that the public might receive from implementation of the rule. EPA's own Science Advisory Board has pointed out major deficiencies in the proposal.

There are a number of other similar examples. AMWA believes that such things are bound to happen with EPA struggling to meet mandated deadlines for issuing regulations. It would be unreasonable to expect perfection given an ever-changing base of scientific knowledge. While AMWA appreciates that the demanding schedule laid out in the Safe Drinking Water Act may lead to some oversights, we urge you to stress to EPA the importance of meeting the sound science provisions of the Act. We also recommend that Congress be open to changing statutory deadlines when there is reasonable expectation that additional, near-term information will better provide for the public's interests. Focusing on the mandated timelines in the Act to the point of ignoring its other provisions will not ultimately lead to the sensible, cost effective regulations the public deserves. The Filter Backwash Rule is a case in point. AMWA recommends that Congress consider an extension of the August 2000 deadline so that basic knowledge of risks, costs and benefits can be developed.

AMWA also recommends that the subcommittee consider requesting an independent review of how well EPA is incorporating science into regulatory decisions. An independent review by the National Academy of Sciences or the General Accounting Office could both serve as a template for EPA and assist the Agency in targeting its resources. It also would help ensure that future regulations have a solid footing based on science.

Health Risk Reduction and Cost Analyses. One of the most significant provisions of the Safe Drinking Water Act is the requirement for preparation of a Health Risk Reduction and Cost Analysis (HRRCA) document to be published for public comment at the same time a rule is proposed. AMWA believes that this document is a key public right-to-know provision of the Act. With a straightforward analysis of risks and costs, the public will know the answer to a very basic question, "What am I getting for my money?"

So far, the cost and risk analyses, with the exception of that for radon, have tended to be buried within a very long and complex Regulatory Impact Analysis. Moreover, the analyses are not published for comment in the Federal Register along with the proposed rule. Rather, HRRCAs must be obtained either from the rule docket or accessed via the Internet, and it is not clear that public comments are desired or whether they will even be reviewed and considered by the Agency.

A key component of HRRCAs required by the Act is an analysis of the "quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each (maximum contaminant) level" (emphasis added). AMWA is concerned that several of the analyses to date have tended to rely, at least in part, on speculative ("what if") analyses.

Additionally, the analyses stray from normal cost-benefit practices. For example, EPA chooses to discount costs, but not benefits. Thus the Agency compares apples to oranges, which obfuscates whether the benefits of a rule justify the costs.

These are but a few of the problems that concern AMWA about how Health Risk Reduction and Cost Analyses are being conducted under the Safe Drinking Water Act. If these analyses are truly intended to inform decisionmakers, then they must be very clear in addressing actual rather than speculative risk reduction benefits. And, if these analyses are truly intended to inform the public about the benefits they may receive for what they will pay, then the HRRCAs must be clear, straightforward, and easy to read.

AMWA recommends that the subcommittee consider requesting an independent review of how well EPA's cost-benefit analyses conform to standard practices and to the requirements of the Act. An independent review by the National Academy of Sciences or the General Accounting Office could both serve as a template for EPA and assist the Agency in targeting its resources. It would also help ensure that future cost-benefit analyses present information that is most useful to decisionmakers and the general public.

Comments on Specific Proposed Regulations

Arsenic Rule. Just last week, EPA proposed regulating arsenic at 5 parts per billion (ppb), but will also be taking comment on 3, 10 and 20 ppb. EPA is required under SDWA to promulgate a final rule by January 2001. The 1996 Amendments also required that the National Academy of Sciences (NAS) conduct a review of EPA's arsenic risk assessment. The NAS report recommended that EPA revise the existing 50 ppb standard for arsenic downward as quickly as possible but did not recommend a specific level. The report also recommended that EPA conduct more studies of its arsenic toxicity analysis and risk characterization, conduct additional

human studies, and identify markers of arsenic-induced cancers. The arsenic standard is a very complex issue, and the proposal rule will draw many valuable comments from stakeholders. Unfortunately, once the comment period closes EPA must finalize the standard only a few months later. We ask the subcommittee to consider extending this deadline by 6 months to give EPA more time to evaluate comments.

In addition, the Science Advisory Board's Drinking Water Committee was charged with reviewing the proposed rule for EPA. In a preliminary draft report prepared earlier this month, the committee suggested that EPA consider setting the arsenic standard higher than the proposed level of 5 ppb. The committee noted that the available science might support a standard in the range of 10 to 20 ppb.

Filter Backwash Rule. The Act also requires EPA to issue a rule governing filter backwash recycle practices by August 2000. The rule is intended to address the concentration of contaminants in the drinking water treatment process resulting from cleaning of water filter beds. AMWA is concerned about the lack of scientific data that is available to support this rule. In the preamble of the rule, EPA acknowledges that there is a paucity of data available regarding the recycle practices of filter backwash.

As noted earlier, AMWA requested that EPA repropose the rule to address several issues including the lack of available data. AMWA suggests that Congress extend the deadline for this rule to provide EPA with an additional year to evaluate the issue.

Radon Rule. EPA is required to finalize the Radon Rule by August 2000. Under the 1996 Amendments, Congress established the need for a mitigation program to reduce radon levels in indoor air. It is generally accepted that indoor air radon mitigation provides greater risk reduction than other methods of removal. Therefore, EPA developed a dual compliance regulatory approach: water systems may comply with an "alternative" maximum contaminant level (MCL) of 4000 picoCuries per liter (pCi/L) where the state, or the water system itself, operates an indoor air radon mitigation program. And where no mitigation program exists, water systems must either initiate one or comply with a "primary" MCL of 300 pCi/L. This approach is intended to attract water systems to participate in indoor air radon mitigation programs and thus achieve a higher risk reduction.

AMWA endorses the concept of addressing radon through multimedia programs that reduce indoor air risk. AMWA agrees that that indoor air radon mitigation provides greater risk reduction than does the treatment of drinking water. AMWA would like to see the Radon Rule refocused on encouraging states to adopt the multimedia program option and reducing the burden on water systems to develop their own indoor air program or be forced to comply with the maximum contaminant level.

Liability Reform for Suits Against Water Suppliers

AMWA also urges the subcommittee to focus its attention on the emerging threat to water suppliers of suits alleging the delivery of unsafe water even where the water surpasses the requirements of EPA rules.

Over the past 2 years, nearly a dozen tort suits some of them class-actions—have been filed against California water suppliers. Other suits could appear in other states at any time. The California suits allege damage from regulated and unregulated contaminants, and they threaten to undermine the ability of water systems to supply affordable water to consumers. The cost of litigation and the financial repercussions of cash awards could push the price of water beyond the reach of millions of families and affect other city services. Judgments could include cash awards or massively expensive treatment facilities to supplement existing ones.

The suits also threaten to render the Safe Drinking Water Act, particularly its mandate for science-based health standards, inconsequential when courts are handed the responsibility of setting drinking water standards. Further, liability against water suppliers makes these agencies the stewards of rivers, streams, lakes and aquifers that supply raw water to the treatment facilities. Meanwhile, neither the Clean Water Act nor the Superfund program provide any assurance to water suppliers that drinking water sources will be priorities for prevention and cleanup.

Infrastructure Challenges

A recent report by the Water Infrastructure Network (WIN), which is comprised of water suppliers, city officials, environmental organizations, and state agencies, shows that drinking water agencies spend roughly $13 billion per year on infrastructure to protect public health. But according to the report, that amount is only about half of what may be needed. The WIN report indicates that approximately $11 billion more per year is needed through 2019. EPA's recent "gap" analysis and a report by the American Water Works Association confirm this overwhelming shortfall.

Mr. Chairman, and members of the subcommittee, AMWA member agencies are exploring every avenue available to fund this anticipated future need. The vast majority of large municipal water systems currently fund 100 percent of their infrastructure as well as 100 percent of all federally mandated treatment requirements. We have embraced public-private partnerships and private investment where it makes sense from a local perspective. We have adopted new efficiencies and streamlined our process. In short, we attempt to run our agencies not only as public services, but as businesses, too.

AMWA is currently working with local governments, other water supply associations, state groups as well as the environmental community to assess the need and to develop appropriate funding solutions. AMWA is committed to evaluating all possibilities for future financing, and as we proceed, will keep the subcommittee apprised of any financing options that impact the long-standing partnerships we have had with the Federal Government.

Methyl Tertiary Butyl Ether (MTBE)

Finally, the issue of MTBE deserves consideration. AMWA wishes to thank Chairman Crapo, full committee Chairman Smith, Chairman Inhofe of the clean air subcommittee, and Senators Boxer and Feinstein for their responses to MTBE contamination.

AMWA urges swift action on the part of the committee and Congress to pass legislation that significantly reduces or eliminates the use of MTBE to prevent further water contamination, to assist water systems where supplies are contaminated, and to support development of treatment technologies to remove existing contamination.

Water systems in at least 31 states have detected MTBE in their wells or surface sources. As you know, the primary sources of contamination are leaking underground gasoline storage tanks, although there is concern that air deposition is another source. Since MTBE is very soluble in water and does not cling to soil well, it has a tendency to migrate much more quickly in water than other components of gasoline. MTBE renders drinking water unfit for human consumption due to strong taste and odor levels, even at levels as low as 2 parts per billion. Most consumers perceive drinking water with an unpleasant taste or odor as being unhealthy, and in some cases the water may very well be unsafe to drink. The bottom line is that consumers will not tolerate MTBE in their water.

Conclusion

Let me conclude by calling your attention to the main points included in this testimony:

- AMWA expresses its support for EPA's Office of Ground Water and Drinking and the state drinking water primacy agencies that implement the Safe Drinking Water Act. Recognition of their hard work is well-deserved, and we encourage Congress to support their efforts.
- Research is critical to ensure that drinking water regulations address contaminants that actually occur in drinking water and that occur at levels of public health concern.
- AMWA looks to EPA to better coordinate their various programs to prevent pollution in sources of drinking water.
- AMWA recommends that the subcommittee consider requesting an independent review of how well EPA is incorporating science into regulatory decisions.
- If Health Risk Reduction and Cost Analysis (HRRCA) are truly intended to inform decisionmakers, then they must be very clear in addressing actual rather than speculative risk reduction benefits. And, if these analyses are truly intended to inform the public about the benefits they may receive for what they will pay, then the HRRCAs must be clear, straightforward, and easy to read.
- AMWA recommends that the subcommittee consider an independent review of how well EPA's cost-benefit analyses conform to standard practices.
- AMWA urges the subcommittee to focus its attention on the emerging threat to water suppliers of suits alleging the delivery of unsafe water even where the water surpasses the requirements of EPA rules.
- AMWA makes note of the $11 billion-per-year shortfall in funding for municipal drinking water agencies anticipated over the next 20 years.
- AMWA urges swift action on the part of the committee and Congress to pass legislation that significantly reduces or eliminates the use of MTBE to prevent further water contamination, to assist water systems where supplies are contaminated, and to support development of treatment technologies to remove existing contamination.

Thank you for the opportunity to provide this testimony today. AMWA is committed to working with the Environment and Public Works Committee, Sub-

committee on Wildlife, Fisheries, and Water, and EPA to ensure safe and affordable drinking water for the nation.

STATEMENT OF MICHAEL J. KOSNETT, M.D., M.P.H., ASSOCIATE CLINICAL PROFESSOR OF MEDICINE DIVISION OF CLINICAL PHARMACOLOGY AND TOXICOLOGY UNIVERSITY OF COLORADO HEALTH SCIENCES CENTER DENVER, COLORADO, ON BEHALF OF THE NATIONAL RESEARCH COUNCIL'S SUBCOMMITTEE ON ARSENIC IN DRINKING WATER

Good morning Mr. Chairman and members of the committee. I am Michael J. Kosnett, MD, MPH, a member of the Committee on Toxicology of the National Research Council (NRC), and a former member of the NRC's Subcommittee on Arsenic in Drinking Water. I am also an Associate Clinical Professor of Medicine in the Division of Clinical Pharmacology and Toxicology at the University of Colorado Health Sciences Center. I am pleased to appear before the committee today to discuss the findings of the NRC Subcommittee with respect to the health risks posed by arsenic in drinking water.

The National Research Council is an operating arm of the National Academy of Sciences, an independent, nongovernmental organization whose work often involves convening expert panels and study groups to address scientific and public health issues of interest to the Federal Government and other parties. The NRC's Subcommittee on Arsenic in Drinking Water was convened in the Spring of 1997 at the request of the U.S. Environmental Protection Agency. The charge to the subcommittee included a request to review EPA's characterization of the human health risk posed by arsenic in drinking water, to determine the adequacy of the EPA's current Maximum Contaminant Level (MCL) for protecting public health, and to identify priorities for research to fill data gaps.

The subcommittee was comprised of a group of experts selected by the chair of the National Research Council on the basis of their knowledge and experience in various aspects of the topics covered in the charge to the committee. It is important to note that the committee membership comprised an international grouping of experts from multiple scientific disciplines, including toxicology, epidemiology, biostatistics, chemistry, and nutrition. As with all NRC committees, the selection process was attentive to achieving balance in scientific perspective, and to avoiding any conflicts of interest. It should be noted that the members were drawn from academic institutions, national health agencies, private corporations, industry supported research organizations, and private consultants. The subcommittee adhered to a collective writing process, and its report reflects the scientific consensus of its members. Moreover, the subcommittee report was subjected to internal NRC institutional oversight, and to external peer review by public and private sector experts drawn from a broad range of backgrounds and perspectives. Every comment and question submitted by these peer reviewers was addressed by subcommittee members before the report was finalized.

The final 310 page report of the NRC Subcommittee on Arsenic in Drinking Water was released in the Spring of 1999. I have attached two key sections of the report as part of this statement: the Executive Summary, and a short but important chapter entitled "Risk Characterization." These sections highlight the key findings and recommendations of the subcommittee.

Arsenic in Drinking Water Subcommittee on Arsenic in Drinking Water Committee on Toxicology Board on Environmental Studies and Toxicology Commission on Life Sciences National Research Council March 1999

NATIONAL RESEARCH COUNCIL SUBCOMMITTEE ON ARSENIC IN DRINKING WATER

Robert A. Goyer (Chair), University of Western Ontario (emeritus), London, Ontario, Canada
H. Vasken Aposhian, University of Arizona, Tucson, Arizona
Kenneth G. Brown, Kenneth G. Brown, Inc., Chapel Hill, North Carolina
Kenneth P. Cantor, National Cancer Institute, Bethesda, Maryland
Gary P. Carlson, Purdue University, West Lafayette, Indiana
William R. Cullen, University of British Columbia, Vancouver, Canada
George P. Daston, The Procter & Gamble Company, Cincinnati, Ohio
Bruce A. Fowler, University of Maryland Medical School, Baltimore, Maryland
Curtis D. Klaassen, University of Kansas Medical Center, Kansas City, Kansas
Michael J. Kosnett, University of Colorado Health Sciences Center, Denver, Colorado
Walter Mertz, Retired Director of Beltsville Human Nutrition Research Center, Rockville, Maryland

R. Julian Preston, Chemical Industry Institute of Toxicology, Research Triangle Park, North Carolina
Louise M. Ryan, Harvard School of Public Health and Dana Farber Cancer Institute, Boston, Massachusetts
Allan H. Smith, University of California, Berkeley
Marie E. Vahter, Karolinska Institute, Stockholm, Sweden
John K. Wiencke, University of California, San Francisco
Carol A. Maczka, Director, Toxicology and Risk Assessment Program
Kulbir S. Bakshi, Program Director for the Committee on Toxicology
Margaret E. McVey, Project Director (prior to January 1998)
Ruth E. Crossgrove, Editor
Mirsada Karalic-Loncarevic, Information Specialist
Catherine M. Kubik, Senior Program Assistant
Lucy V. Fusco, Project Assistant

Executive Summary

The Safe Drinking Water Act (SDWA) directs the U.S. Environmental Protection Agency (EPA) to establish national standards for contaminants in public drinking-water supplies. Enforceable standards are to be set at concentrations at which no adverse health effects in humans are expected to occur and for which there are adequate margins of safety. Enforceable standards are standards that can be achieved with the use of the best technology available.

Arsenic is a naturally occurring element present in the environment in both inorganic and organic forms. Inorganic arsenic is considered to be the most toxic form of the element and is found in groundwater and surface water, as well as in many foods. A wide variety of adverse health effects, including skin and internal cancers and cardiovascular and neurological effects, have been attributed to chronic arsenic exposure, primarily from drinking water. EPA's interim maximum contaminant level (MCL) for arsenic in drinking water is 50 micrograms per liter (ug/L). Under the 1996 SDWA amendments, EPA is required to propose a standard (an MCL) for arsenic in drinking water by January 2000 and finalize it by January 2001.

THE CHARGE TO THE SUBCOMMITTEE

In 1996, EPA's Office of Water requested that the National Research Council (NRC) independently review the arsenic toxicity data base and evaluate the scientific validity of EPA's 1988 risk assessment for arsenic in drinking water. The NRC assigned this project to the Committee on Toxicology (COT), which convened the Subcommittee on Arsenic in Drinking Water, whose membership includes experts in toxicology, pharmacology, pathology, chemistry, nutrition, medicine, epidemiology, risk assessment, and biostatistics. The subcommittee was charged with the following tasks: (1) review EPA's characterization of human health risks from ingestion of arsenic compounds found in food and drinking water and the uncertainties associated that characterization; (2) review available data on cancer and noncancer health effects from exposure to arsenic compounds in drinking water and the implications of these effects on the Assessment of the human health risks from arsenic exposure; (3) review data on the toxicokinetics, metabolism, and mechanism or mode of action of arsenic and ascertain how these data could assist in assessing human health risks from drinking-water exposures, and (4) identify research priorities to fill data gaps. EPA did not request, nor did the subcommittee endeavor to provide, a formal risk assessment for arsenic in drinking water.

THE SUBCOMMITTEE'S APPROACH TO ITS CHARGE

The subcommittee evaluated data relating to key elements of the risk-assessment process—hazard identification, dose response, and risk characterization—that addresses the protective nature of the current MCL. Specifically, the subcommittee reviewed information on the health effects of arsenic exposure and data on the disposition and the mechanism or mode of action of arsenic. The subcommittee also evaluated other information that could affect the risk assessment, such as variations in human susceptibility, and current capabilities to measure arsenic in various media, including biological tissues. The major conclusions and recommendations of the subcommittee in each of those areas are discussed in the remainder of this summary. The implications of these findings on the assessment of human health risk is provided below in the section on risk characterization.

THE SUBCOMMITTEE'S EVALUATION

Health Effects

The subcommittee concludes that there is sufficient evidence from human epidemiological studies in Taiwan, Chile, and Argentina that chronic ingestion of inor-

ganic arsenic causes bladder and lung cancer, as well as skin cancer. With minor exceptions, epidemiological studies for cancer are based on populations exposed to arsenic concentrations in drinking water of at least several hundred micrograms per liter. Few data address the degree of cancer risk at lower concentrations of ingested arsenic. Noncancer effects resulting from chronic ingestion of inorganic arsenic have been detected at doses of 0.01 milligram per kilogram (mg/kg) and higher per day. Of the noncancer effects, cutaneous manifestations of exposure have been studied most widely. Developmental and reproductive effects resulting from chronic ingestion of inorganic arsenic have not been demonstrated in humans, although arsenic is known to pass through the placenta. Parenteral administration of inorganic and organic forms of arsenic are known to be teratogenic in a number of mammalian species, and oral administration affects fetal growth and prenatal viability. Arsenic has not been tested for essentiality in humans, nor has it been found to be required for any essential biochemical processes. Arsenic supplementation at very high concentrations (e.g., 350–4,500 nanograms per gram (ng/g)) in the diet has been shown to affect growth and reproduction in minipigs, chicks, goats, and rats.

Recommendations

Additional epidemiological evaluations are needed to characterize the dose-response relationship for arsenic-associated cancer and noncancer end points, especially at low doses. Such studies are of critical importance for improving the scientific validity of risk assessment. With respect to cancer, studies are recommended to refine the dose-response relationship between arsenic ingestion and cancer of the skin, bladder, and lung, and to investigate the effect of arsenic on cancer at other sites. With respect to noncancer effects, particular emphasis should be placed on epidemiological study of arsenic-associated cutaneous effects, cardiovascular and cerebrovascular disease, diabetes mellitus, and adverse reproductive outcomes.

Future studies on the beneficial effects of arsenic in experimental animals should carefully monitor the amount and speciation of arsenic in diets and water, use biomarkers to assess arsenic exposure and bioavailability, and use techniques that assess the toxicity and benefits of arsenic in a more specific manner than is possible through measurement of growth and reproductive success. In humans, the concentration of arsenic in total parenteral nutrition (TPN) should be determined by validated analytical methods and related to the health status of patients on long-term TPN.

Disposition (Absorption, Distribution, Metabolism, and Excretion)

In humans, inorganic arsenic is readily absorbed from the gastrointestinal tract and is primarily transported in the blood bound to sulfhydryl groups in proteins and low-molecular-weight compounds, such as amino acids and peptides. The half-life of arsenic in the body is about 4 days, and it is primarily excreted in the urine. Humans and some animals methylate inorganic arsenic to forms that are less acutely toxic and more readily excreted. However, the methylation process varies among animal species, making most animal models less suitable for studying the disposition of arsenic in humans. The methylation of ingested arsenic is not inhibited or overloaded, unless acute toxic doses are ingested. Substantial variations in the fractions of methylated forms of arsenic in urine are also known to occur among different populations and individuals within the same exposed population. Such variations might be indicative of genetic differences in the enzymes responsible for the methylation of arsenic. Methylation of arsenic might also be influenced by such factors as the arsenic species absorbed, high acute doses, nutrition, and disease. The extent to which variation in arsenic methylation affects its toxicity, including carcinogenicity, is not known.

Recommendations

Because of interspecies differences in the disposition of arsenic, more human studies are needed, including research using human tissues. Factors influencing the methylation, tissue retention' and excretion of arsenic in humans also need to be investigated.

Mechanism or Mode of Action

The mechanism or mode of action by which inorganic arsenic causes toxicity, including cancer, is not well established. In vivo studies in rats and mice to determine the ability of organic arsenic to act as a cocarcinogen or as a promoter have produced conflicting results. on the arsenic metabolite, dimethylarsinate (DMA), suggest that it is not an initiator but might act as a promoter. However, those studies used verse high doses, making interpretation of the results difficult, especially if DMA is formed in situ following the administration of inorganic arsenic.

The most accepted explanation for the mode of action for arsenic carcinogenicity is that it induces chromosomal abnormalities without interacting directly with DNA.

These markers of tumor response would lead to a dose-response curve that exhibits sublinear characteristics at some undetermined region in the low-dose range, although linearity cannot be ruled out.

The mechanism of action by which arsenic induces noncancer effects is centered on its inhibitory effects on cellular respiration at the level of the mitochondrion. Hepatotoxicity is a major health effect related to decreased cellular respiration. Oxidative stress might also have an important role in both cancer and noncancer effects.

Recommendations

Identification of proximate markers of arsenic-induced cancers and their application in carefully designed epidemiological studies might better define the cancer dose-response curves at low concentrations. Molecular and cellular characterization of neoplasms from arsenic exposed populations and appropriate controls might aid in identifying the mechanism by which arsenic induces tumors. Chronic low-dose studies in a suitable animal model (mouse, hamster, or rabbit) might increase our understanding of the mode of action of arsenic carcinogenicity, particularly the potential role of chromosomal alterations.

A greater understanding is needed of the inter-relationships between arsenic's effects on cellular respiration and its effects on biochemical processes, including methylation, formation of reactive oxygen species, oxidative stress, and protein stress response.

Variation in Human Sensitivity

Human sensitivity to the toxic effects of inorganic arsenic exposure is likely to vary based on genetics, metabolism, diet, health status, sex, and other possible factors. These factors can have important implications in the assessment of risk from exposure to arsenic. A wider margin of safety might be needed when conducting risk assessments of arsenic because of variations in metabolism and sensitivity among individuals or groups. For example, people with reduced ability to methylate arsenic retain more arsenic in their bodies and be more at risk for toxic effects. One study suggests that children have a lower arsenic-methylation efficiency than adults. Similarly, poor nutritional status might decrease the ability of an individual to methylate arsenic, resulting in increased arsenic concentrations in tissues and the development of toxic effects. There is some evidence from animal studies that low concentrations of S-adenosylmethionine, choline, or protein decrease arsenic methylation.

Recommendations

Factors that influence sensitivity to or expression of arsenic-associated cancer and noncancer effects need to be better characterized. Particular attention should be given to the extent of human variability and the reasons for it with respect to arsenic metabolism, tissue accumulation, and excretion (including total and relative amounts of urinary arsenic metabolites) under various conditions of exposure. Gene products responsible for metabolism, diet, and other environmental factors that might influence the susceptibility to or expression of arsenic-associated toxicity also need to be characterized in human studies and in suitable animal models. Potential differences between young children and adults in arsenic-methylation efficiency need to be validated and considered in any risk assessment of arsenic. Finally, quality-control data are needed to ensure that reported variations are not due to the analytical methods or procedures used. Standard reference materials are needed to analyze arsenic species in urine.

Other Considerations

Assessment of arsenic exposure via drinking water is often based on the measurements of arsenic concentrations in drinking water and assumptions regarding the amount of water consumed. Such data are estimates, the uncertainty of which will depend on the method used. The subcommittee evaluated various biomarkers (e.g., arsenic in urine, blood, hair, and nails) to measure the absorbed dose of inorganic arsenic and concluded that blood, hair, and nails are much less sensitive than urine as biomarkers of exposure. Specifically, the subcommittee concluded that the total concentration of inorganic arsenic and its metabolites in urine is a useful biomarker for both recent (previous day) and ongoing exposure. The concentration of urinary inorganic arsenic and its metabolites is less influenced by the consumption of seafood than is the total concentration of urinary arsenic. The concentration of arsenic in blood is a less-useful biomarker of continuous exposure because the half-life of arsenic in blood is short (approximately 1 fur), the concentration might be markedly affected by recent consumption of seafood, and it is difficult to speciate arsenic in blood. Measurements of arsenic in hair and nails have little use as biomarkers of

absorbed dose, largely because of the difficulty in distinguishing between arsenic absorbed from ingestion and arsenic uptake in hair and nails from washing with contaminated water.

At present, the practical quantitation limit (PQL) for arsenic in water in most commercial and water utility laboratories is 4 ug/L. Measurement of total concentration of arsenic in drinking water is adequate for regulatory purposes.

Recommendations

More data are needed that tie biomarkers of absorbed arsenic dose (especially urinary Concentrations of arsenic metabolites) to arsenic exposure concentrations, tissue concentrations, and the clinical evidence of arsenic toxicity. Data are particularly lacking for people living in different parts of the United States. Possible relationships between arsenic concentrations in urine, blood, hair, and nails need to be evaluated. In particular, the degree of external binding of arsenic to hair and nails should be examined.

There is a need for further development of analytical techniques to determine the chemical species of arsenic in various media—water, food, urine, and biological tissues. Quality-control data and certified standards for arsenic speciation are also needed.

RISK CHARACTERIZATION

In the context of its task, the subcommittee was asked to consider whether cancer or noncancer effects are likely to occur at the current MCL. No human studies of sufficient statistical power or scope have examined whether consumption of arsenic in drinking water at the current MCL results in an increased incidence of cancer or noncancer effects. Therefore, the subcommittee's characterization of risks at the current MCL is based on observed epidemiological findings, experimental data on the mode of action of arsenic, and available information on the variations in human susceptibility.

In the absence of a well-designed and well-conducted epidemiological study that includes individual exposure assessments, the subcommittee concluded that ecological studies from the arsenic endemic area of Taiwan provide the best available empirical human data for assessing the risks of arsenic-induced cancer. The cultural homogeneity of this region reduces concern about unmeasured confounders, although the potential for bias still exists due to considerable uncertainty about the exposure concentrations assigned to each village. Ecological studies in Chile and Argentina have observed risks of lung and bladder cancer of the same magnitude as those reported in the studies in Taiwan at comparable levels of exposure.

Information on the mode of action of arsenic and other available data that can help to determine the shape of the dose-response curve in the range of extrapolation are inconclusive and do not meet EPA's 1996 stated criteria for departure from the default assumption of linearity. Of the several modes of action that are considered most plausible, a sublinear dose-response curve in the low-dose range is predicted, although linearity cannot be ruled out. In vitro studies of the genotoxic effects of arsenic indicate that changes in cellular function related to plausible modes of carcinogenesis can occur at arsenic concentrations similar to the current MCL. However, the subcommittee believes that those data and the confidence with which they can be linked to arsenic-induced neoplasia are insufficient to determine the shape of the dose-response curve in the low-dose range (point of departure). The subcommittee also finds that existing scientific knowledge regarding the pattern of arsenic metabolism and disposition across this dose range does not establish the mechanisms that mitigate neoplastic effects.

Human susceptibility to adverse effects resulting from chronic exposure to inorganic arsenic is likely to vary based on genetics, nutrition, sex, and other possible factors. Some factors, such as poor nutrition and arsenic intake from food might affect assessment of risk in Taiwan or extrapolation of results in the United States.

The subcommittee also concludes that the choice of model for statistical analysis can have a major impact on estimated cancer risks at low-dose exposures, especially when the model accounts for age as well as concentration. Applying different statistical models to the Taiwanese male bladder-cancer data revealed that a more stable and reliable fit is provided by Poisson regression models that characterized the log relative risk as a linear function of exposure. The estimation of risk at low doses using those models is substantially higher than that using the multistage Weibull model. As an alternative to model-based estimates of risk, the subcommittee finds that the point-of-departure methods discussed in the 1996 draft EPA guidelines for cancer risk assessment give much more consistent low-dose estimates across a wide range of dose-response models. For male bladder cancer, a straight-line extrapolation from the 1 percent point of departure yielded a risk at the MCL of 1 to 1.5

per 1,000. Because some studies have shown that excess lung cancer deaths attributed to arsenic are 2-S fold greater than the excess bladder cancer deaths, a similar approach for all cancers could easily result in a combined cancer risk on the order of 1 in 100.' It is also instructive to note that daily arsenic ingestion at the MCL provides a margin of exposure less than 10 from the point of departure for bladder cancer alone. The public health significance of daily ingestion of a given amount of arsenic in drinking water will be influenced by the background levels of arsenic consumed in food.

Recommendations

On the basis of its review of epidemiological findings, experimental data on the mode of action of arsenic, and available information on the variations in human susceptibility, it is the subcommittee's consensus that the current EPA MCL for arsenic in drinking water of 50 ug/L does not achieve EPA's goal for public-health protection and, therefore, requires downward revision as promptly as possible.

Sensitivity analyses should be conducted to determine whether the results, including the way exposure concentrations are grouped together, are sensitive to the choice of model. The potential effect of measurement error and confounding on the dose-response curve and associated confidence limits should be further addressed.

To assist in the application of cancer data observed in different populations to cancer risks predicted for the United States, information on nutritional factors in study populations that pertains to susceptibility to arsenic-induced cancer should be investigated.

Modeling of epidemiological data should not be limited to the multistage Weibull model. Over models, including those which incorporate information from an appropriate control population, should be considered. The final risk value should be supported by a range of analyses over a broad range of feasible assumptions.

Risk Characterization

In its Statement of Task to the subcommittee, EPA requested guidance regarding "the adequacy of the current EPA maximum contaminant levels (MCLs) and ambient-water-quality-criteria (AWQC) values for protecting human health in the context of stated EPA policy. . . ." EPA's stated policy in setting MCLsfor known human carcinogens has the "goal of ensuring that the maximum risk at the MCL falls within the 10_4 to 10_6 range that the Agency considers protective of the public health, therefore achieving the overall purpose of the SDWA (Safe Drinking Water Act)" (EPA 1992). EPA has not requested, nor has the subcommittee endeavored to provide, a formal risk assessment for arsenic in drinking water. However, the subcommittee believes it can provide EPA with an up-to-date summary appraisal of two key elements of the risk-assessment process—hazard identification and dose response—that qualitatively, if not quantitatively, address the protective nature of the current MCL.

As the subcommittee discussed in detail elsewhere in this report, there is sufficient evidence from human epidemiological studies in Taiwan, Chile, and Argentina to conclude that ingestion of arsenic in drinking water poses a hazard of cancer of the lung and bladder, in addition to cancer of the skin. Overt noncancer effects of chronic arsenic ingestion have been detected at arsenic doses on the order of 0.01 mg/kg per day and higher. Ofthe noncancer effects, cutaneous manifestations of exposure have been studied most widely. No human studies of sufficient statistical power or scope have examined whether consumption of arsenic in drinking water at the current MCL (approximately 0.001 mg/kg per day) results in an increased incidence of cancer or noncancer effects. Therefore, a characterization of the risk that exists at the current MCL must rely on extrapolation by using observed epidemiological findings, experimental data on mode-of-action-related end points, and available information regarding the anticipated variability in human susceptibility.

At present, studies from the arsenic endemic area of Taiwan continue to provide the best available empirical human data for use in assessing the dose-response relationship for arsenic-induced cancer. The current state of knowledge is insufficient to reliably apply a biologically based model to those data. In accordance with EPA's "Proposed Guidelines for Carcinogen Risk Assessment" (EPA 1996), the subcommittee reviewed modes of action based on markers of tumor response and on available data that can determine the shape of the dose-response curve in the range of extrapolation. As discussed in Chapter 7, the several modes of action that are considered most plausible would lead to a dose-response curve that exhibits sublinear characteristics at some undetermined region in the low-dose range. Nonetheless, in the context of its task, the subcommittee considered the magnitude of the likely cancer risks within the range of human exposure at approximately the current MCL.

In vitro studies of the genotoxic effect of submicromolar concentrations of arsenite on human and animal cells and one study of bladder-cell micronuclei in humans with arsenic concentrations of 57 to 137 ug/L in urine indicate that perturbations in cellular function related to plausible modes of carcinogenesis might be operating at arsenic exposure concentrations associated with the current MCL. The subcommittee believes that those data and the confidence with which they can be linked to arsenic-induced neoplasia are insufficient to determine the shape of the dose response curve between the point of departure and the current MCL. The subcommittee also finds that existing scientific knowledge regarding the pattern of arsenic metabolism and disposition across this dose range does not establish mechanisms that mitigate neoplastic effects. In light of all the uncertainties on mode of action, the current evidence does not meet EPA's stated criteria (EPA 1996) for departure from the default assumption of linearity in this range of extrapolation.

In Chapters 2 and 10, the subcommittee reviewed the strengths and limitations of the Taiwanese data. Chapter 10 also discussed the implications of applying different statistical models to the Taiwanese internal-cancer data for the purpose of characterizing cancer risk at the current MCL in the United States. With respect to EPA's 1988 risk assessment for arsenic-induced skin cancer in which the multistage Weibull model was used, a sensitivity analysis, within the limits of the available data, suggests that misclassification arising from the ecological study design and the grouping of exposures would likely have only a modest impact on EPA's risk estimates. Sensitivity analyses applied to male bladder-cancer risk estimated by the multistage Weibull model had a greater impact on results. However, a more stable and reliable fit was provided by Poisson regression models that characterized the log relative risk as a linear function of exposure. For male bladder cancer, a straight-line extrapolation from the 1 percent point of departure (LED,) yielded a risk at the MCL of 1 to 1.5 per 1,000. Considering the data on bladder and lung cancer in both sexes noted in the studies in Chapter 4, a similar approach for all cancers could easily result in a combined cancer risk on the order of 1 in 100. It is also instructive to note that daily arsenic ingestion at the MCL, approximately 100 ug in adults, provides a margin of exposure less than 10.

As discussed in Chapter 8, the subcommittee recognizes that human susceptibility to the adverse effects of chronic arsenic exposure is likely to vary based on genetics, sex, and over possible factors. Some factors, such as poor nutrition and arsenic intake from food, Night affect assessment of risk in Taiwan or extrapolation of results in the United States.

Upon assessing the available evidence, it is the subcommittee's consensus that the current EPA MCL for arsenic in drinking water of 50 ug/L does not achieve EPA's goal for public health protection and therefore requires downward revision as promptly as possible.

REFERENCES

EPA (U.S. Environmental Protection Agency). 1992. Drinking water; national primary drinking water regulations—synthetic organic chemicals and inorganic chemicals; national primary drinking water regulations implementation. Fed. Regist. 57(138):31797.

August 28, 2000.

Senator BARBARA BOXER,
Senator MIKE CRAPO,
U.S. Senate,
Committee on Environment and Public Works,
Subcommittee on Fisheries, Wildlife, and Water,
Washington, DC 20510–6175

Re: Arsenic in Drinking Water and EPA's Implementation of the Safe Drinking Water Act

Dear Senators Boxer and Crapo: I am pleased to respond to your letter of July 13, 2000 in which you requested that I address supplemental questions on arsenic in drinking water posed by Senators Crapo and Smith. As you are aware, I testified before the Subcommittee on Fisheries, Wildlife, and Water as a representative of the National Research Council's Subcommittee on Arsenic in Drinking Water. The peer-reviewed product of this expert panel was a report to the United States Environmental Protection Agency released in March, 1999. Entitled "Arsenic in Drinking Water" (NRC, National Academy Press: Wash, DC, 1999) this report alone represents the consensus opinion of the National Research Council. In responding to the inquiries by Senators Crapo and Smith, I will endeavor to quote or clearly para-

phrase sections of this report that address their particular questions. For questions that were not specifically addressed by the NRC report, I am providing my personal opinion, based on my experience and expertise in the area of the human health effects of arsenic exposure.

MICHAEL J. KOSNETT.

RESPONSES BY MICHAEL J. KOSNETT TO ADDITIONAL QUESTIONS FROM SENATOR CRAPO

Question 1. How would you characterize the scientific soundness of the Taiwan study on arsenic? Do you believe this represents a firm foundation for the proposed EPA standard with regard to dose-response modeling?

Response. In its report, the NRC subcommittee stated, "At present, studies from the arsenic endemic area of Taiwan continue to provide the best available human data for use in assessing the dose-response relationship for arsenic-induced cancer." (NRC, p. 300). In chapters 2 and 10, the NRC subcommittee reviewed the strengths and limitations of the Taiwanese data. The NRC subcommittee made particular note of the fact that epidemiological studies in Chile and Argentina have observed arsenic-related risks of lung and bladder cancer of the same magnitude as those reported in the studies in Taiwan at comparable levels of exposure (NRC, p 292). This finding lends support to the scientific validity and generalizability of the Taiwanese data. By virtue of its considerable discussion on dose-response modeling using the Taiwanese data-set, the NRC subcommittee, in my opinion, clearly envisioned that EPA could further utilize this dataset in its assessment of health risk at lower levels of arsenic exposure. However, it should be emphasized that the NRC subcommittee did not base its concerns on the health risks of arsenic exposure at the current MCL of 50 ppb solely on dose-response modeling using the Taiwanese data. The NRC subcommittee noted that the margin of exposure between the current MCL of 50 ppb and levels of exposure associated with an observed risk of death from arsenic induced cancer in the Taiwanese, Chilean, and Argentine studies was less than 10 fold. The NRC subcommittee also noted that "In vitro studies of the genotoxic effect of submicromolar concentrations of arsenite on human and animal cells, and one study of bladder cell micronuclei in humans with arsenic concentrations of 57 to 137 ug/L in urine indicate that perturbations in cellular function related to plausible modes of carcinogenesis might be operating at arsenic exposure concentrations associated with the current MCL." (NRC, p 300).

Question 2. What arsenic level do you believe the existing science supports?

Response. The NRC subcommittee was not asked to recommend a specific new MCL for arsenic, nor did it do so in its report. However, in its concluding chapter on Risk Characterization, the NRC subcommittee addressed implications of the available human epidemiological data regarding the potential human cancer risk associated with the current MCL of 50 ppb. The report stated, "Considering the data on bladder and lung cancer in both sexes noted in the studies in Chapter 4, a similar approach for all cancers could easily result in a combined cancer risk [at the current MCL of 50 ppb] on the order of 1 in 100." (NRC, p 301).

The NRC subcommittee assessed the available scientific evidence, and did not find a scientific basis for EPA to depart from the default assumption of linearity in extrapolating cancer risk from arsenic exposure. Based on EPA'S 1996 document, "Proposed Guidelines for Carcinogen Risk Assessment," EPA's criteria for abandoning the default assumption of linearity have not been met. As such, given that the lifetime cancer risk at the current MCL of 50 ppb could be on the order of 1 in 100, (and that the observed lifetime cancer risk in a Chilean population consuming drinking water of 500 ppb was 1 in 10, per Smith et al, 1998), the cancer risk at EPA's new proposed MCL of 5 ppb could be on the order of 1 in 1000. This exceeds by at least one order of magnitude the lifetime cancer risks of 1 in 10,000 to 1 in 1,000,000 that EPA has traditionally accepted as protective of the public health. Therefore, in my opinion, the existing science supports lowering the MCL to the lowest feasible level, namely 3 ppb, if the only considerations are a desire to be protective of the public health in a manner consistent with EPA'S overall science policy.

Question 3. How does a 5 ppb level of exposure compare to dietary or organic [sic] exposures?

Response. The NRC subcommittee referred to a study by Tao and Bolger (1998) that estimated daily dietary exposure to arsenic for the US population. (NRC p 47). The NRC subcommittee report stated, ". . . if water contains 5 ug/L of arsenic and

2 L per day is consumed, the contribution of inorganic arsenic from diet and water are comparable." (emphasis added).

On the premise that the submitted question is also inquiring about dietary exposure to organic arsenic, it should be noted that the study cited above assumes that the arsenic in seafood consists 10 percent of inorganic forms and 90 percent of organic forms. Because the average American diet is estimated to include some seafood, total arsenic consumption (sum of inorganic and organic), is expected to exceed intake of inorganic arsenic intake alone.

Question 4. Do you believe that a linear application of the existing data on arsenic exposure levels is appropriate or do you believe it is likely that a threshold exists below which no adverse effects occur?

Response. The NRC subcommittee report stated, "In light of all the uncertainties on mode of action, the current evidence does not meet EPA'S stated criteria (EPA 1996) for departure from the default assumption of linearity in this range of extrapolation." (NRC, p 300). The range of extrapolation referred to was between the level of arsenic in drinking water associated with observed increases in cancer and the current MCL of 50 ppb.

The NRC subcommittee stated, "For arsenic carcinogenicity, the mode of action has not been established, but the several modes of action that are considered plausible (namely, indirect mechanisms of mutagenicity) would lead to a sublinear dose-response curve at some point below the point at which a significant increase in tumors is observed." (NRC p. 206; emphasis added). However, the committee found no evidence that the "point" where the dose-response might become nonlinear occurs between the current MCL of 50 ppb and the proposed MCL of 5 ppb. Moreover, the subcommittee noted, "Because a specific mode (or modes) of action has not yet been identified, it is prudent not to rule out the possibility of a linear response." The NRC subcommittee could not identify a threshold for arsenic exposure below which no cancer risk exists. I therefore consider it appropriate that EPA adhered to the default assumption of linearity in developing a revised MCL.

RESPONSES BY MICHAEL J. KOSNETT TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1. How comfortable are you with the science that was used for EPA'S proposed rule compared to other proposed standards, such as the radon rule?

Response. The NRC subcommittee did not compare the state of the science available to rulemakers for arsenic to that available to rulemakers for other toxic substances, such as radon.

It is my understanding that the radon rule, like the arsenic rule, has been based in part on estimating the human cancer risk at low environmental levels by extrapolating observed human cancer risks at higher exposure levels. However, in the case of arsenic, the range of extrapolation is smaller than has been the case for radon.

The body of scientific knowledge available to EPA in reaching a decision to lower the arsenic MCL is extensive. In addition to the material summarized in the NRC report, EPA now has available several very recent human epidemiological studies (from Chile, Finland, and Utah), that have provided additional health risk data. In particular, EPA now has available the new case-control study by Ferreccio C et al, Lung cancer and arsenic concentrations in drinking water in Chile, Epidemiology, 2000, in press, that supports an arsenic-related lung cancer risk as high or higher than estimated from the studies in Taiwan. Unlike regulations that are based largely on findings of animal studies, the health risks from arsenic have been demonstrated in human populations. The data base includes several epidemiological studies in different countries demonstrating an observed human cancer risk from arsenic ingestion at levels of exposure that are only one order of magnitude above the current MCL. In addition, in vitro (laboratory) studies have demonstrated a cellular effect arsenic on functions related to plausible carcinogenic modes of action at concentrations that are relevant to the current MCL. Although human arsenic metabolism has been the subject of many studies, none have established the presence of detoxification mechanisms or other in vivo factors that would mitigate or prevent a neoplastic effect at the current MCL of 50 ppb, or for that matter at 5 ppb.

In my opinion, the quality and quantity of the available scientific data provides a sufficient scientific basis for EPA'S recommended revision in the arsenic MCL.

Question 2. Did NRC find a clear link between low levels of arsenic and adverse health effects?

Response. The NRC subcommittee reported that, "No human studies of sufficient statistical power or scope have examined whether consumption of arsenic in drink-

ing water at the current MCL (approximately 0.001 mg/kg per day) results in an increased incidence of cancer or noncancer effects." (NRC, p 299). The NRC subcommittee took note of several studies that observed very high human risks of fatal bladder and lung cancer at levels of arsenic exposure that were less than or equal to 1 order of magnitude above the current MCL of 50 ppb, and less than or equal to 2 orders of magnitude above the proposed MCL of 5 ppb. The NRC subcommittee documented a number of noncancer effects of arsenic that have been associated with levels of human exposure less than or equal to one order of magnitude above the current MCL. As has been noted previously, the NRC subcommittee also reported that "In vitro studies of the genotoxic effect of submicromolar concentrations of arsenite on human and animal cells, and one study of bladder cell micronuclei in humans with arsenic concentrations of 57 to 137 ug/L in urine indicate that perturbations in cellular function related to plausible modes of carcinogenesis might be operating at arsenic exposure concentrations associated with the current MCL." (NRC, p 300).

STATEMENT OF DR. J. WILLIAM HIRZY, NATIONAL TREASURY EMPLOYEES UNION CHAPTER 280

Good morning Mr. Chairman and Members of the subcommittee. I appreciate the opportunity to appear before this subcommittee to present the views of the union, of which I am a Vice-President, on the subject of fluoridation of public water supplies.

Our union is comprised of and represents the professional employees at the headquarters location of the U.S. Environmental Protection Agency in Washington D.C. Our members include toxicologists, biologists, chemists, engineers, lawyers and others defined by law as "professionals." The work we do includes evaluation of toxicity, exposure and economic information for management's use in formulating public health and environmental protection policy.

I am not here as a representative of EPA, but rather as a representative of EPA headquarters professional employees, through their duly elected labor union. The union first got involved in this issue in 1985 as a matter of professional ethics. In 1997 we most recently voted to oppose fluoridation. Our opposition has strengthened since then.

Summary of Recommendations

1) We ask that you order an independent review of a cancer bioassay previously mandated by Congressional committee and subsequently performed by Battelle Memorial Institute with appropriate blinding and instructions that all reviewer's independent determinations be reported to this committee.

2) We ask that you order that the two waste products of the fertilizer industry that are now used in 90 percent of fluoridation programs, for which EPA states they are not able to identify any chronic studies, be used in any future toxicity studies, rather than a substitute chemical. Further, since Federal agencies are actively advocating that each man woman and child drink, eat and bathe in these chemicals, silicofluorides should be placed at the head of the list for establishing a MCL that complies with the Safe Drinking Water Act. This means that the MCL be protective of the most sensitive of our population, including infants, with an appropriate margin of safety for ingestion over an entire lifetime.

3) We ask that you order an epidemiology study comparing children with dental fluorosis to those not displaying overdose during growth and development years for behavioral and other disorders.

4) We ask that you convene a joint Congressional Committee to give the only substance that is being mandated for ingestion throughout this country the full hearing that it deserves.

National Review of Fluoridation

The subcommittee's hearing today can only begin to get at the issues surrounding the policy of water fluoridation in the United States, a massive experiment that has been run on the American public, without informed consent, for over 50 years. The last Congressional hearings on this subject were held in 1977. Much knowledge has been gained in the intervening years. It is high time for a national review of this policy by a Joint Select Committee of Congress. New hearings should explore, at minimum, these points:

- 1) excessive and un-controlled fluoride exposures;
- 2) altered findings of a cancer bioassay;
- 3) the results and implications of recent brain effects research;
- 4) the "protected pollutant" status of fluoride within EPA;

- 5) the altered recommendations to EPA of a 1983 Surgeon General's Panel on fluoride;
- 6) the results of a fifty-year experiment on fluoridation in two New York communities;
- 7) the findings of fact in three landmark lawsuits since 1978;
- 8) the findings and implications of recent research linking the predominant fluoridation chemical with elevated blood-lead levels in children and anti-social behavior; and
- 9) changing views among dental researchers on the efficacy of water fluoridation

Fluoride Exposures Are Excessive and Un-controlled

According to a study by the National Institute of Dental Research, 66 percent of America's children in fluoridated communities show the visible sign of over-exposure and fluoride toxicity, dental fluorosis.[1] That result is from a survey done in the mid-1980's and the figure today is undoubtedly much higher.

Centers for Disease Control and EPA claim that dental fluorosis is only a "cosmetic" effect. God did not create humans with fluorosed teeth. That effect occurs when children ingest more fluoride than their bodies can handle with the metabolic processes we were born with, and their teeth are damaged as a result. And not only their teeth. Children's bones and other tissues, as well as their developing teeth are accumulating too much fluoride. We can see the effect on teeth. Few researchers, if any, are looking for the effects of excessive fluoride exposure on bone and other tissues in American children. What has been reported so far in this connection is disturbing. One example is epidemiological evidence[2] showing elevated bone cancer in young men related to consumption of fluoridated drinking water.

Without trying to ascribe a cause and effect relationship beforehand, we do know that American children in large numbers are afflicted with hyperactivity-attention deficit disorder, that autism seems to be on the rise, that bone fractures in young athletes and military personnel are on the rise, that earlier onset of puberty in young women is occurring. There are biologically plausible mechanisms described in peer-reviewed research on fluoride that can link some of these effects to fluoride exposures.[3] [4] [5] [6] Considering the economic and human costs of these conditions, we believe that Congress should order epidemiology studies that use dental fluorosis as an index of exposure to determine if there are links between such effects and fluoride over-exposure.

In the interim, while this epidemiology is conducted, we believe that a national moratorium on water fluoridation should be instituted. There will be a hue and cry from some quarters, predicting increased dental caries, but Europe has about the same rate of dental caries as the U.S.[7] and most European countries do not fluoridate.[8] I am submitting letters from European and Asian authorities on this point. There are studies in the U.S. of localities that have interrupted fluoridation with no discernable increase in dental caries rates.[9] And people who want the freedom of choice to continue to ingest fluoride can do so by other means.

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[1] Dental caries and dental fluorosis at varying water fluoride concentrations. Heller, K.E, Eklund, S.A. and Burt, B.A. J. Pub. Health Dent. 57 136–43 (1997).

[2] A brief report on the association of drinking water fluoridation and the incidence of osteosarcoma among young males. Cohn, P.D. New Jersey Department of Health (1992).

Time trends for bone and joint cancers and osteosarcomas in the Surveillance, Epidemiology and End Results (SEER) Program. National Cancer Institute. In: Review of fluoride: benefits and risks. Department of Health and Human Services. 1991: F1-F7.

[3] Neurotoxicity of sodium fluoride in rats. Mullenix, P.J., Denbesten, P.K., Schunior, A. and Kernan, W.J. Neurotoxicol. Teratol. 17 169–177 (1995)

[4] Fluoride and bone—quantity versus quality [editorial] N. Engl. J. Med. 322 845–6 (1990)

Summary of workshop on drinking water fluoride influence on hip fracture and bone health. Gordon, S.L. and Corbin, S.B. Natl. Inst. Health. April 10, 1991.

[5] Effect of fluoride on the physiology of the pineal gland. Luke, J.A. Caries Research 28 204 (1994).

[6] Newburgh-Kingston caries-fluorine study XIII. Pediatric findings after 10 years. Schlesinger, E.R., Overton, D.E., Chase, H.C., and Cantwell, K.T. JADA 52 296–306 (1956).

[7] WHO oral health country/area profile programme. Department of Non-Communicable Diseases Surveillance/Oral Health. WHO Collaborating Centre, Malmo University, Sweden. URL: www.whocollab.odont.lu.se/countriesalphab.html

[8] Letters from government authorities in response to inquiries on fluoridation status by E. Albright. Eugene Albright: contact through J. W. Hirzy, P.O. Box 76082, Washington, D.C. 20013.

[9] The effects of a break in water fluoridation on the development of dental caries and fluorosis. Burt B.A., Keels ., Heller KE. J. Dent. Res. 2000 Feb;79(2):761–9.

Cancer Bioassay Findings

In 1990, the results of the National Toxicology Program cancer bioassay on sodium fluoride were published,[10] the initial findings of which would have ended fluoridation. But a special commission was hastily convened to review the findings, resulting in the salvation of fluoridation through systematic down-grading of the evidence of carcinogenicity. The final, published version of the NTP report says that there is, "equivocal evidence of carcinogenicity in male rats," changed from "clear evidence of carcinogenicity in male rats."

The change prompted Dr. William Marcus, who was then Senior Science Adviser and Toxicologist in the Office of Drinking Water, to blow the whistle about the issue, which led to his firing by EPA. Dr. Marcus sued EPA, won his case and was reinstated with back pay, benefits and compensatory damages. I am submitting material from Dr. Marcus to the subcommittee dealing with the cancer and neurotoxicity risks posed by fluoridation.

We believe the subcommittee should call for an independent review of the tumor slides from the bioassay, as was called for by Dr. Marcus, with the results to be presented in a hearing before a Select Committee of the Congress. The scientists who conducted the original study, the original reviewers of the study, and the "review commission" members should be called, and an explanation given for the changed findings.

Brain Effects Research

Since 1994 there have been six publications that link fluoride exposure to direct adverse effects on the brain. Two epidemiology studies from China indicate depression of I.Q. in children.[11] [12] Another paper (*see footnote 3 above*) shows a link between prenatal exposure of animals to fluoride and subsequent birth of off-spring which are hyperactive throughout life. A 1998 paper shows brain and kidney damage in animals given the "optimal" dosage of fluoride, viz. one part per million.[13] And another[14] shows decreased levels of a key substance in the brain that may explain the results in the other paper from that journal. Another publication (*see footnote 5 above*) links fluoride dosing to adverse effects on the brain's pineal gland and pre-mature onset of sexual maturity in animals. Earlier onset of menstruation of girls in fluoridated Newburg, New York has also been reported (*see footnote 6 above).*

Given the national concern over incidence of attention deficit-hyperactivity disorder and autism in our children, we believe that the authors of these studies should be called before a Select Committee, along with those who have critiqued their studies, so the American public and the Congress can understand the implications of this work.

Fluoride as a Protected Pollutant

The classic example of EPA's protective treatment of this substance, recognized the world over and in the U.S. before the linguistic de-toxification campaign of the 1940's and 1950's as a major environmental pollutant, is the 1983 statement by EPA's then Deputy Assistant Administrator for Water, Rebecca Hanmer,[15] that EPA views the use of hydrofluosilicic acid recovered from the waste stream of phosphate fertilizer manufacture as,

". . . an ideal solution to a long standing problem. By recovering by-product fluosilicic acid (sic) from fertilizer manufacturing, water and air pollution are minimized, and water authorities have a low-cost source of fluoride. . . "

In other words, the solution to pollution is dilution, as long as the pollutant is dumped straight into drinking water systems and not into rivers or the atmosphere. I am submitting a copy of her letter.

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[10] Toxicology and carcinogenesis studies of sodium fluoride in F344/N rats and B6C3F1 mice. NTP Report No. 393 (1991).

[11] Effect of high fluoride water supply on children's intelligence. Zhao, L.B., Liang, G.H., Zhang, D.N., and Wu, X.R. Fluoride 29 190–192 (1996).

12. Effect of fluoride exposure on intelligence in children. Li, X.S., Zhi, J.L., and Gao, R.O. Fluoride 28 (1995).

[13] Chronic administration of aluminum-fluoride or sodium-fluoride to rats in drinking water: alterations in neuronal and cerebrovascular integrity. Varner, J.A., Jensen, K.F., Horvath, W. And Isaacson, R.L. Brain Research 784 284–298 (1998).

[14] Influence of chronic fluorosis on membrane lipids in rat brain. Z.Z. Guan, Y.N. Wang, K.Q. Xiao, D.Y. Dai, Y.H. Chen, J.L. Liu, P. Sindelar and G. Dallner, Neurotoxicology and Teratology 20 537–542 (1998).

[15] Letter from Rebecca Hanmer, Deputy Assistant Administrator for Water, to Leslie Russell re: EPA view on use of by-product fluosilicic (sic) acid as low cost source of fluoride to water authorities. March 30, 1983.

Other Federal entities are also protective of fluoride. Congressman Calvert of the House Science Committee has sent letters of inquiry to EPA and other Federal entities on the matter of fluoride, answers to which have not yet been received.

We believe that EPA and other Federal officials should be called to testify on the manner in which fluoride has been protected. The union will be happy to assist the Congress in identifying targets for an inquiry. For instance, hydrofluosilicic acid does not appear on the Toxic Release Inventory list of chemicals, and there is a remarkable discrepancy among the Maximum Contaminant Levels for fluoride, arsenic and lead, given the relative toxicities of these substances. Surgeon General's Panel on Fluoride We believe that EPA staff and managers should be called to testify, along with members of the 1983 Surgeon General's panel and officials of the Department of Human Services, to explain how the original recommendations of the Surgeon General's panel [16] were altered to allow EPA to set otherwise unjustifiable drinking water standards for fluoride.

Kingston and Newburg, New York Results

In 1998, the results of a fifty-year fluoridation experiment involving Kingston, New York (un-fluoridated) and Newburg, New York (fluoridated) were published. [17] In summary, there is no overall significant difference in rates of dental decay in children in the two cities, but children in the fluoridated city show significantly higher rates of dental fluorosis than children in the un-fluoridated city.

We believe that the authors of this study and representatives of the Centers For Disease Control and EPA should be called before a Select Committee to explain the increase in dental fluorosis among American children and the implications of that increase for skeletal and other effects as the children mature, including bone cancer, stress fractures and arthritis.

Findings of Fact by Judges

In three landmark cases adjudicated since 1978 in Pennsylvania, Illinois and Texas, [18] judges with no interest except finding fact and administering justice heard prolonged testimony from proponents and opponents of fluoridation and made dispassionate findings of fact. I cite one such instance here.

In November, 1978, Judge John Flaherty, now Chief Justice of the Supreme Court of Pennsylvania, issued findings in the case, Aitkenhead v. Borough of West View, tried before him in the Allegheny Court of Common Pleas. Testimony in the case filled 2800 transcript pages and fully elucidated the benefits and risks of water fluoridation as understood in 1978. Judge Flaherty issued an injunction against fluoridation in the case, but the injunction was overturned on jurisdictional grounds. His findings of fact were not disturbed by appellate action. Judge Flaherty, in a July, 1979 letter to the Mayor of Aukland New Zealand wrote the following about the case:

"In my view, the evidence is quite convincing that the addition of sodium fluoride to the public water supply at one part per million is extremely deleterious to the human body, and, a review of the evidence will disclose that there was no convincing evidence to the contrary. . .

"Prior to hearing this case, I gave the matter of fluoridation little, if any, thought, but I received quite an education, and noted that the proponents of fluoridation do nothing more than try to impune (sic) the objectivity of those who oppose fluoridation."

In the Illinois decision, Judge Ronald Niemann concludes: "This record is barren of any credible and reputable scientific epidemiological studies and or analysis of statistical data which would support the Illinois Legislature's determination that fluoridation of the water supplies is both a safe and effective means of promoting public health."

Judge Anthony Farris in Texas found: "[That] the artificial fluoridation of public water supplies, such as contemplated by {Houston} City ordinance No. 80–2530 may cause or contribute to the cause of cancer, genetic damage, intolerant reactions, and chronic toxicity, including dental mottling, in man; that the said artificial fluoridation may aggravate malnutrition and existing illness in man; and that the value of said artificial fluoridation is in some doubt as to reduction of tooth decay in man."

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[16] Transcript of proceedings—Surgeon General's (Koop) ad hoc committee on non-dental effects of fluoride. April 18–19, 1983. National Institutes of Health. Bethesda, MD.

[17] Recommendations for fluoride use in children. Kumar, J.V. and Green, E.L. New York State Dent. J. (1998) 40–47.

[18] Highlights in North American litigation during the twentieth century on artificial fluoridation of public water supplies. Graham, J.R. and Morin, P. Journal of Land Use and Environmental Law 14 195–248 (Spring 1999) Florida State University College of Law.

The significance of Judge Flaherty's statement and his and the other two judges' findings of fact is this: proponents of fluoridation are fond of reciting endorsement statements by authorities, such as those by CDC and the American Dental Association, both of which have long-standing commitments that are hard if not impossible to recant, on the safety and efficacy of fluoridation. Now come three truly independent servants of justice, the judges in these three cases, and they find that fluoridation of water supplies is not justified.

Proponents of fluoridation are absolutely right about one thing: there is no real controversy about fluoridation when the facts are heard by an open mind.

I am submitting a copy of the excerpted letter from Judge Flaherty and another letter referenced in it that was sent to Judge Flaherty by Dr. Peter Sammartino, then Chancellor of Fairleigh Dickenson University. I am also submitting a reprint copy of an article in the Spring 1999 issue of the Florida State University Journal of Land Use and Environmental Law by Jack Graham and Dr. Pierre Morin, titled "Highlights in North American Litigation During the Twentieth Century on Artificial Fluoridation of Public Water. Mr. Graham was chief litigator in the case before Judge Flaherty and in the other two cases (in Illinois and Texas).

We believe that Mr. Graham should be called before a Select Committee along with, if appropriate, the judges in these three cases who could relate their experience as trial judges in these cases.

Hydrofluosilicic Acid

There are no chronic toxicity data on the predominant chemical, hydrofluosilicic acid and its sodium salt, used to fluoridate American communities. Newly published studies[19] indicate a link between use of these chemicals and elevated level of lead in children's blood and anti-social behavior. Material from the authors of these studies has been submitted by them independently.

We believe the authors of these papers and their critics should be called before a Select Committee to explain to you and the American people what these papers mean for continuation of the policy of fluoridation.

Changing Views on Efficacy and Risk

In recent years, two prominent dental researchers who were leaders of the profluoridation movement announced reversals of their former positions because they concluded that water fluoridation is not an effective means of reducing dental caries and that it poses serious risks to human health. The late Dr. John Colquhoun was Principal Dental Officer of Aukland, New Zealand, and he published his reasons for changing sides in 1997.[20] In 1999, Dr. Hardy Limeback, Head of Preventive Dentistry, University of Toronto, announced his change of views, then published a statement[21] dated April 2000. I am submitting a copy of Dr. Limeback's publications.

We believe that Dr. Limeback, along with fluoridation proponents who have not changed their minds, such as Drs. Ernest Newbrun and Herschel Horowitz, should be called before a Select Committee to testify on the reasons for their respective positions.

Thank you for you consideration, and I will be happy to take questions.

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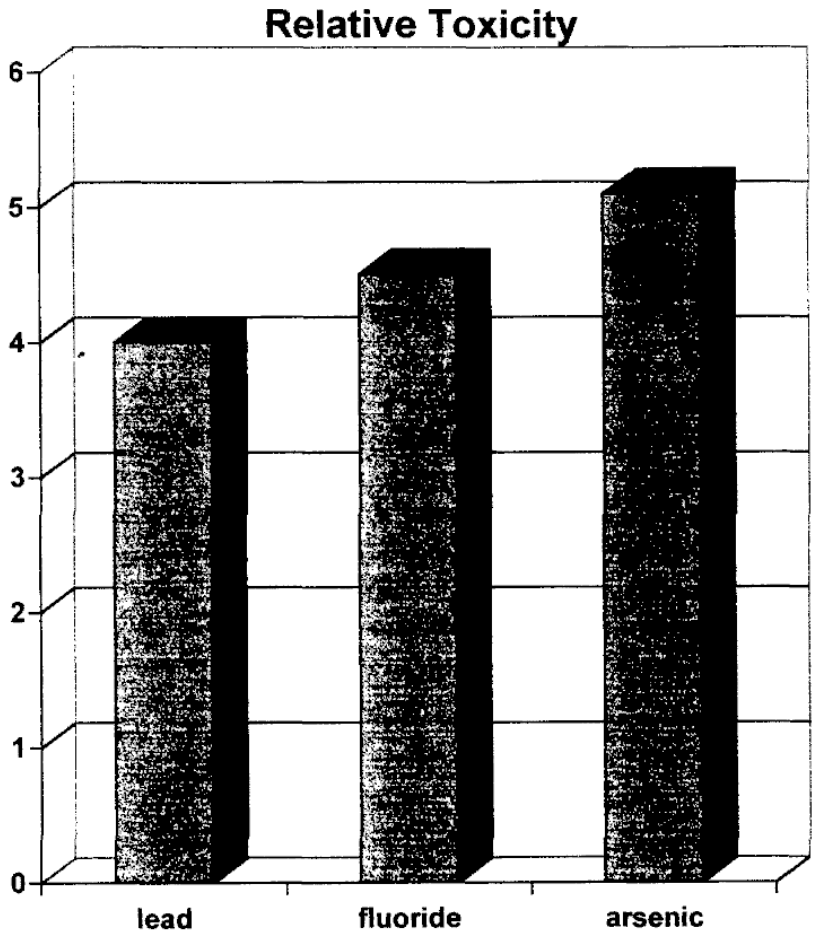
[19] Water treatment with silicofluorides and lead toxicity. Masters, R.D. and Coplan, M.J. Intern. J. Environ. Studies 56 435–49 (1999).

[20] Why I changed my mind about water fluoridation. Colquhoun, J. Perspectives in Biol. And Medicine 41 1–16 (1997).

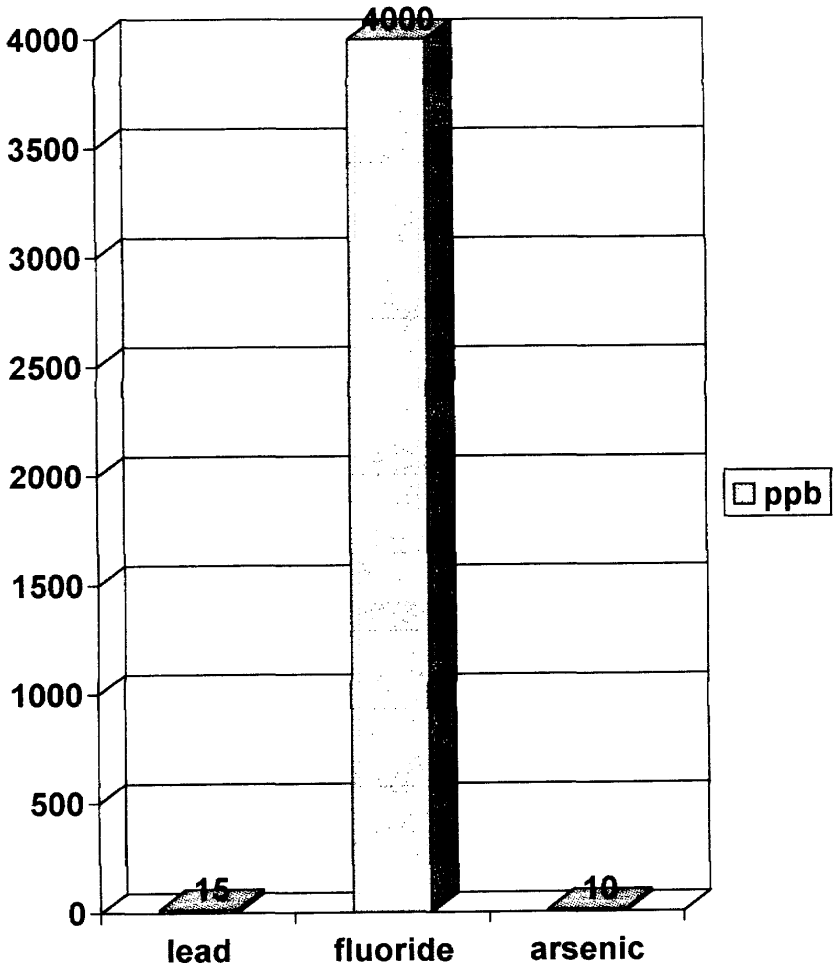
[21] Letter. Limeback, H. April 2000. Faculty of Dentistry, University of Toronto.



1 Practically nontoxic
2 Slightly toxic
3 Moderately toxic
4 Very toxic
5 Extremely toxic
6 Super toxic

From Robert E. Gosselin et al., *Clinical Toxicology of Commercial Products*, 5th ed., 1984.

Maximum Contaminant Levels



Österreichische Vereinigung
für das
Gas- und Wasserfach
ÖVGW
Schubertring 14, Postfach 26
A-1015 Wien
Tel. +43/1/513 15 88-0*
Fax +43/1/513 15 88-25
email: info@fv-ovgw.or.at
Internet: www.ovgw.at

Mister
Eugene Albright

429 Washington Rd.
North Versailles
PA 15137-1956
USA

Wien, am 2000-02-17

Dear Mister Albright,

referring to your letter dated 5.2.2000 we allow us to inform you that toxic fluorides have never been added to the public water supplies in Austria.

If you need further information about the public water supply in Austria please do not hesitate to contact us again.

Kind regards

i.A. Dipl-HTL-Ing M. Eisenhut
Head of Water Department

Sachbearbeiter
Dipl-HTL-Ing M. Eisenhut
Tel.: +43/1/513 15 88/19
eisenhut@fv-ovgw.or.at

DVR0201189, UID ATU37166106
F:\wasser\temp\Albright.doc

Brussels, February 28, 2000

Mr. Eugene Albright
429 Washington Road
N.Versailles, PA 15137-1956

USA

o/ref: CL/046:

Re: Fluoridation of drinking Water
Your letter of February 20, 2000

Dear Sir,

Thank you for your very kind letter and your statements about fluoridation of drinking water.

I can fully confirm your information about the fact that this water treatment has never been of use in Belgium and will never be (we hope so) into the future.

The main reason for that is the fundamental position of the drinking water sector that it is not its task to deliver medicinal treatment to people. This is the sole responsibility of health services. Persons needing an addition of fluoride to their diet must take specific medicine prescribed by their doctor, taking into account also other sources like foodstuff, tooth cleaning cream and so on.

Yours truly,

Chr. LEGROS
Directeur

BELGAQUA: Rue Colonel Bourg, 127 - BE 1140 Brussels
Tél: +322/ 706 40 90 - Fax: +322/ 706 40 99 - Email: info@belgaqua.be

中华人民共和国卫生部
MINISTRY OF HEALTH PEOPLE'S REPUBLIC OF CHINA
北京西城区西直门外南路1号 100044
1 NANLU, XIZHIMENWAI, XICHENG DISTRICT, BEIJING, CHINA

Mr. Eugene Albright
429 Washingtong Road
North Versailles, PA 15137-195C
USA

March 1, 2000

Dear Mr. Albright,

Thank you for your letter dated February 8, 2000 with regard to the current situation of fluoridation in China.

Having consulted with the Ministry of Construction, we would like to inform you that it is not allowed to add fluorides into public drinking water in accordance with the regulations of *the Hygiene Standard of Public Drinking Water in China.*

We hope that the answer fits into your question and please do not hesitate to contact us for more queries.

With best regards,

Sincerely yours,

Gao Xishui
Deputy Director General
Department of International Cooperation
Ministry of Health, China
Fax: +86 10 6879 2295

ROYAL DANISH EMBASSY
Washington, D.C.

Mr. Eugene Albright
429 Washington Road
North Versailles, PA 15137-195C

3200 Whitehaven Street, N.W.
Washington, D.C. 20008
Phone (202) 234 4300
Fax (202) 328 1470
e-mail: wasamb@wasamb.um.dk
http://www.denmarkemb.org

Enclosure File

22 December, 1999

Dear Mr. Albright,

Thank you very much for your interest in Danish affairs.

First of all, please excuse us for not responding to your request until now.

We are pleased to inform you that according to the Danish Ministry of Environment and Energy, toxic fluorides have never been added to the public water supplies in Denmark. Consequently, no Danish city has ever been fluoridated.

We sincerely hope this answers your questions. Should you have any further questions concerning Danish environmental affairs I advice you to contact the Information Centre of the Ministry of Environment and Energy (Læderstræde 1-3; 1201 Copenhagen K; Denmark). For any other information concerning Denmark please do not hesitate to contact us again.

Yours truly,

Klaus Werner

Nyt fra miljøstyrelsen

Special issue
February 1977

The background is that the National Agency of Environmental Protection in a letter of 3rd January 1977 recommended the Minister not to permit fluoridation of drinking water in Denmark. The recommendation of the Agency is among other things based upon the fact that a number of questions on human health and environment are not and hardly can be clarified.

Fluoridation of drinking water

In his answer of 5th January 1977 to a question from the Committee on fluoridation of drinking water, the Minister for the Environment, Helge Nielsen, stated that in his opinion the power conferred by section 48 of the Water Supply Act should not be used to allow the addition of fluoride to drinking water.

miljøstyrelsen - Kampmannsgade 1 - 1604 København V - Tlf. (01) 14 83 10

HELSINKI
WATER
Water Treatment
Juha Hämäläinen/ASa

February 7, 2000

Mr. Eugene Albright
429 Washington Road
North Versailles, PA. 15137
U.S.A.

Dear Sir,

In Finland, as far as we know only Kuopio, a city of about 50,000 inhabitants in eastern Central Finland, has actually practised fluoridation of municipal drinking water from approximately 1970 to 1990. The level was adjusted to 1.2 ppm in treated water. However, fluoridation was discontinued because the inhabitants were against the practice. No harmful effects were found in general, although some special groups of water users may have suffered some inconvenience. Also, people realised they can take fluoride as pills.

In Finland, taking fluoride pills has been the common practice and the method advised for children by (who else!) the Finnish Dentists' Association in 1995. This recommendation was based on 32 references from the western world in 1980-1995, showing that fluoride does help to prevent or limit dental caries.

However, we do not favor or recommend fluoridation of drinking water. There are better ways of providing the fluoride our teeth need.

Sincerely yours,

Paavo Poteri
Acting Managing Director

BUNDESMINISTERIUM FÜR GESUNDHEIT

416-6364
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Postanschrift: Bundesministerium für Gesundheit · 53108 Bonn

Bonn, den 11. Februar 2000

Tel.: (0228) 941-4160 oder 941-0
Fax: (0228) 941-4967 oder 941-4900

Mr. Eugene Albright
429 Washington Rpoad
North Versailles, PA 15137
USA

Dear Mr. Albright,

this is in reply to your inquiry regarding fluoridation of drinking water in Germany.

In the Federal Republik of Germany the drinking water is not fluoridated.

In the former Democratic Republik of Germany (DDR) in several districts the drinking water was fluoridated but after the unification of both German states in 1990 fluoridation was stopped.

In the Federal Republiik of Germany there was in about 1952 a drinking water fluoridation experiment. But it was stopped after one or two years,

Yours sincerely

Dr. K. Quem

Hauptgeschäftsführung DVGW

Mr
Eugene Albright

429 Washington Road

North Versailles, PA, 15137/USA

26 April 2000
Md/St
☎ - 653

Drinking water fluoridation

Dear Mr. Albright,

Thank you for your information on your activities concerning the fluoridation of drinking water. The DVGW is the technical and scientific association on gas and water of Germany (s. attached flyer). The address you first tried to reach near Frankfurt (in Eschborn) is the old address of DVGW, so you reached the right organisation with help of E.H. Schickedanz from the German embassy.

Coming to drinking water fluoridation we fully agree with the Belgian opinion pointed out in the copy of a letter dated 28 February 2000 you kindly made available to us. You will find all information in the attached DVGW-Water-Information No. 34 E. The original version in German language is also attached. Fortunately no government of the „Länder" made use of its right to allow fluoridation. The information is dated 1992, but we still fully agree with this statement.

I hope this information will be of any use for you.

Yours sincerely,

DVGW Central Office
Department Water Resources/Water Quality

Birgit Mendel

Dr. Birgit Mendel
Technical Manager

Wasser-Information 34 E
Edition 8/92

DVGW
Information

DVGW Statement on the Fluoridation of Drinking Water

Recent events have caused the DVGW to review its 1974 statement on the fluoridation of drinking water and to publish an updated version.

Fluoridated drinking water has been available since the end of the sixties to consumers in several cities in the former GDR, including Chemnitz, Magdeburg and Erfurt. The legal basis for this was the Second Implementing Regulation of the "Ordinance Regulating the Hygienic Monitoring of Central Water Supply Systems – Hygienic Monitoring of Drinking Water Fluoridation" (Law Gazette of the GDR, Part II, 1970, 659). Due to the transitional regulations of Dec. 18, 1990 implementing EC law (Federal Law Gazette I, 1990, 2915-2926) drinking water continued to be supplied under the old law in the territory of the former GDR until Dec. 31, 1992.

The addition of fluoride to drinking water in the old federal Länder is addressed in Section 37 para 2 no. 5 of the Act on the general reform of food legislation (Act on food and materials coming into contact with food – Lebensmittel- und Bedarfsgegenständegesetz, LMBG) of 1974 (Federal Law Gazette, Part I, 1974, 1945-1966). According to this law, the "addition of fluorides to drinking water to prevent caries" may be permitted upon request in individual cases as an exception to the legal provisions if the facts justify the assumption that there are no health risks. The Land governments are authorized to regulate the conditions and the procedure for such exceptions more precisely in statutory rules and orders. The governments of the Länder include appropriate authorities responsible for the approval of such exceptions.

Since the effective date of the LMBG on Jan. 1, 1975, no Land government has laid down such statutory rules and orders.

After the water supply companies in the new federal Länder ceased the practice of adding fluorides to drinking water, relevant professional bodies have expressed the fear that this could result in an increase in the incidence of caries.

Therefore the DVGW feels bound to publish a new statement, even though there is no new basic evidence since the mid-seventies that would induce the DVGW to revise its position as stated at that time. Two comprehensive studies of the literature illustrate this. These studies assess scientific publications on the subject of drinking water fluoridation over the last fifteen years.

These studies of the literature will be included in the DVGW series of publications on water for the information of water supply companies and specialists in the population.

The position of the DVGW concerning drinking water fluoridation is as follows:

1. Drinking water is a food. It is the duty of water companies to supply drinking water that meets all requirements of a food. This means that drinking water must be of such a quality that there are no known adverse health effects resulting from its consumption or use.

DVGW information

Compliance with DIN 2000 and the Drinking Water Ordinance guarantee this.

It is not the task of water supply companies to add substances to drinking water intended as prophylactics against illness not caused by drinking water.

The DVGW therefore is against the addition of fluorides to drinking water.

2. Caries is not the manifestation of a fluoride deficiency, but is the result of a generally false nutrition and inefficient dental hygiene. Unwholesome habits resulting in caries are not eliminated by the fluoridation of drinking water; on the contrary, they are promoted.

3. The suggested optimal fluoride concentration of 1 mg per litre is very close to the dose with which long term detrimental effects in people cannot be excluded. The limit of fluoride as specified in the Drinking Water Ordinance is 1,5 mg per litre.

   The very small difference between the concentration regarded as beneficial as a prophylactic and the limit value in drinking water cannot be justified in view of different habits and therefore differing consumption of drinking water and the uncontrolled intake of fluorides from other sources. The safety of a lifelong accumulation of fluoride in the human body as a result of increased intake is disputed in medical science throughout the world.

4. Less than 1 per cent of the fluoride contained in drinking water would act as a prophylactic. More than 99 per cent would be discharged with waste water directly into the environment. This additional fluoride emission into waters is unacceptable for ecological reasons.

5. The consumer cannot avoid fluoridated drinking water made available by public water supply. This mandatory intake of fluoride violates the basic right to bodily freedom from injury and free development of personality provided by the Basic Law of the Federal Republic of Germany.

6. Fluoride intake for the prevention of caries is more effective with specific measures taken by the individual than by fluoridation of drinking water.

7. An assessment of risks vs. benefits involving both the health aspects and ecological consequences justifies DVGW's rejection of the fluoridation of drinking water.

MINISTRY FOR ENVIRONMENT
REPUBLIC OF HUNGARY
Department for International Relations

Mr. Eugene Albright
429 Washington Road
North Versailles
Pa 15137

January 24, 2000

Dear Mr. Albright,

Thank you for your letter of January 12, 2000 requesting information on water fluoridation in Hungary.

I kindly inform you that fluorides are not added to the water supplies in Hungary. In the early sixtieth one city /Szolnok/ was fluoridated but it was very soon stopped. The reason for it was that some technical problems had emerged and so fluoridation did not seem to be reasonable.

May I wish you good health and the best for the year 2000 and a trip to Hungary as well.

Best regards,

Eszter Szövényi
Chief Counsellor

FLUOROSIS RESEARCH & RURAL DEVELOPMENT FOUNDATION
C-103, Saransh, No. 34 Indraprastha Extention, Delhi – 110 092, India
Phone: Off. 272 5156, 273 1886, Resi. 272 6725, E-mail: susheela@ndf.vsnl.net.in

Professor A.K. Susheela, Ph.D., F.A.Sc., F.A.M.S.
Programme Director

May 15, 2000

Mr Engene Albright
429, Washington Road
North Versailles
P.A 15 137 – 1956
USA

Dear Mr Albright,

This has reference to your letter dated Feb. 4.2000 addressed to the Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi – 110 011.

I have been given a copy of your letter wherein, you have enquired about my address.

I wish to provide the information that you have sought, very briefly.

- In India, there is no Fluoridation of drinking water, rather the Government is removing fluoride (defluoridating) the water. Fluoride pollutes the water naturally; fluoride arises from the geological crust.

Toothpaste: In India, we have two kinds of toothpaste available in the market.
(1) Labeled as Fluoridated – where there is deliberate addition of fluoride and it may be as high as 2000 – 3000 ppm.
(2) Plain – where there is no label / mention of fluoride. But it contains fluoride as high as 800 – 1000 ppm. The fluoride arises as a contaminant from the raw material used by the manufacturer. The raw materials used are talc, chalk, calcium carbonate etc.

In reality all Indian toothpastes contain fluoride.

In view of the above, and as we know that fluoride is injurious to health, the Government set-up a committee during late 1980s to review the issue and wanted to amend the Drugs and cosmetic act of 1945, under which toothpaste is manufactured.

The Government introduced 3 stipulations in the Act, after several years of debate.

Viz. 1. All manufacturers should indicate the fluoride content in the paste on the carton / tube.

2. That children below 4 years should not use fluoridated toothpaste as fluoride is injurious to health and that need to be inscribed on the tube and carton.

3. The manufacturing and expiry date of toothpaste need to be inscribed on the tube and carton.

The Draft Gazette notification was published during 1990; after 60 days the final notification was to be published; instead the final Gazette notification appeared in 1992. Then it was discovered that the 2nd stipulation [◯] had disappeared and we are not aware how that happened.

This was widely published by all news papers. The then Minister of Health and Family Welfare had to give the details to a question raised in the Parliament. The Minister appointed a committee to examine the issue and re-introduce the clause. Thereafter what has happened is not known to us to date.

We conduct training-cum-updates on Prevention of Fluorosis for Doctors, Public Health Engineers, Health Workers and Grass-root Level Functionaries. Because of the widespread occurrence of Fluorosis in 17 states out of the 32 states, we decided to educate the public not to use fluoridated toothpaste and other products. That is another way of publicizing the harmful effects of fluoride.

India has an extentive programme on Fluorosis Control and Provision of safe drinking water where we use indigenous technologies to remove fluoride. These activities in the country are supported by Central and State Governments. A large number of Bilateral and UN Agencies also support the activities in India for provision of safe drinking water and Prevention of Fluorosis.

I wonder whether you are aware of the U.K. Government – Review currently "on" under the aegis of the University of York: NHS Centre for Review and Dissemination. The details of the Review is available on **York Website** (www.york.ac.uk/inst/crd/fluorid.htm).

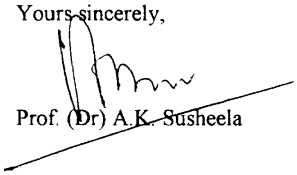
I am also enclosing a Scientific Document which I presented to MPs and LORDs of the House of Commons: The All Party Group against Fluoridation in Westminster, London in October 1998. I had given a number of TV & Radio programmes in U.K.; besides addressed two public meetings: one in Bradford and the other in Birmingham on adverse

effects of fluoride on health. Why don't you do something seriously to appraise the Policy Makers / Administrators who are not aware of the harmful side effects of fluoride in your country. The current Review in U.K. is a sequela of the intensive activities for 10 days in U.K. when I was there personally to address and popularize harmful side effects of fluoride.

Kindly note my change of address for correspondence which is given on the letterhead.

With all good wishes,

Yours sincerely,



Prof. (Dr) A.K. Susheela

ENVIRONMENT AGENCY

Government of Japan

1-2-2 KASUMIGASEKI, CHIYODA-KU
TOKYO 100-8975, JAPAN

TEL. 81-3-3580-1375
FAX. 81-3-3504-1634
TLX. J33855 JPNEA

8 March 2000

Mr. Eugene Albright
429 Washington Rd.
N. Versailles, PA 15137-1956

Title: Fluoridation in Japanese Water Supply System.

Dear Mr. Albright,

With reference to your further letter on fluoridation of drinking water, dated February 15, 2000, I would like to convey some additional information.

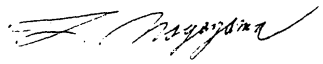
First, you were asking the reason for the no-application of fluoridation in Japan. Colleagues of Ministry of Health and Welfare informed to me the reasons and relevant backgrounds as follows,

In 1958, our government set the standards for Fluorine as 0.8mg/litre (cf. WHO guideline: 1.5mg/litre). This figure has not been changed in the two later revisions of water quality standards in 1978 and 1992, by taking into account the prevention from the occurrence of patched-stain on teeth by excess intake of fluorine.

Japanese government and local water suppliers have considered there is no need to supply fluoridated water to ALL users because 1) impacts of fluoridated water on human health depends on each human being so that inappropriate application may cause health problems of vulnerable people, and 2) there is other ways for the purpose of dental health care, such as direct F-coating on teeth and using fluoridated dental paste and these ways should be applied at one's free will.

I hope above information will help your research.

Sincerely Yours,



Toru Nagayama

Section Chief
Planning Division, Global Environment Department

GRAND-DUCHÉ DE LUXEMBOURG

**ADMINISTRATION
DE
L'ENVIRONNEMENT**

DIRECTION

Luxembourg, May 3, 2000

Mr. Eugene ALBRIGHT
429 Washington Road
North Versailles, PA15137-1956
USA

Dear Mr. Albright,

referring to your letter, dated April 24, 2000 with the request of information regarding fluoridation of drinking water, we would like to confirm your information that fluoride has never been added to the public water supplies in Luxembourg.

In our views, the drinking water isn't the suitable way for medicinal treatment and that people needing an addition of fluoride can decide by there own to use the most appropriate way, like the intake of fluoride tablets, to cover their diary needs.

Best regards

Jean-Marie RIES
Head of the Water Department

Ministerie van Volkshuisvesting,
Ruimtelijke Ordening en Milieubeheer

Rijnstraat 8
2515 XP Den Haag
Interne postcode 630
Tel: 070-339 4261
Fax: 070-339 1288

Directoraat-Generaal Milieubeheer
Drinkwater, Water en Landbouw
Drinkwater, Industriële Emissies en Afvalwaterketen

Eugene Albright
429 Washington Road
North Versailles, PA. 15137
Unites States of America

Uw kenmerk	Uw brief	Kenmerk	Datum
	15 January ~~1999~~		26 January 2000

Onderwerp

Fluoridation

Dear Mr Albright

In reply to your letter of 15 January 2000 I can inform as follows.
From the end of the 1960s until the beginning of the 1970s drinking water in various places in the Netherlands was fluoridated to prevent caries. However, in it's judgement of 22 June 1973 in case No. 10683 (Budding and co. versus the City of Amsterdam) the Supreme Court (Hoge Raad) ruled there was no legal basis for fluoridation. After that judgement amendment to the Water Supply Act was prepared to provide a legal basis for fluoridation. During the process it became clear that there was not enough support from Parlement for this amendment and the proposal was withdrawn (Tweede Kamer, 1975-1976, 12738, No. 24).

The main reason for opposition against fluoridation of drinking water (and against amendment of the law) was that fluoridation was seen as putting a medical additive into drinking water by the government "for the benefit of the society".

Yours sincerely

Wilfred Reinhold
Legal Advisor
Directorate Drinking Water, Water, Agriculture

FOLKEHELSA
Statens institutt for folkehelse
National Institute of Public Health

Mr. Eugene Albright
429 Washington Road
North Versailles, PA 15137-1956
USA

Deres ref. / *Your ref.*:

Vår ref. / *Our ref.*: 523.0, 00/14
MIVA/THO

Saksbeh. / *Inquiries to*: Toril Hofshagen
Phone: +4722042603

Dato / *Date*: Oslo, March 1, 2000

FLUORIDATION OF DRINKING WATER

Dear Mr. Albright,

We refer to your letter, dated February 3, 2000, with questions regarding fluoridation of Norwegian drinking water.

We can confirm that drinking water in Norway is not being fluoridated. In other words, no cities in Norway supply their citizens with fluoridated drinking water.

In Norway we had a rather intense discussion on this subject some 20 years ago, and the conclusion was that drinking water should not be fluoridated. It was thereby up to each individual to decide whether to use fluoride tablets, toothpaste or mouthwash to prevent caries.

Today, most people in Norway are using toothpaste with fluoride, and some parents give their children fluoride tablets. There is no ongoing political discussion in Norway concerning fluoridation of drinking water.

We do hope this answers your questions.

Yours sincerely,

Truls Krogh (authorized)

Toril Hofshagen

ROMÂNIA
MINISTERUL SĂNĂTĂȚII
Direcția Relații Internaționale
Str.Ministerului 1-3, 70109 București, tel./fax: (40 1) 310 05 420

To Mr. Eugene Albright
429 Washington Rd.
North Versailles
PA 15137-1956
U.S.A.

April 6, 2000.

Dear Mister Albright,

I thank you for the information on the water fluoridation situation in U.S.A.

Referring to your letter dated March 14, 2000, I can inform you that in Romania the drinking water is not fluoridated.

Kind regards,

Luminita Popescu
Director

LIVSMEDELS VERKET
NATIONAL FOOD ADMINISTRATION
Drinking Water Division
G Guzikowski

28 February 2000 Dnr 612/00

Eugene Albright
429 Washington Road
North Versailles, PA. 15137
USA

Dear Mr. Albright,

Subject: Drinking Water Fluoridation in Sweden

Thank you for the information on the water fluoridation situation in USA!

Your letter January 12, 2000 on water fluoridation has been forwarded to the National Food Administration (NFA) from the Ministry of Health and Social Affairs. NFA is the central authority in Sweden responsible for drinking water.

Drinking water fluoridation is not allowed in Sweden due to repeal in 1971 of the Drinking Water Fluoridation Act issued 1962.

Since the beginning of the 1980's the discussion on drinking water fluoridation in Sweden has been sparse. New scientific documentation or changes in the dental health situation that could alter the conclusions of the Commission have not been shown.

Nowadays drinking water chemicals and other drinking water matters are regulated under the Drinking Water Ordinance, SLV FS 1993:35, published by NFA. Unfortunately we have the ordinance in Swedish only. In 11 § with annex 2 you find a positive list (enclosed) for chemicals approved for drinking water treatment in Sweden. Fluoride chemicals are not included in the list.

Yours sincerely,

Gunnar Guzikowski
Chief Government Inspector

Community Dent Health 1999 Sep;16(3):160-5

Distribution of caries in 12-year-old children in Sweden. Social and oral health related behavioural patterns.

Flinck A, Kallestal C, Holm AK, Allebeck P, Wall S

Department of Epidemiology and Public Health, Umea University, Sweden.

[Medline record in process]

OBJECTIVE: To describe the distribution of caries in 12-year-old children in Sweden according to socio-demographic and oral health related behaviour. PARTICIPANTS: The study group consisted of 3,373 12-year-old children residing in catchments of 26 different public dental health clinics in Sweden, geographically well represented. METHOD: The clinical examination for dental caries was performed by 28 calibrated dentists. A questionnaire on lifestyle was distributed to the children with questions on ethnicity, socio-economic level and oral health as well as overall health attitudes. RESULTS: The proportion of 12-year-old children with no experience of dentine caries was 47% and 35% were completely free from all caries. Intraoral distribution of caries showed most lesions on the first molar mesial surface, with 80% enamel and 20% dentine caries. Almost all children brushed their teeth twice a day and a third of the children had an extra intake of fluoride. Decayed surfaces including enamel caries (DeS) was chosen as a measure of ongoing caries and used when dividing children into three caries groups; caries free (50%), 1-3 lesions (40%) and the high caries group (10%) with more than 3 lesions. These groups showed distribution differences. More non-Swedish children, children from workers' homes, and children who brushed their teeth less than twice a day were found in the high caries group. More children from workers' homes living in big cities and snacking more than once a week were also found in the high caries group. This could not be shown for other social groups. Also children who had an extra intake of fluoride were classified in the high caries group.

PMID: 10641075, UI: 20105829

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

One of Four

OFFICE OF WATER

DATE: May 1, 1990

SUBJECT: Fluoride Conference to Review the NTP Draft Fluoride Report

FROM: Wm L. Marcus, Ph.D., Senior Science Advisor
Criteria & Standards Division, ODW (WH-550D)

TO: Alan B. Hais, Acting Director
Criteria & Standards Division, ODW (WH-550D)

The conference was held in RTP at the NIEHS headquarters on April 26, 1990. The subject of the conference was a peer review of the NTP draft report on the toxicology and carcinogenesis studies of Sodium Fluoride in F344/N Rats and B6C3F$_1$ Mice (Drinking Water Studies) NTP Report Number 393. Dr. Robert Scala was to chair this meeting but was unable to attend because of ill health. Dr. Michael Gallo was appointed acting Chairperson. One of the attenders seated with the panel members was David Rall, Ph.D., M.D., Director of NIEHS. Dr. Rall took an extremely active interest in the proceedings and remained seated for the entire proceedings with only two minor interruptions.

The most disturbing part of the report was the continual reference to the historical controls as having the same or higher cancers as the test groups. On pages 89 - 90 of the report starting with the last paragraph the authors state the following:

> *An important consideration which limits the usefulness of the historical control data base in the interpretation of the current studies is that the diet used in all other NTP studies had not been closely controlled or monitored for fluoride content. Fluoride concentrations in typical batches of NIH-07 diet range between 28 and 47 ppm (.7 and 1.2 mg/kg/day)(Rao and Knapka[1], 1987). **Assuming** a maximum bioavailability of 60% (Tests show 64% absorption page I-18), the historical database animals actually constitute a group receiving sufficient fluoride sufficient to place them **between** the low- and mid-concentration group in the current (the studies reviewed at RTP at this conference). The fact that this fluoride is available for absorption from the standard diet is supported by the levels of fluoride found in the **bones of animals maintained on this diet in the six months studies** (Appendix 1).* (The levels in the bones of the rats on the standard NIH chow was **ten [10] times** the levels of those

[1]Roa, G.N., and Knappa, J.J. 1987. Contaminant and nutrient concentrations of natural ingredient rat and mouse diet used in chemical toxicology studies. *Fundam. Appl. toxicol.* **9**, 329-338.

fed the semisynthetic diet and deionized water, 0.922 vs 0.0901). *If the fluoride in fact influencing the "spontaneous" or background incidence of osteosarcomas in male rats, comparisons with those in the historical database maybe misleading. This forces an even greater reliance on the within-study comparisons, i.e., the incidences of the dosed groups compared with the concurrent control, in the interpretation of the results of the sodium fluoride studies.*

When I plotted a bar graph of osteosarcoma in male rats and placed the historical controls on the graph 0.6% is just where expected. This helps demonstrate a relationship between osteosarcoma and fluoride. The purpose of such graphs is to predict occurrence. Since the historical controls comprise some 6,000 animals, this data point is extremely significant compared to the other three. Osteosarcoma is an extremely rare animal tumor and may be the result of the variable high fluoride content in the feed. In order to demonstrate this, all that need be done is require that the fluoride content of animal chow be lowered dramatically and that fluoride be removed from the water given to the animals under study.

The dose of fluoride to which the concurrent controls were exposed is 0.2 mg/kg/day. A 70 kg man who drinks 2 liters daily is exposed to 0.03 mg/kg/day. The "control" animals were exposed to an amount of fluoride six to seven (6-7 X) greater. Lois Gold, Ph.D. of the review panel concluded that, "this group of animals therefore, can hardly be termed a control group. It can best be described as a lowest dosed group." This is an important consideration because as the document reports on page 9, the levels of fluoride in bone are linearly dependent upon dose and length of exposure ("depend upon total intake") in people. The level of fluoride in ashed samples of bone of 20-30 year old people is 200 - 800 mg/kg compared to 70 to 80 year old people of 1,000 - 2,500 mg/kg. In the document, the authors cited *Zipkin[2] who reported on bone fluoride concentrations in four groups of individuals with average ages of 56 to 76 who lived in areas with fluoride concentrations in drinking water of 0.1, 1, 2.6, or 4 ppm. The relationship to bone fluoride concentrations and water fluoride content was linear; bone fluoride ranged from about 800 to 7,000 ppm ash with increasing water fluoride."*

In the animal studies the levels of fluoride (Appendix I) found in the bones of the animals were the same as or lower than those found in people. The highest dosed level of rats had lower levels of fluoride in their bones (5,470 ppm) compared to people (7,000 ppm) at the MCL of 4 ppm. This can be interpreted as people who ingest drinking water at the MCL have 1.3 times more fluoride in their bones than male rats who get osteosarcoma. This is the first time in my memory that animals have lower

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[2]Zipkin, L., McClure, F.J., Leone, N.C., and Lee, W.A. 1958. Fluoride deposition in human bones after prolonged ingestion of fluoride in drinking water. *Public Health Rep.* **73**, 732-740.

concentrations of the carcinogen at the sight of adverse effect than do humans. An important toxicologic consideration is that a toxic substance stores at the same place it exerts it toxic activity. This is true of benzene and now for fluoride. Fluoride however, is at twice the concentration in human bones compared to benzene which is 10 to 100 greater in animal marrow. This portends a very serious problem. One would expect to be able to discern a carcinogenic effect in the exposed population when compared to the unexposed population especially if data exist on the populations before fluoridation.

Yiamouyiannis and Burk published epidemiology studies that have since been revised twice[3], by Burk (former head of the Cytochemistry section at NIH). In these extensively peer reviewed papers, the authors found that about 10,000 deaths a year are attributable to fluoride water treatment. The U.S. Public Health Service (U.S.PHS) criticized the original studies by erroneously asserting that the results reported by the authors were a result of changes in the age, race and sex composition of the sample. The U.S.PHS made mathematical errors and did not include 90% of the data. The U.S.PHS method of analysis when applied to the database, confirmed that 10,000 excess cancer deaths yearly were linked to fluoridation of water supplies. This evidence has been tested most recently in the Pennsylvania Courts and found scientifically sound after careful scrutiny.

There were three different short term *in vitro* tests performed on fluoride and all these tests proved fluoride to be mutagenic. An Ames test was performed and reported to be negative. Bruce Ames, in a letter to Arthur Upton introduced in the Congressional Record, stated that his test system was inappropriate for fluoride testing based on a number of technical considerations. EPA's own guidelines require that *in vitro* tests be taken into consideration when found positive. In this case, the mutagenicity of fluoride supports the conclusion that fluoride is a probable human carcinogen.

Melvin Reuber, M.D., a board certified pathologist and former consultant to EPA and part time EPA employee, reviewed some of pathology slides and the Battelle report. Dr. Reuber has had his pathologic diagnoses questioned several times in the past. When an independent board together with Dr. Reuber went over the slides his opinion was always upheld. He first published the work that identified hepatocholangiocarcinoma as a pathologic entity. The report changed Battelle's board certified veterinary pathologists diagnoses from hepatocholangiocarcinoma to hepatoblastoma and finally to hepatocarcinoma. Dr. Reuber reviewed the pathology slides and stated that these lesions are indeed hepatocholangiocarcinoma. Because Dr. Reuber first identified and

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[3]Graham, J.R., Burk, D., and Morin, P. 1987. A current restatement and continuing reappraisal concerning demographic variables in American time-trend studies on water fluoridation and human cancer. *Proc Pennsylvania Academy of Sci.* **61**:138-146.

published his findings on this tumor, I trust his opinion in this matter. These tumors are extremely rare. Dr. Reuber's diagnoses would make the liver cancers significant because of their rarity. This changes the equivocal finding of the board to at least some evidence or clear evidence of carcinogenicity. In addition, the oral changes in the report were down-graded from dysplasia and metaplasia to degeneration. Dr. Reuber said that this change should also be reviewed. The report also down-graded adrenal pheochromocytomas and tumors to hyperplasia. This needs to be reviewed by an independent board. The other liver carcinomas were down-graded to foci by artificially defining a need for 75% compression in the tumor before it was no longer a foci. Using this changed definition carcinomas were down-graded to adenomas and adenomas down-graded to eosinophilic foci. In almost all instances, the Battelle board certified pathologists' findings were down-graded. It is my suggestion that a board independent of NIEHS should be assembled by ODW consisting of human pathologists (for their experience in diagnosing osteosarcoma), the Battelle pathologist (to defend his original diagnoses), Dr. Melvin Reuber, Dr. Thomas Squires and two other well known independent board-certified animal pathologists. The charge to this board is to meet as a body, review the slides, agree on a pathologic diagnoses and prepare a report to be submitted to ODW for incorporation in our docket for the fluoride regulation.

The report talks about the efficacy of fluoride and tooth decay. Since the studies were performed to determine the carcinogenicity of fluoride this should not have been addressed. There appear to be at least four different publications from the U.S., Canada, and New Zealand that have reported similar or lower tooth decay rates in non-fluoridated areas as compared to fluoridated areas[4,5,6,7]. Therefore, the entire question of the efficacy of fluoridation based on extensive and multiple studies has been called into question. Our job is to set safe levels for fluoride in drinking water based on the scientific evidence.

The problem with this meeting was the inability of independent reviewers to get to see the slides prior to the meeting. We must perform our own scientific review of the slides and write our conclusions for use in the development of the revised fluoride regulation.

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[4]Colquhoun, J. 1987. *Comm. Health Studies.* **11**:85.

[5]Gray, S. 1987. *J. Canadian Dental Assoc.* **53**:763.

[6]Hildebolt, C.F. et al. 1989. *Amer J. Physiol. Anthropol.* **78**:79-92.

[7]Diesendorf, M. 1986. *Nature.***322**:125.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
WATER

MEMORANDUM

DATE: May 4, 1998

SUBJECT: A 10% Decrement in I.Q. in Chinese Children as a Result of Fluoride

FROM: William L. Marcus, Ph.D., D.A.B.T., Senior Science Advisor
Office of Science and Technology, 4301

TO :James A. Hanlon, Deputy Director
Office of Science and Technology, 4301

Keeping abreast of the literature, I came across and perused two papers from China[1,2] that report the effect of fluoride on the intelligence of children in the provinces of China detailed below. The authors determined that fluoride caused a 10% decrement in I.Q. Lead caused approximately 1% decrement in I.Q. was responsible for the current lead regulation and the prohibition of adding lead [tetra ethyl (methyl)lead] to gasoline.

The Chinese using their own I.Q. tests measured more than 900 children in Guizhou Province between the ages of 8 and 13. The Dean's method of dental fluorosis and urinary fluoride concentrations was used by the Chinese to divide the cohort of children into geographical areas of fluorosis: slight fluorosis, medium fluorosis, and severe fluorosis. The cohort of children was also divided by I.Q. into <70 low; 70-79 borderline; 80-89 medium; 110-119 upper medium; 120-129 excellent; 129 special excellence. The data shows that there is on average a 10 point decrease in I.Q. of children between the non-fluorosis area and the medium or severe fluorosis areas. The authors state, "that the central nervous systems of children ... are adversely affected by fluoride." "Because no correlation was found between age and I.Q. for children in the medium and severe fluorosis areas, it appears that the influence of a high

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[1]Zhao, L.B., Liang, H.H., Zhang, D.N. and Wu, X.R. 1996. Effect of a High Fluoride Water Supply on Children's Intelligence. Fluoride. 29(4) 190-192. Lu-Liang Public Health Bureau, and Epidemic Station Shanxi.

[2]Li. X.S., Zhi, J.L. and Gao, R.O. 1995. Effect of Fluoride Exposure on Intelligence in Children. Fluoride 28(4): 189-192. Guizhou Provincial Sanitary and Anti-Epidemic Station, Guiyang City, Anshun Prefecture Sanitary and Anit-Epidemic Station and Zhijin County Sanitary and Anit-Epidemic Station.

fluoride environment on the development of intelligence may occur early in development such as during stages of embryonic life or infancy when the differentiation of growth of the nervous system is most rapid (ibid.)."

The Chinese obtained "human embryonic brain tissue from termination of pregnancy operations (ibid.)" that showed the differentiation of brain nerve cells was poor, and brain development was delayed.

The paper from Lu-Liang Province compared a village that had high-fluoride drinking water (4.12 mg/l) where 86% of the population have dental fluorosis, and 9% have bone fluorosis to a village in which only 14% of the population have dental fluorosis with no bone fluorosis. "The results of this study indicate that intake of high-fluoride drinking water from before birth has a significant deleterious influence on children's I.Q. in one of two similar villages. No real difference was found for gender. .. The number of children with I.Q. scores of 69 or below was 6 times that in the healthier low-fluoride village." There was a significantly lower number of children with I.Q. scores that are 110 or higher (45 vs 70) in the high fluoride village. When the adults were screened it showed that the I.Q. scores did not improve with age.

I want to work with the Agency through the established chain of command to insure that the scientific issues are addressed in a professional and proper manner. Given my expertise on the effect of lead on the development of children's I.Q., my position as Senior Science Advisor, and my position description, I should lead a small group of scientists in a preliminary inquiry to determine if this research reaches a potential threshold of scientific validity. The validity and the methods used to collect and analyze the data first have to be carefully examined before the conclusions of these two papers can be tested.

If the preliminary review confirms that the data, methods and analyses as presented have merit I will request immediate permission to go to China along with a small committee of appropriately qualified scientists to interview and review with the authors their research and subsequent findings.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
WATER

MEMORANDUM

DATE: May 22, 1998

SUBJECT: Facsimiles of Requested Fluoride and Related Papers

FROM: William L. Marcus, Ph.D., D.A.B.T., Senior Science Advisor
Office of Science and Technology, 4301

TO: Arnold Kuzmack, Ph.D., Senior Advisor
Office of Science and Technology, 4301

Some recently published research papers on fluoride
Attached are the facsimiles of the papers you requested that I brought to the May 6 meeting.

- The paper, coauthored by EPA scientist Karl F. Jensen, describes alterations in the nervous system as a result of administration of fluoro-aluminum complex (AlF_3) or an equivalent amount of fluoride (F). The authors noted that ingestion of fluoride or aluminum fluoride complex (AlF_3) produced, "striking parallels between Al-induced alterations in the cerebro-vasculature those associated with Alzheimer's disease (AD) and other forms of dementia." Both *free flowing table salt and ground pepper* use aluminum chloride to prevent clumping due to ambient moisture. The fluoride compound commonly added to drinking water systems also contains aluminum.

- The papers from China report that fluoride caused a 10% decrement in I.Q. in children. Lead which causes approximately a 1% decrement in I.Q. was responsible for the current lead regulation and the prohibition of adding lead [tetra ethyl (methyl)lead] to gasoline.

- The Chinese obtained "human embryonic brain tissue from termination of pregnancy operations. " that showed the differentiation of brain nerve cells was poor, and brain development was delayed.

- Dr. Mullinex showed that there are dose dependent increases in brain fluoride up to 7.3 times higher in males that correlate with cognitive deficits. Experience with lead and methylmercury show that *cognitive deficits occur in children at much lower exposure levels* than can be reliably measured in animals. The blood and/or tissue levels of exposed

infants or children that correlate with cognitive deficits are at least one or more often two magnitudes lower than the animal model.

- Appendix C of the Schatz paper is a critical analysis of Report 122 by the British Department of Public Health and Social Security in London, "Special Committee on Research into Fluoridation report. "Figure 1(derived from Table 7 of Report 122) conclusively proves that fluoride does *not* reduce the amount or rate of tooth decay." The figure shows that there was no difference between the slopes (rate of decayed, missing and filled teeth versus age) of the nonfluoridated and fluoridated children (8 to 14+ years of age). The onset of dental caries was delayed about 1.2 years.

In the Jensen paper, the simple addition of sodium fluoride increased aluminum (Al)brain levels two fold when compared to controls. Similarly AlF_3 produced brain Al levels more than two fold greater than controls. The paper concludes that fluoride contributes to higher levels of aluminum in the brain in animals which received AlF_3 as well as those who received just F.

Those animals with higher aluminum levels had in the left hemisphere of their brains the following abnormalities:

- Chromatin clumping (in the cell nucleus)
- Enhanced protein staining
- Pyknosis
- Vacuolization
- And the presence of ghost like cells

The kidney Al levels were twice control in the NaF group and at least four times that of controls. Twenty-seven adult Long-Evans rats were divided into three groups of nine rats. One group of nine imbibed either double distilled deionized drinking water (ddw) , a second group of nine imbibed 0.5 ppm of AlF_3 dissolved in ddw, and the third group 2.1 ppm of NaF. The molar amount of available F in the drinking water was identical in both treatment groups.

Brain Research Journal article:

Varner, J.A., Jensen, K.F.[1],Horvath, W. and R.L. Isaacson. 1998. *Chronic Administration* of Aluminum-fluoride or Sodium-fluoride to Rats in Drinking Water: Alterations in Neuronal and Cerebrovascualr Integrity. Brain Research **784**:284-298.

The two Chinese studies:

Zhao, L.B., Liang, H.H., Zhang, D.N. and Wu, X.R. 1996. Effect of a High Fluoride Water Supply on Children's Intelligence. Fluoride. **29(4)** 190-192. Lu-Liang Public Health Bureau, and Epidemic Station Shanxi.

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[1]Neurotoxicology Division, NHEERL, EPA, Research Triangle Park, NC, USA

Li. X.S., Zhi, J.L. and Gao, R.O. 1995. Effect of Fluoride Exposure on Intelligence in Children. Fluoride **28**(4): 189-192. Guizhou Provincial Sanitary and Anti-Epidemic Station, Guiyang City, Anshun Prefecture Sanitary and Anit-Epidemic Station and Zhijin County Sanitary and Anit-Epidemic Station.

Dr. Mullinex showed that there are dose dependent increases in brain fluoride levels of 5 to 6 month old rats exposed for twenty weeks beginning at 21 days of age. The brain fluoride levels were up to 5.4 or 7.3 times higher than controls in female or male rats respectively. There are cognitive deficits in rats exposed as weanlings or adults. Prenatal exposure induces behavioral changes such as those seen in drug induced hyperactivity.

Experience with lead and methylmercury show that cognitive deficits occur in children at much lower exposure levels than can be reliably measured in animals. The blood and/or tissue levels of exposed infants or children that correlate with cognitive deficits are also one or two magnitudes lower.

Mullenix, P.J., Denbesten, P.K., Schunoir, A. and W.J. Kernan. 1995. Neurotoxicity of Sodium Fluoride in Rats. Neurotoxicology and Teratology. **17**(2):169-177.

The Spittle review paper examines most of the well known high level fluoride effects. Included however is a description of psychological effects that occurred in people ingesting 1.5 ppm during a double blind experiment. Some of the individuals experienced migraine headaches, visual disturbances and depression[2]. A causal relationship between the initiation of HF emissions from a new factory showed both time, meteorological and physical distance to be related to the chronological onset and severity of the following symptomology: generalized progressive fatigue (most often reported), decline in mental acuity, increased forgetfulness, inability to coordinate thought, and a reduced ability to write; 15 cases of parathesias, 14 cases of cephalgia, 7 cases of vertigo, 6 cases of impaired vision and 6 cases of scotomata.

Spittle, B. Psychopharmacology of Fluoride: a review. 1994. Int. Clin. Pyschopharmacol. 9:79-82.

Foulkes, R.G. The Fluoride Connection. 1996. Fluoride. **29**(4):230-236.

This paper further discusses in detail the Chinese papers. There is substantial editorializing and speculation. However Dr. Foulkes put the Chinese data in a graphic format. This analyses demonstrates unequivocally: a flattening of the bell curve for I.Q., the significant lowering of children's I.Q. in the highly fluoridated areas (figures 2 and 4)based on the percentage of the population at a given age with a specific I.Q.

Shatz, A. 1996. Low level fluoridation and low level radiation. Two cases of misconduct in science.

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[2]Grimbergen, G.W. 1974. A Double Blind Test for determination of Intolerance to Fluoridated Water. Fluoride. 7:146-152.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
WATER

May 25, 1999

MEMORANDUM

DATE: May 25, 1999

SUBJECT: Fluoride Update on Adverse Effects on Intellect

FROM: William L. Marcus, Ph.D., D.A.B.T., Senior Science Advisor
Office of Science and Technology, 4301

TO: Tudor Davies, Office Director
Office of Science and Technology, 4301

During the past year I have written three memoranda to the Office Of Science and Technology concerning emerging science literature reporting a 10% decrease in I.Q. caused by drinking water exposure to fluoride. I do not know if my efforts were lost in transit for I have not received any indication or acknowledgment of the new information. I have therefore attached copies for your review.[1]

In August 1998 my concern reached a level of intensity such that I thought that review by an independent working group would be needed to provide unbiased judgement and direction. A memorandum was written to this effect. It too has gone un acknowledged. A copy is enclosed.[2]

The third memorandum dealt with the potential direction which our programs might consider in response to the fluoride data. Once again it appears to have been lost.[3]

Time has only heightened my concern. Drinking water supplies are being fluoridated using fluorosilicic acid. Now there have been additional developments in this field of knowledge.

A scholarly work published by the Ohio Experiment Station Bulletin (no. 558) pages 3-77,in 1935, established that fluorosilicic acid is absorbed by chickens, pigs and rats at three times or more than the rate of other fluoride containing compounds. The paper is entitled, Fluorine in Animal Nutrition was written by Kick CH., Bethke RM., Edington B H, Wilder OHM, Record PR, Wilder W, Hill TJ and Chase SW.

It would appear highly likely that humans also absorb at least three times more fluoride from fluorosilicic acid than from other forms of fluoride as well. Thus allowable exposure levels might yield intakes 3 times higher than assumed in the regulatory process.

Our regulations are based on sodium fluoride addition. The switch to fluorosilicic acid means that the 1 ppm level is in effect the same as a three or more ppm.

Dr. Phyllis Mullinex wrote a letter, on May 5, 1999 to BSA Environmental Services hired by Headquarters, U.S. Army Medical and Material Research Command to look in to the potential problems in fluoridation. Her letter (attached) contains significant new information and associations concerning the adverse effects of fluoride on intellect.

She performed a literature review that "assembled case reports spanning 60 years on neurological effects of in humans exposed to fluoride. A common theme in these reports was that fluoride exposure impaired memory and concentration and it caused lethargy, headache, depression, and confusion. The depression is not something to ignore because suicide occurs more frequently than expected in populations of fluoride workers."

A clinical study of children treated for leukemia... found that the fluorinated steroid (dexamethasone) was more detrimental to IQ than its non-fluorinated steroid counterpart (prednisolone). The study in children showed there were greater deficits " in reading comprehension, arithmetic calculation and short term working memory."

"There is a recent study funded by EPA (Coplan and Masters) which reports that silicofluorides in fluoridated drinking water increase levels of lead in children's blood, a risk factor that predicts higher crime rates, attention deficit disorder and learning disabilities ."

These findings correlate with the animals studies carried out by Dr. P.J. Mullinex which showed that:

- brain function was vulnerable to fluoride in rats;
- the effects on behavior depended on age at time of exposure;
- fluoride accumulated in brain tissue;
- exposed adults displayed behavior-specific changes typical of cognitive deficits;
- prenatally exposed rats had behaviors typical of hyperactivity.

I strongly recommend that it would be prudent for the Office carry out a plan similar to that outlined in my memorandum of August 11, 1998, Establishment of Fluoride Working Group.

I wrote three memoranda concerning a potential 10% decrease in I.Q. caused by fluoride nearly one year ago. (Attached):

1. A 10% Decrement in I.Q. in Chinese Children as a Result of Fluoride, May 4, 1998;
2. Establishment of Fluoride Working Group, August 11, 1998;
3. Programmatic Response to Emerging Toxicology Data-Fluoride, August 31, 1998.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C 20460

MAR 30 1983

OFFICE OF
WATER

Leslie A. Russell, D.M.D.
363 Walnut Street
Newtonville, Mass. 02160

Dear Dr. Russell:

Thank you for your letter of March 9, 1983, in regard to the fluoridation of drinking water.

The information available to the Environmental Protection Agency is that fluoridation is a safe and effective means for reducing the occurrence of dental caries. The fluoridation process has been endorsed by several Presidents of the United States and by several Surgeons General, including the current Surgeon General, Dr. C. Everett Koop. A copy of Dr. Koop's statement on fluoridation is enclosed.

Water treatment chemicals, including fluosilicic acid, have been evaluated for their potential for contributing to the contamination of drinking water. The Water Treatment Chemicals Codex, published by the National Academy of Sciences, prescribes the purity requirements for fluosilicic acid and other fluoridation chemicals.

In regard to the use of fluosilicic acid as a source of fluoride for fluoridation, this Agency regards such use as an ideal environmental solution to a long-standing problem. By recovering by-product fluosilicic acid from fertilizer manufacturing, water and air pollution are minimized, and water utilities have a low-cost source of fluoride available to them. I hope this information adequately responds to your concern.

Sincerely yours,

Rebecca Hanmer

Rebecca Hanmer
Deputy Assistant Administrator
for Water

COMMONWEALTH OF PENNSYLVANIA

SUPREME COURT
SIX GATEWAY CENTER
PITTSBURGH, PENNSYLVANIA 15222

P. FLAHERTY
JUSTICE

July 31, 1979

Sir Dove-Myer Robinson, Mayor
Auckland, New Zealand

Dear Sir Mayor:

I am in receipt of your letter of July 25, 1979, and thank you for it.

You are correct that I entered an injunction against the fluoridation of the public water supply for a large portion of Allegheny County, Pennsylvania. I did this after a very lengthy series of hearings on the issue. The trial brought into my court experts on the subject of fluoridation, and I meticulously considered the objective evidence. In my view, the evidence is quite convincing that the addition of sodium fluoride to the public water supply at one part per million is extremely deleterious to the human body, and, a review of the evidence will disclose that there was no convincing evidence to the contrary. Since my decision, I have received hundreds of letters, quite a few of which have been sent by physicians and dentists, all concurring with my decision. Contrary to your information, my decree has not been set aside by a higher court. Presently, the issue is on appeal to the Commonwealth Court of Pennsylvania, but the appeal involves merely the jurisdiction of the court--it does not involve the substantative merits of the case.

Prior to my hearing this case, I gave the matter of fluoridation little, if any, thought, but I received quite an education, and noted that the proponents of fluoridation do nothing more than try to impune the objectivity of those who oppose fluoridation. I seriously believe that few responsible people have objectively reviewed the evidence. If you are interested, I suggest that you review the twenty-eight hundred pages of testimony and all of the exhibits presented in this case.

Thank you very much for your inquiry.

Sincerely,

JOHN P. FLAHERTY
Justice
Supreme Court of Pennsylvania

JPF:n:d

Fairleigh Dickinson University
Chancellor's Office
140 Ridge Road
Rutherford, New Jersey 07070
201 · 438-6134
201 · 438-1970

PETER SAMMARTINO
CHANCELLOR

December 19, 1978

The Hon. John P. Flaherty, Jr.
Alleghany County Common Pleas Court
Pittsburgh, Pa. 15219

Dear Judge Flaherty:

Every once in a while a judge makes a watershed decision of great moral import. You have made one in regard to fluoridation. It will take about five years for the turn of events to catch up with the seriousness of your decision.

Having founded a school of dentistry I accepted fluoridation like everyone else and had faith in my faculty, in the A.D.A., in the Public Health Service which made sizable grants to our school.

Then one day I read somewhere that water for kidney machines had to be defluoridated. Since I am prone to kidney stones, the statement aroused my interest. I found that the fluorides combine with the calcium in the body and could cause serious illness or even death.

I began to ask my dentists all of whom are specialists in the field and for whom I have great regard. In a pleasant way they said, "Look Peter, this is not your field. Fluoridation is good and it decreases cavities by 60%."

But I began to read and the more I read the more I became convinced that fluoridation was evil. I began to prod the A.D.A. Again, the cavalier response: "Why everyone knows fluoridation is good. Do you think the Public Health Service would be for it if it wasn't good?"

So I began to poke around in Washington. I ran into a wall of gobbledegook. They pointed majestically to the Kingston-Newburgh experiment. Well, I read the report of that experiment six times. That was the most unscientific and souped-up experiment ever foisted as a breakthrough.

The strange part of it all is that the Department of Agriculture tells farmers not to use fluoridated water, and of course, the F.D.A. forbade the manufacture of pre-natal fluoride tablets.

But even if the case for the 60% decrease had been established (which it hasn't) the fact remains that in the United States and in a number of other countries, it is becoming abundantly clear

that the medical side-effects are most serious.

And then, even if fluoridation were effective and even if there were no side effects, the forced medication is totally repugnant to basic principles.

Now, it is becoming evident that the fluoridated communities have eventually a higher rate of tooth defects than non-fluoridated communities.

I am 74 and it doesn't make too much difference to me, but when I think how every day, in fluoridated communities, we are adding a little poison to bodies knowing full well that some of it (probably about 40%) is cumulative, I cringe at our stupidity.

You probably will find that the greatest decision of your professional career will be that on fluoridation and that should give you the greatest moral satisfaction.

I should like to meet you sometime. Do you ever come to New York? Perhaps we could have lunch or dinner at the University Club.

A Merry Christmas to you.

Sincerely,

Peter Sammartino
Chancellor

Dr. Hardy Limeback, BSc, PhD, DDS
Associate Professor and Head, Preventive Dentistry
124 Edward St., Toronto, Ontario, M5G-1G6

Fax (416) 979-4936
Telephone (416) 979-4929
E-mail: hardy.limeback@utoronto.ca

Faculty of Dentistry

University of Toronto

April, 2000

To whom it may concern:

Re: A summary of why I am now officially opposed to adding fluoride to drinking water.

Since April of 1999, I have publicly decried the use of hydrofluosilicic acid as an additive in drinking water. In brief, the following summarize my reasons.

New evidence for lack of effectiveness of fluoridation in modern times.

1. Modern studies (published in the 1980's 1990's) show dental decay rates are so low in North America that fluoridation is no longer effective. They also show that halting fluoridation may result in only a marginal increase in dental decay that cannot be measured. The major reasons for the general decline of tooth decay worldwide, even in non-fluoridated areas, is the widespread use of fluoridated toothpaste, improved diets, and overall improved general and dental health (antibiotics, preservatives, hygiene etc).

2. There is now a better understanding of how fluoride prevents dental decay. What little benefit fluoridated water still provides is derived primarily through topical means (after the teeth erupt and come in contact with fluorides in the oral cavity). Fluoride does not need to be swallowed to be effective. It is not an essential nutrient. Nor should it be considered a desirable 'supplement' in children living in non-fluoridated areas. The notion that systemic fluorides are need in non-fluoridated areas is an outdated one that should be abandoned.

3. Fluoridation has been shown to delay the eruption of teeth and may simply postpone dental decay. No fluoridation study has ever been conducted to investigate this affect on public health surveys or clinical studies investigating the effectiveness of fluoridated water; nor has there been any study conducted to properly separate out any systemic benefit from ingesting fluoride

New evidence for potential serious harm from long-term fluoride ingestion.

4. Hydrofluorosilicic acid is recovered from the smokestack scrubbers during the

production of phosphate fertilizer and sold to most of the major cities in North America, which use this industrial grade source of fluoride to fluoridate drinking water, rather than the more expensive pharmaceutical grade sodium fluoride salt. Fluorosilicates have never been tested for safety in humans. Furthermore, these industrial-grade chemicals are contaminated with trace amounts of heavy metals such as lead, arsenic and radium that accumulate in humans. Increased lead levels have been found in children living in fluoridated communities. Osteosarcoma (bone cancer) has been shown to be associated with radium in the drinking water. Long-term ingestion of these harmful elements should be avoided altogether.

5. Fluoride itself accumulates in bone. Several recent epidemiological studies suggest that only a few years of fluoride ingestion from fluoridated water increases the risk for bone fracture. The relationship between the milder symptoms of bone fluorosis (joint pain and arthritic symptoms) and fluoride accumulation in humans has never been investigated. People unable to eliminate fluoride under normal conditions (kidney impairment) or people who ingest more than average amounts of water (athletes, diabetics) are more at risk for the harmful effects of fluoride.

6. There is a dose-dependent relationship between the prevalence and severity of dental fluorosis. Studies published in the 1980's and 1990's have already shown that dental fluorosis has increased dramatically in North America. A relatively small percentage of the children affected require extensive restorative dental work to correct the damage. Children fed formula made with fluoridated tap water are at higher risk to develop dental fluorosis. The long-term effect of fluoride accumulation on dentin colour and biomechanics is unknown. Generalized dental fluorosis indicates that the skeleton also contains an excess amount of fluoride. Whether stress bone fractures occur more often in children with dental fluorosis has not been studied.

7. A life-time of excessive fluoride ingestion will undoubtedly have detrimental effects on a number of biological systems in the body and it is illogical to assume that tooth enamel is the only tissue affected by low daily doses of fluoride ingestion. Fluoride activates G-protein and a number of cascade reactions in the cell. At high concentrations it is both mitogenic and genotoxic. Some published studies point to fluoride's interference with the reproductive system, the pineal gland and thyroid function. Fluoride is a proven carcinogen in humans exposed to high industrial levels. No study has yet been conducted to determine what level of fluoride bone cells are exposed to when they turn over bone that has accumulated fluoride. The issue of fluoride causing bone cancer cannot be dismissed as being a non-issue when carefully conducted studies have not been carried out determine that the fluoride chemicals added to the water are indeed safe.

The issue of mass medication of an unapproved drug without the expressed informed consent of each individual must also be addressed. The dose cannot be controlled. Fluoride as a drug has contaminated most processed foods and beverages throughout

North America. Individuals who are susceptible to fluoride's harmful effects cannot avoid ingesting this drug. This presents a medico-legal and ethical dilemma and sets water fluoridation apart from vaccination as a public health measure where doses and distribution can be controlled. The rights of individuals or even groups of society to enjoy the freedom from involuntary medication certainly outweigh the right of society to enforce public health measures when the evidence of benefit is marginal at best.

Based on the above 7 points outlined briefly above, new evidence has convinced me that the benefits of water fluoridation no longer outweigh the risks. The money saved from halting water fluoridation programs can be more wisely spent on concentrated public health efforts to reduce dental decay in the populations that are still at risk and this will, at the same time, lower the incidence of the harmful side effects that a large segment of the general population is currently experiencing because of this outdated public health measure.

Sincerely,

Dr. Hardy Limeback BSc PhD (Biochemistry) DDS
Head, Preventive Dentistry

December 13, 1999

Maureen Jones
1205 Sierra Avenue
San Jose, CA 95126

Dear Ms. Jones:

Thank you for your letter on water fluoridation. I also greatly appreciate the reading materials you sent.

Currently, the Committee on Science is investigating this very important issue. As you may know, Ken Calvert, Chairman of the Subcommittee on Energy and Environment, sent a set of questions to EPA Administrator Carol Browner in an attempt to better understand EPA's position on this issue. I am sorry to say that EPA's answers were extremely insufficient, and as such, the investigation will continue.

As Chairman of the House Science Committee, I have always fought to see that the very best science is used in making regulatory decisions. Specifically in this case, many questions still remain concerning the effects different kinds of fluoride might have on the human body. I believe that the science is still out on this issue and I want to assure you that I will continue fighting.

Thank you again for keeping me informed on this very important issue. I hope you will feel free to contact me with any further comments or concerns.

Sincerely,

F. JAMES SENSENBRENNER, JR.
Chairman

May 8, 2000

The Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Dear Administrator Browner:

The Committee on Science received the Environmental Protection Agency's (EPA) response to our letter of May 10, 1999, regarding EPA's maximum contaminant level goal MCL (G) for fluoride in drinking water and we would like to ask further questions to clarify or expand on some of EPA's responses. Similar questions are being sent to other federal government agencies. **Please respond to this letter by June 1st, 2000.**

1. On November 18, 1998, two EPA scientists, Drs. James Murphy and William Hirzy, wrote a memorandum to Dr. Oscar Hernandez, Director of the Risk Assessment Division, Office of Pollution Prevention and Toxics (OPPT) on the subject of the then pending Children's Health Test Rule. Drs. Murphy and Hirzy cited six recent studies that indicated that fluoride might pose a risk of neurotoxicity for children. They also pointed out that a Reference Dose (calculated using standard EPA methodology) and the cited studies would have a range of 0.000007 mg/kg day to 0.003mg/kg day. They noted that no chronic studies of any kind appear to have been conducted on hydrofluosilicic acid or its sodium salt -- which are used in around 90% of water fluoridation systems in the U.S. -- and that the potential for those substances to form complexes with heavy metals (such as lead) has not been studied.

   Given the extremely wide spread exposure of millions of American children to fluoride, and in particular to hydrofluosilicic acid and its sodium salt, along with the Administration's concern for the health of children and these two scientists' positions at EPA, surely EPA has responded to their November 18, 1998, memorandum. Please provide a copy of EPA's response, and what action EPA has taken to deal with the concerns raised in the November 18, 1998, memorandum.

2. Given that normal, healthy teeth do not display fluorosis, does EPA consider the appearance of dental fluorosis as a sign of too much exposure to fluoride? If not, why not? If so, at what incidence level would EPA consider that the population is receiving too much exposure to fluoride?

3. What regulations does EPA have -- either promulgated, under development or under consideration -- to control fluoride emissions to the air, water or soil? Regarding emissions of hydrofluosilicic acid, which EPA has characterized as a water and air pollutant, how does EPA explain its willingness to allow this substance to be bled into drinking water systems (especially in the absence of any chronic toxicity studies on it) - as long as the fluoride level does not exceed 4 mg/L? Is it EPA's policy that the "solution to pollution is dilution" as long as the pollutant is applied directly into drinking water systems and not into fresh surface water?

4. What has EPA done to investigate the charges of science fraud made in the amicus curia brief submitted by your headquarters professionals union in 1986 in the NRDC v. EPA lawsuit over drinking water standards that was filed in that year (and subsequently reiterated by Drs. Robert Carton and William Hirzy of the union in a 1998 National Association of Environmental Professionals publication)?

5. What has EPA done to investigate charges made by Office of Ground Water and Drinking Water Senior Science Advisor Dr. William Marcus that data were tampered with and conclusions improperly down graded in the National Toxicology Program (NTP) cancer study on sodium fluoride? Regarding the NTP study, mandated by Congress in 1977 to specifically exclude the Public Health Service and the National Institutes of Health from involvement with it (because they would not be unbiased), how is it that EPA did not challenge the down grading of the study conclusions?

6. What disciplinary action has been taken against the EPA employees involved in firing Dr. Marcus (and thereby incurring unwarranted expenses to the taxpayers)? What personnel actions have been taken against those involved including promotions, awards, transfers, demotions, firing, etc?

7. Fluoride is well recognized as a general enzyme poison (arising from its powerful hydrogen bonding propensity that disrupts protein [and DNA/RNA] structures) and it displays high acute toxicity (ca. 5 mg/kg as threshold lethal dose), ranking as an acute toxicant lying between lead and arsenic. A host of chronic toxic effects of lead and arsenic are acknowledged by EPA (e.g. hematopoietic effects, cardiovascular effects, neurologic effects, carcinogenicity, etc.). The EPA view of fluoride toxicity appears to be that ingested fluoride strengthens teeth, or will kill, or will inflict skeletal fluorosis, but it has no other chronic toxic effects as its neighbors arsenic and lead do. How does EPA explain this unique toxicological behavior of fluoride, especially in light of its known effect on enzymes?

8. How many individuals in the nation does EPA estimate fall into the category depicted as "unusually susceptible" in the *Toxicological Profile for Fluorides, Hydrogen Fluoride, and Fluoride,* published by the Agency for Toxic Substances and Disease Registry? What measures does EPA recommend for these unusually susceptible individuals who live in fluoridated communities or communities whose water contains fluoride at the MCL (G)?

9. Do you interpret Section 101(b)(4) of the Safe Drinking Water Act of 1996 as requiring EPA to set its MCL(G)s at a level that protects all persons, including sensitive subpopulations, such as infants, children, people who drink 4 or more liters of water per day, people with allergies or hypersensitivity to fluoride, and people with renal disease?

10. Is the EPA satisfied that fluoride doses delivered to the public via drinking water under an MCL(G) of 4 milligrams/liter (mg/l) when added to the fluoride intake from dental products, pesticide residues, food and beverages will not cause adverse health effects?

11. What is the margin of safety for infants who consume drinking water containing 4 mg/l of fluoride?

12. What is the margin of safety for persons receiving kidney dialysis treatment, diabetics or those who have a hypersensitivity or allergy to fluoride who consume drinking water containing 4 mg/l of fluoride?

13. Does the incidence of dental fluorosis among at least an estimated 22% of American children indicate that, at least among these children, an overdosing is occurring?

14. What steps has the Agency taken to address the hazards identified with fluoride exposure in the following publications that appeared since the EPA reaffirmed its drinking water standards for fluoride? These publications include:
    (a) Neurotoxicity of sodium fluoride in rats. Mullenix, P.J., Denbesten, P.K., Schunior, A. and Kernan, W.J. *Neurotoxicology and Teratology* 17 169-177 (1995);
    (b) Influence of chronic fluorosis on membrane lipids in rat brain. Z.Z. Guan, Y.N. Wang, K.Q. Xiao, D.Y Dai, Y.H. Chen, J.L. Liu, P. Sindelar and G. Dallner, *Neurotoxicology and Teratology* 20 537-542 (1998);
    (c) Chronic administration of aluminum-fluroide or sodium-fluoride to rats in drinking water: alterations in neuronal and cerebrovascular integrity. Varner, J.A., Jensen, K.F., Horvath, W., and Isaacson, R.L. *Brain Research* 784 284-298 (1998);
    (d) Effect of high fluoride water supply on children's intelligence. Zhao, L.B., Liang, G.H., Wu, X.R. *Fluoride* 29 190-192 (1996);
    (e) Effect of fluoride exposure on intelligence in children. Li, X.S., Zhi, J.L., and Gao, R.O., *Fluoride* 28 (1995);
    (f) Effect of fluoride on the physiology of the pineal gland. Luke, J.A. *Caries Research* 28 204 (1994).

15. Please provide copies of any risk assessment documents in EPA files that pertain to fluorine bearing pesticides, such as cryolite.

16. Have any studies on hydrofluosilicic acid or silicofluorides been submitted to EPA under claimed Confidential Business Information protection?

17. Does the EPA support the recommendations made in the draft report of the Joint Science Advisory Board Scientific Advisory Panel Subcommittee on Data From Testing of Human Subjects that states, "... in no case should developing humans be exposed to neurotoxic chemicals

18. Has the so called "10x factor" been considered or applied in any way for fluorine bearing pesticides under the FQPA?

19. Has the final rule and resulting risk assessment found in FR, Vol. 62, No. 234, Friday, December 5, 1997, "Fluoride has been identified as the residue of toxicological concern in cryolite and synthetic fluoride and the available data show that these compounds which are approximately 52.8% fluoride, act as free fluoride." been applied to any other substances?

20. What is the Water Quality Criterion under the Clean Water Act for protection of aquatic life (and for protection of human health) for fluoride?

Please provide the committee with copies of any EPA publications, studies, reports, memos, or any other correspondence relating to the fluoride MCL(G) and water fluoridation.

I respectfully request your response to our concerns. Thank you for your attention to this matter.

Sincerely,

KEN CALVERT
Chairman
Subcommittee on Energy and Environment

Enc.
KC/tjv

May 8, 2000

The Honorable Jeffrey P. Koplan
Director
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30333

Dear Director Koplan:

The Committee on Science asked for and received the Environmental Protection Agency's (EPA) response to our letter of May 10, 1999 regarding EPA's maximum contaminant level goal MCL (G) for fluoride in drinking water (enclosed). In the response, EPA suggested that some of the answers were within purview of the Centers for Disease Control (CDC). **Please review the enclosure and provide your comments and respond to the enclosed questions by June 1st, 2000.**

1. Given that normal, healthy teeth do not display fluorosis, does CDC consider the appearance of dental fluorosis in an individual as a sign of too much exposure to fluoride? If not, why not? If so, at what incidence level in the population would CDC consider that the population as a whole is receiving too much fluoride. If CDC does not consider dental fluorosis to be a sign of over exposure, would CDC be comfortable with a 100% incidence of dental fluorosis in America's children?

2. What is the cost nation wide of repairing fluorosed teeth? If you do not have data, what is CDC's estimate of the cost, and when will you have the data?

3. What is the basis for using the second most damaged tooth as the index for determining whether dental fluorosis is present and its severity? In other words, why must at least two teeth present with fluorosis before the diagnosis is made?

4. What is CDC's view regarding the value of the Precautionary Principle as a basis for public health protection?

5. Please provide specific citations for the studies that CDC regards as most persuasive in proving that ingested fluoride reduces incidence of dental caries? If the 1986 1987 National Survey is not included, why not? If it is included, please provide the rationale for that study using decayed or filled *surfaces,* rather than decayed, missing or filled teeth, as the reported metric? If it is included, how does CDC account for scatter among fluoridated, partially fluoridated and non fluoridated communities with respect to ranking for lowest caries incidence?

6. Does CDC subscribe to the recommendations of the American Dental Association and the American Medical Association that children under six months of age should receive no fluoride? If not, why not? If so, what measures does CDC recommend for families living in communities with fluoridated water to prevent infant exposure to fluoride?

7. How many individuals in the nation (CDC estimates) fall into the category called "unusually susceptible" in the *Toxicological Profile for Fluorides, Hydrogen Fluoride, and Fluoride,* published by the Agency for Toxic Substances and Disease Registry? What measures does CDC recommend for unusually susceptible individuals who live in fluoridated communities?

Please provide the committee with copies of any CDC publications, studies, reports, memos, or any correspondence relating to fluoride or water fluoridation.

I respectfully request your response to our concerns. Thank you for your attention to this matter.

Sincerely,

KEN CALVERT
Chairman
Subcommittee on Energy and Environment

Enc.
KC/tjv

May 8, 2000

The Honorable Jane E. Henney
Commissioner
US Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henney:

The Committee on Science asked for and received the Environmental Protection Agency's (EPA) response to our letter of May 10, 1999 regarding EPA's maximum contaminant level goal MCL (G) for fluoride in drinking water (enclosed). In the response, EPA suggested that some of the answers were within purview of the Food and Drug Administration (FDA). **Please review the enclosure and provide your comments and respond to the enclosed questions by June 1st, 2000.**

1. If health claims are made for fluoride containing products (e.g., that they reduce dental caries incidence or reduce pathology from osteoporosis), to such claims mandate that the fluoride containing product be considered a drug, and thus subject the product to applicable regulatory controls?

2. Are there any New Drug Applications (NDA) on file, that have been approved, or that have been rejected, that involve a fluoride containing product (including fluoride containing vitamin products) intended for ingestion with the stated aim of reducing dental caries? If any such NDAs have been rejected, on what grounds were they rejected? If any such NDA have been approved, please provide the data on safety and efficacy that FDA found persuasive.

3. Does FDA consider dental fluorosis a sign of over exposure to fluoride?

4. Does FDA have any action level or other regulatory restriction or policy statement on fluoride exposure aimed at minimizing chronic toxicity in adults or children?

The Honorable Jane E. Henney
May 8, 2000
Page two

Please provide the committee with copies of any FDA publications, studies, reports, memos, or any correspondence relating to fluoride and water fluoridation.

I respectfully request your response to our concerns. Thank you for your attention to this matter.

Sincerely,

KEN CALVERT
Chairman
Subcommittee on Energy and Environment

Enc.
KC/tjv

May 8, 2000

Dr. Bruce M. Alberts
President
National Academy of Sciences
2101 Constitution Avenue, NW
Washington, DC 20418

Dear Dr. Alberts:

The Committee on Science asked for and received the Environmental Protection Agency's (EPA) response to our letter of May 10, 1999 regarding EPA's maximum contaminant level goal MCL (G) for fluoride in drinking water (enclosed). Some of the answers appear to be within the purview of the National Academy of Science (NAS). **Please review the enclosure and provide your comments and respond to the enclosed questions by June 1st, 2000.**

1) NAS/IOM's Dietary Reference Intakes (DRI) publication establishes 10 mg/day as a tolerable upper level of intake for those aged 9 years or older. That document also asserts that crippling skeletal fluorosis (defined as Stage III skeletal fluorosis by Roholm) can occur with intakes of 10 mg or greater per day for 10 or more years.
   a) Does NAS/IOM consider it is acceptable for a person to begin intakes of 10 mg/day at age 9 years (let alone previous intake of this cumulative agent at earlier ages) and then by age 19 be at risk of crippling skeletal fluorosis?
   b) Does NAS/IOM consider it acceptable for a person to acquire Stage I or Stage II skeletal fluorosis at any time in life? (Or are these considered "cosmetic" effects?)
   c) What does NAS/IOM consider the minimum dose rate at which Stage I skeletal fluorosis may appear?

2. Please provide a list of publications and curriculum vitae for all members of NAS/IOM responsible for producing the section on fluoride of the DRI.

3. Fluoride is well recognized as a general enzyme poison (arising from its powerful hydrogen bonding propensity that disrupts protein [and DNA/RNA] structures) and it displays high acute toxicity (around 5 mg/kg as threshold lethal dose), ranking as an acute toxicant lying between lead and arsenic. A host of chronic toxic effects of lead and arsenic are acknowledged by the science community (e.g. hematopoietic effects, cardiovascular effects, neurologic effects, carcinogenicity, etc). NAS/IOM's view of fluoride toxicity appears to be that ingested fluoride strengthens teeth, or will kill, or will inflict skeletal fluorosis, but it has no other chronic toxic effects as arsenic and lead do. How does NAS/IOM explain this unique toxicological behavior of fluoride, especially in light of its known effect on enzymes?

4. What is the minimum concentration of fluoride ion at which enzyme inhibition occurs? How does this concentration compare with serum levels of fluoride in individuals of around 45 kg weight who ingest 10 mg/day of fluoride?

Please provide the committee with copies of any NAS publications, studies, reports, memos, or any correspondence relating to fluoride and water fluoridation.

I respectfully request your response to our concerns. Thank you for your attention to this matter.

Sincerely,

KEN CALVERT
Chairman
Subcommittee on Energy and Environment

May 8, 2000

Mr. Joe Cotruvo
Vice President
NSF International Washington DC Office
1301 K Street NW, Suite 225
Washington, DC 20005

Dear Mr. Cotruvo:

The Committee on Science asked for and received the Environmental Protection Agency's (EPA) response to our letter of May 10, 1999 regarding EPA's maximum contaminant level goal MCL (G) for fluoride in drinking water (enclosed). Some of the questions appear to be within the purview of NSF International. The Committee would be interested in receiving your comments and answers to the enclosed document and questions below. **Please respond to the enclosed questions by June 1st, 2000.**

1. Please provide the identification and affiliation of each member of the committee or committees contributing to the policies established for each of the fluorine bearing additives destined for the public water supplies, both current committee members and those responsible for establishing product standards for fluoride.

2. Under General Requirements 3.2.1, Formulation submission and review, ANSI/NSF 60 - 1999, are manufacturers of hydrofluosilicic acid and silicofluorides required to "submit for each product, when available, a list of published and unpublished toxicological studies relevant to the treatment chemical and the chemicals and impurities present in the treatment chemical?" Has your document, General Requirements 3.2.1, Formulation submission and review, ANSI/NSF 60 - 1999, been peer reviewed for accuracy? If so, please provide the names, affiliations and contact information for the peer reviewers.

   Please provide:
   - All lists complying with the above requirement submitted by manufacturers of hydrofluosilicic acid and silicofluorides.
   - The complete record of all tests of each fluorine bearing additive using ion chromatography, atomic absorption spectroscopy, and scintillation counting.

- A true and complete copy of all tests that identify the full composition of each fluorine bearing additive, including all attendant organic substances, radionuclides and other chemicals.
- Copies of any and all tests or studies of each of the fluorine bearing additives that consider or indicate degree of dissociation.
- Copies of any and all studies that have been performed on laboratory animals using hydrofluosilicic acid or silicofluorides.
- Copies of any risk assessment documents in NSF International files that pertain to fluorine bearing pesticides, such as cryolite.

3. Have any studies on hydrofluosilicic acid or silicofluorides been submitted to NSF under claimed Confidential Business Information protection?

4. What are the Maximum Contaminant Levels, or any other regulatory standards, established for the following contaminants (either singularly, in combination with another substance, or in the elements' various forms) or any other contaminants reported as present in the fluorine bearing substances hydrofluosilicic acid and other silicofluorides used in fluoridation programs?

Arsenic
Barium
Beryllium
Cadmium
Chromium
Crystalline Silica
Fluorine
Hydrogen Fluoride
Iron
Iodine
Lead
Lead 210
Mercury
Phosphorous
Polonium 210
Radon 222
Selenium
Silica
Silver

Specific agents used or present in phosphate/hydrofluosilicic processing
- Oil based de foamers
- Dioxins
- Polymers
- Petroleum products
- Naphthalene
- Chlorides
- Sulfides
- Synspar

Any other reagents associated with the phosphate/hydrofluosilicic processing

5. What tests are performed to identify the full and exact consistency of the fluorine bearing product and determine the concentrations of each of the contaminants or combination of contaminants in a sample? Upon what occasion or frequency are these tests performed? Are Certificates of Analysis provided with each shipment of such products from the manufacturer?

6. What is the purpose of establishing a maximum allowable level (MAL) for additives, restricting the contribution to drinking water of any one product to 10% of the Maximum Contaminant Level (MCL)?

7. Under what circumstance or authority is an additive certified when the MAL of 10% of the established MCL is exceeded?

8. What tests and how often are they performed by NSF International to determine the exact consistency and concentrations of all contaminants in hydrofluosilicic acid, silicofluoride and sodium fluoride products? What is the ratio of NSF International tests to shipments by manufacturers of the additives? Are NSF International test results compared with Certificates of Analysis as a quality assurance measure?

Please provide the committee with copies of any NSF International publications, studies, and reports relating to fluoride.

I respectfully request your response to our concerns. Thank you for your attention to this matter.

Sincerely,

KEN CALVERT
Chairman
Subcommittee on Energy and Environment

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FLORIDA STATE UNIVERSITY COLLEGE OF LAW

HIGHLIGHTS IN NORTH AMERICAN LITIGATION DURING THE TWENTIETH CENTURY ON ARTIFICIAL FLUORIDATION OF PUBLIC WATER SUPPLIES

JOHN REMINGTON GRAHAM* AND PIERRE-JEAN MORIN**

Table of Contents

I. INTRODUCTION***

Fluoride is an ubiquitous substance in our environment. It is naturally present in public water supplies, bound with calcium, iron, magnesium, or other minerals, usually at a level of around 0.2-0.4

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* B.A., LL.B., of the Minnesota Bar. Federal Public Defender, 1969-1973; Co-Founder, Instructor, Assistant Professor, Associate Professor, Lecturer, Hamline University School of Law, 1972-1980; Special Counsel for the City of Brainerd, 1974-1980; Crow Wing County Public Defender, 1981-1984; Crow Wing County Attorney, 1991-1995; Advisor on British constitutional law and history to the Amicus Curiae for Quebec in the Supreme Court of Canada, 1997-1998. Mr. Graham has served as counsel in major fluoridation litigation in Minnesota, Washington State, Pennsylvania, Illinois, and Texas, 1974-1984.

** Ph.D. in Experimental Medicine. Chief Profusionist, Royal Victoria Hospital in Montreal, 1957-1967; Coordinator for Research in the Heart Institute and Artificial Organs Group, and Lecturer in Medicine, Laval University, 1967-1979; Director of Medical Research, Laval University Hospital, 1973-1979; Senior Scientific Advisor to the Environment Minister and the Prime Minister of Quebec, 1976-1985; Director, Local Community Services Center, Lotbiniere West, 1979-1990. Dr. Morin was scientific advisor to counsel for the plaintiffs in major fluoridation litigation in Texas in 1982.

*** The authors wish to express their gratitude to J. William Hirzy, Ph.D., Senior Vice President of the National Treasury Employees Union, Chapter 280, at the National Headquarters of the United States Environmental Protection Agency (EPA) for documentation concerning developments at EPA from 1986 through 1998, and also to Rt. Hon. Edward Baldwin, Earl of Bewdley, for his assistance in securing records of important debates on fluoridation in the British House of Lords.

ppm. Except incidentally, this article will not address the natural presence of fluoride in drinking water, which is a distinct question. The focus of this article will be the artificial fluoridation of public water supplies which occurs when the fluoride content of drinking water is artificially adjusted from its natural level to a desired level of 0.9-1.2 ppm. This change is effected by adding sodium silico fluoride, hydrofluosilicic acid, or some such industrial waste product, which releases free fluoride ions into water consumed by human beings.[1]

The theory behind this practice, which now affects about 130 million people in the United States, is that the ingestion of fluoride will harden the surfaces of teeth and make them less susceptible to dental caries. The literature is extensive on whether this practice does or does not reduce tooth decay, and whether it is or is not safe.[2] The standard work, done under auspices of the American Dental Association (ADA) and the United States Public Health Service (USPHS) is the *Newburgh-Kingston Caries-Fluorine Study: Final Report*.[3] Published over forty years ago, it proudly concluded that artificial fluoridation of public water supplies dramatically reduces tooth decay in humans, at no risk to human health.[4] In language tinged with contemporary fanaticism, the *Final Report* announced, "The opposition stems from several sources, chiefly food faddists, cultists, chiropractors, misguided and misinformed persons who are ignorant of the scientific facts on the ingestion of water fluorides, and, strange as it may seem, even among a few uninformed physicians and dentists."[5]

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1. See GEORGE L. WALDBOTT, M.D. ET AL., FLUORIDATION: THE GREAT DILEMMA 47-54, 148-74 (1978) for a detailed discussion of the absorption of fluoride, mainly as free ions, into the soft tissues of the human body. On the other hand, when fluoride is naturally present in public water supplies, it is generally bound with calcium and other minerals and, in such form, it does not readily disassociate and so is more readily excreted. Experiments with trout indicate that fluoride in water so bound tends to be less toxic. *See* Joseph W. Angelovic et al., *Temperature and Fluorosis in Rainbow Trout*, 33 J. WATER POLLUTION CONTROL FED'N 371 (1961). Hence, the artificial presence of fluoride in drinking water should be considered separately from its natural presence, at least in connection with questions about whether or not fluoride in drinking water produces harmful side effects.

2. The most respected scientific works, published during the twentieth century in support of artificial fluoridation of public water supplies, are WORLD HEALTH ORGANIZATION, FLUORIDES AND HUMAN HEALTH (1970), and FRANK J. MCCLURE, U.S. DEP'T OF HEALTH, EDUCATION, AND WELFARE, WATER FLUORIDATION: THE SEARCH AND THE VICTORY (1970). The work of WALDBOTT ET AL., *supra* note 1, is a comprehensive and powerful rebuttal. Considerable research has been done since these classic treatises were published.

3. Herman E. Hilleboe et al., *Newburgh-Kingston Caries Fluorine Study: Final Report*, 52 J. AM. DENTAL ASS'N 290 (1956).

4. *See id.* at 313-14, 316-19 (1956).

5. *Id.* at 294.

From the beginning, this ostentatious pronouncement has set the tone of ADA and USPHS activists and others promoting this practice in the face of growing opposition from eminent scientists and physicians. The ultimate merits of the issues in science and medicine aside, there has always been learned and respectable opposition to artificial fluoridation of public water supplies,[6] and all attempts to deny it can only be characterised as irresponsible.

A few preliminary questions need to be asked. The first is whether the natural or artificial level of fluoride in public water supplies really has any beneficial effect in reducing tooth decay. The main difficulty with the experimental runs at Newburgh and Kingston in New York and elsewhere is that tooth decay is enhanced or diminished by innumerable factors including dietary, socio-economic, environmental, hygienic, and many others. Thus, criticism was voiced, initially in a doctoral dissertation,[7] that there was no control for known and unknown variables and, consequently, the conclusions on the reduction of tooth decay associated with fluoridation were invalid.

Subsequent research, involving vastly more data and sophistication, has entirely upset the Newburgh-Kingston orthodoxy.[8] It has since been persuasively demonstrated that the lowest rates of tooth decay in children occur in areas where the fluoride level is about 0.2-0.4 ppm, which is the normal level in most parts of the world.[9] From all published studies on the question in Europe and North America,

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6. *See, e.g., Hearings on H.R. 2341 Before the House Comm. on Interstate and Foreign Commerce*, 83d Cong. 62-86 (1954) (statement of Frederick Exner, M.D.). In his time, George Waldbott, M.D., was the dean of physicians against fluoridation. His pioneering book, A STRUGGLE WITH TITANS (1965), is bound to be of great interest to scientific historians in future years. He was a founder of the International Society for Fluoride Research, a learned society of about five hundred scientists who specialize in the field, publishing a quarterly journal entitled *Fluoride*.

7. *See* Edward S. Groth III, Two Issues of Science and Public Policy: Air Pollution Control in the San Francisco Bay Area and Fluoridation of Community Water Supplies 146-462 (1973) (unpublished Ph.D. dissertation, Stanford University) (on file with University Microfilms in Ann Arbor, Michigan).

8. *See, e.g.*, H. Kalsbeek & G.H.W. Verrips, *Dental Caries Prevalence and the Use of Fluorides in Different European Countries*, 69 J. DENTAL RES. 728 (1990); Rudolph Ziegelbecker, *WHO Data on Dental Caries and Natural Water Fluoride Levels*, 26 FLUORIDE 263 (1993) (setting forth impressive analyses of data published by the World Health Organization). Trends now evident in Newburgh and Kingston indicate no significant differences in tooth decay rates between the two cities, although dental mottling is somewhat higher in fluoridated Newburgh. *See, e.g.*, Jayanth V. Kumer et al., *Trends in Dental Fluorosis and Dental Caries Prevalences in Newburgh and Kingston, NY*, 79 AM. J. PUB. HEALTH 565 (1989); Jayanth V. Kumer et al., *Changes in Dental Fluorosis and Dental Caries in Newburgh and Kingston, New York*, 88 AM. J. PUB. HEALTH 1866 (1998); Jayanth V. Kumer et al., *Recommendations for Fluoride Use in Children*, N.Y.S. DENTAL J., Feb. 1998, at 40.

9. *See, e.g.*, Yoshitsugu Imai, *Relationship Between Fluoride Concentration in Drinking Water and Dental Caries in Japan*, 6 FLUORIDE 248 (1973).

it has been shown that, while there is a strong positive relationship between dental mottling and the natural level of fluoride in drinking water, there is no statistical relationship between the extent of tooth decay and the natural level of fluoride in drinking water.[10] In more recent years, it has been observed that tooth decay rates have decreased as fast in unfluoridated areas as in fluoridated areas.[11] From massive data gathered by the government of the United States, it has been revealed that there is no statistical relationship between rates of tooth decay in children and the extent or duration of artificial fluoridation of public water supplies.[12]

Another question is whether public officials of the United States have been honest in levelling with the American people about the potential harmful effects of artificially releasing fluoride into the environment. In this regard, some attention needs to be given to the seminal work of Dr. Alfred Taylor, a biochemist at the University of Texas. The facts have been written up by reputable scholars[13] and make up an important episode in scientific history.

In the early 1950s, Dr. Taylor undertook a series of preliminary experiments by which it appeared that cancer-prone mice consuming water treated with sodium fluoride had shorter life spans than mice drinking distilled water.[14] Because the mice in both the control and experimental groups ate chow containing measurable fluoride, probably as CaF, as he learned after his initial runs, Dr. Taylor replicated his earlier work, but used chow containing negligible fluoride. He ran twelve experiments using 645 cancer-prone mice. He found that, as measured for statistical significance, cancer-prone mice drinking water containing fluoride, introduced as NaF, had shorter life spans than mice drinking distilled water.[15] In 1954, the results of Dr. Taylor's reruns were published in a refereed journal.[16]

Dr. Taylor's work was published at a politically sensitive time, because the last stages of the much-boasted surveys at Newburgh and Kingston were underway. The obvious meaning of Dr. Taylor's

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10. Rudolph Ziegelbecker, *Natürlicher Fluoridgehalt des Trinkwassers und Karies* [*Natural Fluoridation of Drinking Water and Caries*], 122 GWF WASSER/ABWASSER 495 (1981), translated in 14 FLUORIDE 123 (1981).

11. John Colquhuon, *Child Dental Health Differences in New Zealand*, 9 COMM. HEALTH STUD. 85 (1987).

12. John Yiamouyiannis, *Water Fluoridation and Tooth Decay: Results from the 1986-1987 National Survey of U.S. Schoolchildren*, 23 FLUORIDE 55 (1990)

13. *See, e.g.*, WALDBOTT ET AL., *supra* note 1, at 222-25.

14. *See id.* at 222.

15. *See id.* at 222-23.

16. *See* Alfred Taylor, *Sodium Fluoride in the Drinking Water of Mice*, 60 DENTAL Dig. 170 (1954).

results was that a possible danger to public health had been overlooked, and that widespread fluoridation should be delayed until the situation had been clarified. However, the ADA and the USPHS had already endorsed and begun the drive to promote fluoridation.

The embarrassment, therefore, had to be addressed. In the *Final Report*, reference was made to Dr. Taylor's original tests two years after the positive results of his reruns had been peer-reviewed and published. Then it was said, contrary to the known state of world literature:

> The reports by Alfred Taylor, a biochemist at the University of Texas, on the increased incidence of cancer in mice drinking fluoride-treated water have been shown to be unfounded, since the food that he was giving the mice had many times the fluoride content of the drinking water, and the food was supplied both to the control and experimental groups. Subsequent tests did not confirm the differences.[17]

Ever since, USPHS officials have insisted, contrary to known facts, that Dr. Taylor's reruns were never done and never published, and that no work supporting Taylor's results exists or has ever been published. For example, in a standard history of the National Institute of Dental Health, published thirty-five years after Dr. Taylor's work first appeared in a refereed journal, Roth Roy Harris said, "Alfred Taylor, the investigator with a doctorate in biochemistry, indicated that he would not publish his findings because he was unable to confirm those results in a second experiment."[18] Harris added still another misrepresentation, also contrary to known facts, "A literature search of scientific journals failed to show any publication of this work by Taylor -an indication that it was not subjected to review by his peers."[19] The most powerful forensic evidence of the importance of Dr. Taylor's work is that USPHS officials have done so much to conceal it.

After his first study, Dr. Taylor and his wife, also a Ph.D. biochemist, published the results of yet another large-scale study, in which fluoride in water, introduced as NaF, was shown to induce growth in implanted tumors in mice.[20] Dr. Taylor's pioneering work

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17. Hilleboe et al., *supra* note 4, at 313.

18. RUTH ROY HARRIS, DENTAL SCIENCE IN A NEW AGE, HISTORY OF THE NATIONAL INSTITUTE OF DENTAL RESEARCH 112 (1989).

19. *Id.* at 396 n.33.

20. *See* Alfred Taylor & Nell Carmichael Taylor, *Effect of Sodium Fluoride on Tumor Growth*, 119 PROC. OF SOC'Y FOR EXPERIMENTAL BIOLOGY AND MED. 252 (1965).

has been confirmed and reconfirmed by a considerable multitude of laboratory studies done by world class scientists, all published in peer-reviewed journals.[21] Meanwhile, it has been held in some environmental litigation during the twentieth century that, if laboratory tests indicate the capacity of a certain substance to produce harmful side effects in laboratory animals, the same substance may also be presumed deleterious to man in the environment.[22]

The main inquiry of this article will be whether the several States have constitutional authority to impose artificial fluoridation of public water supplies. The question depends in part on scientific and medical facts. As we shall relate in detail, trial judges over the past twenty years have repeatedly found, after hearing experts, that fluoridation is injurious to public health. We proceed, first, to review the legal fundamentals.

II. THE NATURE OF POLICE POWER

The first clause of Article I, Section 8 of the United States Constitution states that Congress shall have the power to "provide for the common Defence and general Welfare." James Madison showed that this provision was intended to define the objects of federal spending, not to confer a general legislative authority upon

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21. *See, e.g.*, Irwin H. Herskowitz & Isabel L. Norton, *Increased Incidence of Melanotic Tumors in Two Strains of Drosophila Melanogaster Following Treatment with Sodium Fluoride*, 48 GENETICS 307 (1963); Chong Chang, *Effect of Fluoride on Nucleotides and Ribonucleic Acid in Germinating Corn Seedling Roots*, 43 PLANT PHYSIOLOGY 669 (1968); Danuta Jachimczak & Bogumila Skotarczak, *The Effect of Fluorine and Lead Ions on the Chromosomes of Human Leucocytes in Vitro*, 19 GENETICA POLONCIA 353 (1978); John Emsley et al., *An Unexpectedly Strong Hydrogen Bond: Ab Initio Calculations and Spectroscopic Studies of Amide-Fluoride Systems*, 103 J. AM. CHEM. SOC'Y 24 (1981); John Emsley et al., *The Uracil-Fluoride Interaction: Ab Initio Calculations including Solvation*, 8 J. CHEMICAL SOC'Y CHEMICAL COMMUN. 476 (1982); A.H. Mohamed & M.E. Chandler, *Cytological Effects of Sodium Fluoride on Mice*, 15 FLUORIDE 110 (1982); Toshio Imai et al., *The Effects of Fluoride on Cell Growth of Two Human Cell Lines and on DNA and Protein Synthesis in HeLa Cells*, 52 ACTA PHARMACOLOGICA ET TOXICOLOGICA 8 (1983); Takeki Tsutsui et al., *Cytotoxicity, Chromosome Aberrations and Unscheduled DNA Synthesis in Cultured Human Diploid Fibroblasts Induced by Sodium Fluoride*, 139 MUTATION RES. 193 (1984); Takeki Tsutsui et al., *Induction of Unscheduled DNA Synthesis in Cultured Human Oral Keratinocytes by Sodium Fluoride*, 140 MUTATION RES. 43 (1984); Takeki Tsutsui et al., *Sodium Fluoride-induced Morphological and Neoplastic Transformation, Chromosome Aberrations, Sister Chromatid Exchanges, and Unscheduled DNA Synthesis in Cultured Syrian Hamster Embryo Cells*, 44 CANCER RES. 938 (1984); Carol A. Jones et al., *Sodium Fluoride Promotes Morphological Transformation of Syrian Hamster Embryo Cells*, 9 CARCINOGENESIS 2279 (1988); Marilyn J. Aardema et al., *Sodium Fluoride-induced Chromosome Aberrations in Different Stages of the Cell Cycle: A Proposed Mechanism*, 223 MUTATION RES. 191 (1989); Takeki Tsutsui et al., *Cytotoxicity and Chromosome Aberrations in Normal Human Oral Keratinocytes Induced by Chemical Carcinogens: Comparison of Inter-Individual Variations*, 5 TOXICOLOGY IN VITRO 353 (1991).

22. *See e.g.*, Environmental Defense Fund v. Environmental Protection Agency, 548 F.2d 998, 1006 (D.C. Cir. 1976).

Congress, because, if this clause conferred such a general legislative authority, it would render the enumeration of specific legislative powers redundant and pointless.[23]

Madison's observation was important because he showed that if Congress had a general legislative authority such, it would be nothing other than a power to provide for the common defense and the general welfare. It would be a power, subject to the limitations inherent and implied in every republican form of government,[24] to enact only by laws necessary and proper or, in other words, laws fairly proportioned to and consistent with the common defense and general welfare, in keeping with legal principle and legal tradition.[25] Alexander Hamilton made unmistakably clear that a bill of rights, including all essential privileges and immunities of a free people, is always implied, if not expressed, in any republican form of government.[26] And every republican form of government, as an outgrowth of the American Revolution, necessarily presupposes the essential truths of the Declaration of Independence, which begins, before all else, with a tribute to the "Laws of Nature and Nature's God."[27]

So it was that Justice Samuel Chase of the United States Supreme Court, one of the signers of the Declaration of Independence, thus

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23. *See* THE FEDERALIST NO. 41, at 276-77 (Clinton Rossiter ed., 1961). In reaching this conclusion, Madison applied the rule of construction from the common law that clauses dealing with the same general subject or question should be construed together, if possible, to give every distinct provision some useful purpose and to coalesce into a harmonious whole with the others. *See* THE FEDERALIST NO. 40, at 260 (Clinton Rossiter ed., 1961). The same idea is advanced in the 7th of the Kentucky Resolutions of 1798, authored by Thomas Jefferson. *See* 4 DEBATES ON THE FEDERAL CONSTITUTION 542 (Elliot ed., Lippencott & Co., Philadelphia) (2d ed. 1859).

24. James Madison emphasized that the government of the Union, like the government of every State, is a republican form of government which has its origin in the people and features distinctive of the American Revolution. *See* THE FEDERALIST NO. 39, at 240-42 (Clinton Rossiter ed., 1961). The first mature prototype of such a republican form of government, see the Virginia Bill of Rights and Constitution of 1776, reprinted in 9 Hening's Statutes at Large, at 109-19.

25. *See* THE FEDERALIST NO. 33, at 203-04 (Alexander Hamilton) (Clinton Rossiter ed., 1961); THE FEDERALIST NO. 44, at 285 (James Madison) (Clinton Rossiter ed., 1961). Both Hamilton and Madison agreed that the eighteenth clause of Article I, Section 8, of the United States Constitution, granting Congress the power to enact necessary and proper laws, would have been implied if it had not been expressed. Also, while it allows implied powers, it also imposes implied limits on powers of just legislation. The standard judicial definition of necessary and proper laws is found in *M'Colloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 421 (1819).

26. *See* THE FEDERALIST NO. 84, at 512-14 (Clinton Rossiter ed., 1961).

27. THE DECLARATION OF INDEPENDENCE para. 1 (U.S. 1776). Sir William Blackstone gave incomparable exposition to the meaning of natural law as the foundation of constitutional government in 1 COMMENTARIES ON THE LAWS OF ENGLAND 38-43 (1765) [hereinafter BLACKSTONE].

expounded in a celebrated case the inherent limitations on general legislative authority under any republican form of government:

> The nature, and ends of legislative power will limit the exercise of it. This fundamental principle flows from the very nature of our free Republican governments, that no man should be compelled to do what the laws do not require; nor to refrain from acts which the laws permit. There are acts which the Federal, or State, Legislatures cannot do, without exceeding their authority. There are certain vital principles in our free Republican governments, which will determine and over-rule an apparent and flagrant abuse of legislative power; as to authorize manifest injustice by positive law; or to take away that security for personal liberty, or private property, for the protection whereof the government was established.[28]

There can be no serious dispute as to the nature of the original idea. In view of the transformations accomplished by the American Revolution, general legislative authority was understood to be the power of enacting necessary and proper laws to provide for the common defense and general welfare, in conformity with natural law and legal tradition. And this idea, fully justiciable, was imposed before the Fourteenth Amendment was ever thought of, by the so-called Guarantee Clause in of the United States Constitution, which demands that in and for every State of the Union there shall be a "Republican Form of Government."[29]

The term "police power" later appeared as a term of jurisprudence in antebellum litigation which arose under the Guarantee Clause, used to describe the legislative powers of the several States to enact regulations of domestic life.[30] The Guarantee Clause largely disappeared as a restraint upon the several States as a consequence of misunderstanding the interesting old case of *Luther v. Borden*.[31] Many generations of judges and lawyers have been deeply confused about it.

In 1842, there was a civil war between two state governments in Rhode Island, each claiming to be lawful.[32] Both the majority and the dissent agreed that the court could not resolve this question[33], which was said to be nonjusticiable, because of the enormous

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28. Calder v. Bull, 3 U.S. (3 Dal.) 386, 388 (1798).
29. U.S. CONST. art IV, § 4.
30. *See* Thurlow v. Massachusetts, 46 U.S. (5 How.) 504, 582-83 (1847).
31. 48 U.S. (7 How.) 1 (1849).
32. *See id.* 34-38, 48-57.
33. *See id.* at 39-47, 51-58.

practical difficulties involved. Thus began the doctrine of political questions which says that a question is nonjusticiable and so cannot be judicially decided if, in the circumstances, a practical remedy cannot be given by the courts if there are no objective legal standards upon which a judicial decision can be made, or if the question is plainly referred by fundamental law to the political organs of government or society.[34] Nothing could ever be so likely to injure the dignity or reputation of the bench than failure of judges to honor these inherent limits to their power.

But there was another important question in the case which most students have overlooked. This question was whether the charter government of Rhode Island, assumed legitimate, could impose martial law during the unrest which appears in retrospect to have been remarkably trivial. This question was decided on the merits.[35] The majority held that the charter government could impose martial law, but there was a strong dissent, mainly based on the Petition of Right.[36]

In any event, there has never been any reason for saying, as has sometimes been held,[37] that any constitutional question arising under the Guarantee Clause is per se nonjusticiable. And a number of courts have occasionally recognized the Guarantee Clause as an appropriate basis of judicial decision,[38] as clearly suggested by Justice Samuel Chase when John Adams was President. During the twentieth century, the Guarantee Clause has been a sleeping giant of the United States Constitution, yet there is no reason why, if the need becomes urgent in future years, the giant cannot be awakened and put to good use.

The Fourteenth Amendment followed the American Civil War and has since been the main basis in the United States Constitution for judicial decisions restraining the exercise of police power by the several States. There are some well-kept secrets about the Fourteenth Amendment, which are highly pertinent to the question of police power, and these may conceivably become more widely understood or even become legal orthodoxy in the twenty-first century.

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34. *See* Baker v. Carr, 369 U.S. 186, 208-37(1962).

35. *See* Luther v. Borden, 48 U.S. (7 How.) at 46, 58-88.

36. 3 Car. I, ch. 1 (1628).

37. *See, e.g.*, Taylor v. Beckham, 178 U.S. 548, 578-79 (1900); Pacific States Tel. & Tel. Co. v. Oregon, 223 U.S. 118, 142-53 (1912).

38. *See, e.g.*, Harrington v. Plainview, 6 N.W. 777 (Minn. 1880).

In the *Slaughter House Cases*,[39] the majority spoke the dark language of police power and upheld a Louisiana statute which required all slaughtering of animals as food for consumption in and around New Orleans to be done in facilities maintained under the auspices of a certain corporation.[40] The holding rests mainly on a notoriously unconvincing rationalization to accommodate an unwillingness to face the full impact of the Fourteenth Amendment.

The first well-kept secret about the Fourteenth Amendment is found in the four dissenting votes to the *Slaughter House Cases*, which rest mainly on the very capable and powerful opinions of Justice Stephen Field[41] and Justice Joseph Bradley.[42] Section 1 of the Fourteenth Amendment restrains the several States from abridging the privileges and immunities of citizens of the United States. Most certainly these dissenters were right in maintaining that this clause serves to incorporate all guarantees of civil liberty found in the United States Constitution as further restraints on the several States, including the First through Ninth Amendments.[43] And in light of legal tradition, they were right in maintaining that the Fourteenth Amendment, by incorporating the Ninth Amendment, imposes the old Statute of Monopolies[44] upon the several States.

Another well-kept secret about the Fourteenth Amendment, which may be unpleasant to some people yet ever so true, is that the article was never lawfully adopted,[45] mainly because it was proposed by a Congress which unlawfully excluded representatives and senators from ten States for having had the temerity of holding views not to the liking of an impassioned and factious majority.[46] Moreover, adoption was unlawful because ratification by those ten States, essential to adoption, was coerced by keeping them under

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39. 83 U.S. (16 Wall.) 36 (1873).

40. *See id.* at 58-82.

41. *See id.* at 83-111

42. *See id.* at 111-24.

43. It is impossible to attribute any other cogent meaning to this clause in light of *Corfield v. Coryell*, 6 F. Cas. 546 (C.C.E.D. Pa. 1823) (No. 3230), and *Barron v. Baltimore*, 32 U.S. (7 Pet.) 243 (1833).

44. *See* 21 Jac., ch. 3 (1623). The Statute of Monopolies expressly ordained that monopolies granted by the Crown were "contrary to the ancient and fundamental laws of the realm, and are utterly void." *Id.* at § 1. The statute created an express proviso allowing patents of invention for terms of fourteen years. *See id.* at § 6. Royal grants of monopoly had previously been declared unlawful in the *Case of Monopolies*, 11 Coke 84a (K.B. 1603).

45. This unhappy truth has been subject to protest from the most respectable quarters. *See, e.g.*, Dyett v. Turner, 439 P.2d 266 (Utah 1968).

46. Such exclusion was unconstitutional for reasons then clearly understood and long since judicially settled. *See, e.g.*, Powell v. McCormick, 395 U.S. 486 (1969).

martial law until they ratified,[47] contrary to principles already known and adjudicated to be unconstitutional.[48] Because time is a wonderful solvent of truth, we may anticipate that in the twenty-first century the Fourteenth Amendment may well be stricken from the United States Constitution.

The final well-kept secret about the Fourteenth Amendment is this: if and when it is finally acknowledged that the Fourteenth Amendment was never lawfully adopted, we shall not be deprived of means, under the fundamental law of the Union, to restrain the several States from acts of invidious discrimination or other forms of injustice. The reason is that everything worthwhile so far done in the name of the Fourteenth Amendment, and much more besides, can also be done, upon a more enlightened view of the American Revolution, in the name of the Guarantee Clause.[49] *E pluribus unum. Annuit coeptis novus ordo seclorum.*

III. NATURAL LAW JURISPRUDENCE

Between now and the hopeful future of clearer vision, we can use principles common both to the Guarantee Clause or the Fourteenth Amendment as a constitutional restraint on the "police power" of the several States, and we may be guided by judicial decisions rendered under either provision. And for this purpose, especially as it relates to artificial fluoridation of public water supplies, it is important to understand what has been done right, what has been done wrong, and why there has consequently been both progress and deterioration in American jurisprudence.

We first need to understand what has been done wrong and learn from it. With this objective in mind, we need to pay attention to Justice Hugo Black. During his tenure on the United States Supreme Court, Justice Black managed to sow more confusion, yet with important kernels of truth and distinguished erudition, than almost

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47. The Reconstruction Act was passed over a veto based on constitutional grounds. *See* 14 Stat. 428 (1867). The unanswerable veto message of President Andrew Johnson is reprinted in, 1 DOCUMENTS OF AMERICAN HISTORY 481-85 (Henry Steele Commager ed., 9th ed. 1973).

48. Although the Reconstruction Act imposed martial law under circumstances disallowed in *Ex Parte Milligan*, 71 U.S. (4 Wall.) 2 (1866), the constitutional infraction was allowed by systematic evasion of the question by the judiciary. *See generally* Texas v. White, 74 U.S. (7 Wall.) 700 (1869); Georgia v. Stanton, 73 U.S. (6 Wall.) 50 (1868); *Ex Parte* McCardle, 73 U.S. (6 Wall.) 318 (1868); *Ex Parte* Yerger, 75 U.S. (8 Wall.) 85 (1868); Mississippi v. Johnson, 71 U.S. (4 Wall.) 475 (1867).

49. The possibilities for this development have already been considered in two articles by Arthur E. Bonfield, Baker v. Carr: *New Light on the Constitutional Guarantee of Republican Government*, 50 CAL. L. REV. 245 (1962) and *The Guarantee Clause of Article IV, Section 4: A Study in Constitutional Desuetude*, 46 MINN. L. REV. 513 (1962).

any judicial figure in the world during the twentieth century. His mistakes have pronounced characteristics which are particularly instructive when viewed in retrospect.

His trademark position, stated in his famous dissent in *Adamson v. California*,[50] was that the Fourteenth Amendment incorporates the Federal Bill of Rights, including the First through Eighth Amendments.[51] But, if the Fourteenth Amendment incorporates the Federal Bill of Rights, it necessarily also incorporates the Ninth Amendment which says that the enumeration of certain rights "shall not be construed to deny or disparage others retained by the people."[52] Why no mention of the Ninth Amendment?

Throughout his dissent, Justice Black fairly radiated hostility against the ancient and venerable idea of natural law,[53] which he plainly did not understand either as a force shaping legal tradition or as a category of jurisprudence.[54] He acted as if the Ninth Amendment did not exist, because this article of fundamental law, construed in light of constitutional history, cannot possibly exclude those "certain unalienable Rights" with which all human beings are "endowed by their Creator" under the "Laws of Nature and Nature's God."[55]

Justice Black carried his hostility to natural law even further in his majority opinion in *Ferguson v. Skrupa*.[56] At issue in that case was a Kansas statute prohibiting any person from engaging in the business of debt adjusting, except as incident to the authorized practice of law.[57] At the time, there was a venerable precedent which held that, under the 14th Amendment, no state has constitutional authority to prohibit a useful business which is not inherently immoral or

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50. 332 U.S. 46, 68-123 (1947).

51. The historical evidence supporting this thesis is found in the appendix to Justice Black's opinion. *See id.* at 92-123.

52. This provision was intended to meet the objection of Alexander Hamilton in THE FEDERALIST NO. 84, at 513-14 (Clinton Rossiter ed., 1961), that an enumeration of rights was dangerous, because it might be used as a false pretext to claim power for seizing rights not mentioned. See the observations of James Madison in the United States House of Representatives on June 8, 1789, recorded in 1 ANNALS OF CONGRESS 439-40 (Gales & Seaton 1834).

53. *See* Adamson v. California, 332 U.S. at 79-80, 91.

54. Justice Black was plainly not aware of such distinguished works on natural law as HEINRICH A. ROMMEN, *DIE EWIGE WIEDERKEHR DES NATÜRRECHTS* (1936), translated as THE NATURAL LAW (Thomas R. Hanley trans., 1955). Hanley's introduction movingly relates how Rommen as a lawyer in Nazi Germany discovered the reality of natural law and was led to reject legal positivism in resisting Hitler's violations of human rights. *See id.* at xi-xxxviii.

55. THE DECLARATION OF INDEPENDENCE para. 1, 2 (U.S. 1776). This language obviously corresponds to those "certain inherent rights" which are mentioned in the first article of the Virginia Bill of Rights of 1776, reprinted in 9 Hening's Statutes at Large, at 109.

56. 372 U.S. 726 (1963).

57. *See id.* at 727.

dangerous to public welfare.[58] Black flippantly overruled this old case with the remark, "Whether the legislature takes for its textbook Adam Smith, Herbert Spencer, Lord Keynes, or some other is no concern of ours."[59]

Black's attitude was founded upon one of the most unfortunate falsehoods ever to pollute American jurisprudence. He assumed, out of ignorance, that cases like *Lochner v. New York*,[60] were founded on political prejudice, not legal standards. In *Lochner*, the court held that a law limiting the right of bakers to contract for their hours of work was unconstitutional.[61] No reason was even suggested on the record why bakers should not enjoy such discretion, or why they needed the protection of the law, as might have been true if, say, it had been shown that the bakers are typically in an uneven bargaining position in dealing with their employers. If such a showing had been at least attempted, as might well have been easily done, the statute would certainly have been upheld.[62]

It is true that the freedom to contract, cited as the justification for holding the statute unconstitutional, came from natural law jurisprudence. But the theory was not woven out of thin air. It came from venerable and historic roots, ultimately the decision of Lord Mansfield in *Sommerset's Case*[63] which held that, because slavery runs against natural law, it could be sustained only by acts of Parliament,

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58. *See* Adams v. Tanner, 244 U.S. 590 (1917). As with many other cases like it, this case turned on the clause of the Fourteenth Amendment which forbids any state from denying life, liberty, or property without due process of law. The clause is ultimately traceable to the 39th Article of the Magna Carta of King John. It was probably added to the Fourteenth Amendment to cure the unfortunate holding of the majority in *Satterlee v. Matthewson*, 27 U.S. (2 Pet.) 380 (1829), and drew inspiration from cases such as *University of North Carolina v. Fox*, 5 N.C. (1 Mur.) 83 (1805).

59. 372 U.S. at 732. This case echoed of the thoughtless satyrism of Oliver Wendell Holmes in *Lochner v. New York*, 198 U.S. 45, 75 (1905) ("The Fourteenth Amendment does not enact Mr. Herbert Spencer's Social Statics"). Under this theory, we should be equally indifferent as to whether the legislature of a State were to take guidance from Maxmillien de Robespierre, Vladimir Lenin, Adolf Hitler, Joseph Stalin, Mao Tse Tung, or Pol Pot.

60. 198 U.S. 45 (1905).

61. *See id.* at 64-65.

62. Pope Leo XIII issued the encyclical *Rerum Novarum* (1891), which was one of the greatest statements on natural law in history. He expounded rights of labor and the duty of governments to enact legislation protecting labor from unjust exploitation. It was on this basis that legislation protecting labor from unjust exploitation was repeatedly approved as constitutional in natural law jurisprudence, whenever a plausible justification of legislative judgment was made to appear on the record. *See, e.g.*, Bunting v. Oregon, 243 U.S. 426 (1917); Muller v. Oregon, 208 U.S. 412 (1908); Holden v. Hardy, 169 U.S. 366 (1898).

63. 20 How. St. Tr. 1, 82 (K.B. 1771).

and all statutes allowing it had to be strictly construed so as to make a slave free the moment he set foot on the free soil of England.[64]

This idea was, of course, adopted and expanded by the Thirteenth Amendment. It follows, by legal inference, that nobody in the United States may be denied a liberal right to earn a livelihood or to engage in business as he or she sees fit. Thus, it has been held under the Fourteenth Amendment, that unless a statute limiting the right of a citizen to contract freely can be plausibly justified, it is unconstitutional.[65] The idea does not embrace irresponsible freedom and it does not outlaw legislation to prevent unjust exploitation of labor or activity harmful to the public good. The right is confirmed by natural law and legal tradition and is suited to the circumstances of a free people. There has always been just cause to apply this notion with judicious caution,[66] but there never has been any reason to reject or overrule it altogether.[67]

Black took his extremism to the *ne plus ultra* in his bitter dissent in *Griswold v. Connecticut*.[68] Complaining that natural law is mysterious and uncertain and that the Ninth Amendment has only nominal but no substantive meaning, Black insisted that even a statute intruding into the sexual intimacy of a husband and wife, disallowing them to be instructed by their physician on artificial methods of birth control, could not be struck down as unconstitutional.[69] Fortunately, his fellow justices had no trouble in understanding privacy as

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64. This principle originated in the policy of the common law which favored liberty, and thus nudged villeinage into extinction. *See, e.g.*, Pigg v. Caley, Noy 27 (K.B. 1618). Strict construction of laws allowing slavery was adopted by judges of the old South, and many slaves were freed because of it. *See, e.g.*, Murray v. M'Carty, 16 Va. (2 Mun.) 393 (1811). It was also applied by the circuit court of Missouri in granting Dred Scott and his family their freedom, and was the main basis of the dissent of Justice Benjamin Curtis in *Dred Scott v. Sandford*, 60 U.S. (19 How.) 391, 602-603 (1857).

65. *See* Allgeyer v. Louisiana, 165 U.S. 578 (1897).

66. So as to avoid unfortunate decisions like *Coppage v. Kansas*, 236 U.S. 1 (1915), which was simply a mistake. No apology can be offered for it in any school of thought.

67. *Nebbia v. New York*, 291 U.S. 502 (1934), is sometimes cited as the beginning of the end of natural law jurisprudence in the field of economic regulation, but the case is better understood as a just extension of *Munn v. Illinois*, 94 U.S. 113 (1877), in light of pressing economic circumstances not existing at the time of *Fairmont Creamery Co. v. Minnesota*, 274 U.S. 1 (1926). Likewise, *West Coast Hotel Co. v. Parrish*, 300 U.S. 379 (1937), is often cited as the definitive end of natural law jurisprudence in the field of economic regulation. Yet in *Parrish*, the majority disregarded the intended meaning of the Nineteenth Amendment as expounded in *Adkins v. Children's Hospital of the District of Columbia*, 261 U.S. 525, 552-53 (1923), and later revived in *Frontiero v. Richardson*, 411 U.S. 677, 686-88 (1977). *Parrish* allowed a kind of sex discrimination which would never be allowed today and may be considered virtually overruled.

68. 381 U.S. 479, 507-27 (1965).

69. *See id.* at 523-25.

a liberty protected by fundamental law, and they declared the statute unconstitutional.[70]

If Hugo Black condemned natural law because he did not understand it, the founding fathers of the United States did understand it, and they built a new constitutional order upon it. They knew that natural law is a timeless moral and physical order which enforces itself and can be discovered by natural reason.[71] They knew that it constrains governments no less than markets. They knew that if its lofty commands were disobeyed, there would be misfortunes in public affairs, requiring the accommodations of temporal law. They knew, therefore, that natural law was elaborated and given objective form by legal tradition.

The dissenters in the *Slaughter House Cases* rested their erudite opinions on the facts of history. They did not make things up to suit their political fancies but relied instead on legal custom acknowledged by the King's Bench and an organic statute of the English Parliament. In light of long experience, it became clear in the past, as it is impossible to deny today, that, by the wonderful operation of unseen but undeniable forces of nature, the practice of monopoly creates painful economic congestions. So it was that legal tradition accommodated and expressed the reality of natural law.

Likewise, if the statute in *Griswold* had not been left to fade in desuetude, but had been actively enforced, Connecticut would have faced political upheaval or revolution. Hence, the reality of natural law, which, fortunately, did not produce unhappy consequences, but only because prosecutors had the good sense not to file accusations, and the statute was eventually found unconstitutional. In this way temporal law honored privacy as an unenumerated constitutional immunity which had always existed by natural law. After transitions and adjustments, legal tradition will mature into a sturdier and

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70. *See id.* at 484-86 (penumbras of the Bill of Rights), 498-99 (the Ninth Amendment), 500-04 (due process of law under the Fourteenth Amendment). By acknowledging a constitutional right of privacy on the basis of natural law jurisprudence, the Court in no way committed itself to *Roe v. Wade*, 410 U.S. 113 (1973), which did not rest on natural law jurisprudence but rather overthrew the traditional protection of the unborn by both the common law and the civil law. *See e.g.*,Thulluson v. Woodford, 4 Ves. Jr. 227, 321-22 (Ch. 1799); Montreal Tramways v. Leveille, [1933] 4 D. L. R. 337, 340-41 (Can.). Nor did the Court contradict the moral teaching of Pope Paul VI against artificial birth control in the encyclical HUMANE VITAE (1968). Natural law jurisprudence actually restrains temporal law from attempting to prohibit some activities, especially those of a private nature, which, right or wrong, are not proper subjects for public regulation. *See, e.g.*, THOMAS AQUINAS, SUMMA THEOLOGICA, II-I, q. 93, art. 3, ad 3, *translated in*, BASIC WRITINGS OF SAINT THOMAS AQUINAS, 766 (Anton Pegis ed. 1945).

71. For abundant references to natural law, see the opening passages of THE DECLARATION OF INDEPENDENCE (U.S. 1776) and the corresponding language of Sir William Blackstone, *supra* note 27, at 38-43.

sounder landmark which can be used with greater wisdom and confidence in future years.

IV. HEALTH FREEDOM

One of the most distinguished civil liberties decisions of the twentieth century, never overruled and often cited,[72] rests on the opinion of Justice James McReynolds in *Meyer v. Nebraska*.[73] Citing the duty of government to promote education, founded on the Northwest Ordinance, McReynolds struck down as unconstitutional under the Fourteenth Amendment a law prohibiting the teaching of German to children in the primary grades of public schools in Nebraska. His general formula is particularly worthy of notice:

> While this court has not attempted to define the exactness the liberty thus guaranteed, the term has received much consideration, and some of the included things have been definitively stated. Without doubt, it denotes not merely freedom from bodily restraint, but also the right of the individual to contract, to engage in any of the common occupations in life, to acquire useful knowledge, to marry, to establish a home and bring up children, to worship God according to the dictates of conscience, and, generally, to enjoy privileges long recognized at common law as essential to the orderly pursuit of happiness by free men.[74]

It is noteworthy that Sir William Blackstone mentioned the "preservation of man's health from such practices as may prejudice or annoy it" not as a legislative power, but as among "absolute rights of individuals,"[75] in other words, as among "those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men."[76]

Therefore, it is clear enough that there are natural rights protected by fundamental law, even if not constitutionally enumerated. As there is such a natural right to marry and have children, to seek knowledge, to enjoy personal privacy, and to earn a livelihood by honest work of choice, subject only to such regulation as may be reasonably needed to protect the rights of others and the common good, so too there is a domain of personal freedom, which limits the

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72. *See, e.g.*, Griswold v. Connecticut, 381 U.S. at 481-82, 495, 502.
73. 261 U.S. 390 (1923).
74. *See id.* at 399-400.
75. BLACKSTONE, *supra* note 27, at 134.
76. 261 U.S. at 400.

"police power" of a State in regulating health. It is an area given some but not full judicial development in the twentieth century.

Two classic cases stand out like beacons, the first being *Jacobson v. Massachusetts*,[77] in which a citizen challenged a statute compelling small pox vaccinations to counteract a pending epidemic of deadly disease. The act of the legislature was upheld under the Fourteenth Amendment. The holding is understandable, because the statute addressed a public danger, and failure to comply might have tangibly increased the chances that an offender might become a carrier of disease which thereby could infect others. Public emergency has always justified intrusions, even upon incomplete knowledge, which normal situations will not.

Of much interest in this case is the discussion of the fact that, while the general belief of the legislature on the need for smallpox vaccinations was supported by respectable medical authority, there was nevertheless responsible dissent within the medical profession over the efficacy and in some degree even of the safety of this particular measure. In *Jacobson*, the court reasoned "[t]he possibility that the belief [favoring smallpox vaccinations] may be wrong, and that science may yet show it to be wrong is not conclusive; for the legislature has the right to pass laws which, according to [reasonable belief] are adapted to prevent the spread of contagious diseases."[78]

No less of interest is an exception to the general principle of the judgment. The court plainly said that the statute could never be interpreted to compel a vaccination where it could be shown "with reasonable certainty" that application of the statute to an objecting citizen "would seriously impair his health or probably cause his death."[79] This observation was added as an essential feature of the *ratio decidendi* to avoid misinterpretation.

The court did not define what exactly it meant in saying that a statutory regulation of public health may not be extended to situations in which serious impairment of personal health is shown with "reasonable certainty." But this characteristic phrase has long been a term of art in the law of damages. It has long been used to

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77. 197 U.S. 11 (1905).

78. *Id.* at 35. Language has been substituted in brackets for the phrase "the common belief of the people" in the opinion, because the obvious intent of the court was that the belief of the legislature acting on behalf of the people must at least be reasonable in view of available knowledge and evidence. The court said, "if a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, has no real or substantial relation to those objects," then it is the duty of the judiciary to intervene and declare such statute unconstitutional. *Id.* at 31.

79. *Id.* at 39.

describe the legal standard of proving an injury in civil proceedings: while damages cannot be based on speculation or guess, it will be enough to show the approximate degree of harm by fair preponderance of the evidence adduced in a judicial hearing.[80] And, in such case, injury can be proved by the opinions of experts who can demonstrate that they are well informed on the subject investigated.[81]

The other outstanding case on generic principles of health freedom is *Toronto v. Forest Hill*,[82] in which the majority opinion was written by Justice Ivan Rand, who was probably the most eminent jurist on the Supreme Court of Canada, in any event one of the finest natural law judges in the world during the twentieth century.[83] This case arose under the British North America Act of 1867, before it was possible, except on a very limited basis,[84] for the judiciary of Canada to strike down acts of the dominion Parliament or of the provincial Legislatures as unconstitutional and thus null and void.[85] The judiciary of Canada was then obliged to protect civil liberties by strict construction of statutes, as far as possible, so as to avoid collision with natural law and legal tradition.[86] It was by using such conservative

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80. *See, e.g.*, Bigelow v. RKO Radio Pictures Inc., 327 U.S. 251 (1946); Story Parchment Co. v. Paterson Parchment Paper Co., 282 U.S. 555 (1930); Eastman Kodak Co. v. Southern Photo Material Co., 273 U.S. 359 (1927).

81. *See, e.g.*, Julian Petroleum Corp. v. Courtney Petroleum Co., 22 F.2d 360, 362 (9th Cir. 1927).

82. [1957] 9 D.L.R. 2d 113 (Can.).

83. *See, e.g.*, Michael Schneiderman, *The Positivism of Hugo Black v. The Natural Law of Ivan Rand: A Study in Contrasting Judicial Philosophies*, 33 SASKATCHEWAN LAW REV. 267 (1968). Another great natural law jurist in Canada during the twentieth century was Chief Judge Jules Deschenes of the Superior Court of Quebec. *See, e.g.*, Nissan Auto. Co. v. Pelletier, 77 D.L.R. 3d 646 (Que. 1976).

84. Mainly where statutes were enacted contrary to the organic provisions of the British North America Act of 1867, as held by the British Privy Council in *In re Initiative and Referendum Act* [1919] App.Cas. 935, and the Supreme Court of Canada in *Saumer v. Quebec*, [1953] 4 D.L.R. 641 (Can.).

85. The situation has since changed beginning with the Canadian Bill of Rights of 1960, an organic statute of the dominion Parliament, which unlike the English Bill of Rights of 1689, was more than a venerable guide for the interpretation of statutes. In *Queen v. Drybones* [1970] 9 D.L.R. 3d 473 (Can.), the Canadian Bill of Rights of 1960 was held to be a statutory directive to restrain federal laws from operation. Later came the Canadian Charter of Rights and Freedoms consisting of sections 1 through 35 of the Constitution Act of 1982, which restrains the federal and provincial governments, and cannot be repealed by legislative act. Even so, section 33 of the Constitution Act of 1982 concedes to legislative power the prerogative of making statutes operable for five-year intervals, notwithstanding important provisions of the Canadian Charter. The Constitution Act of 1982 is part of the Canada Act of 1982, an organic statute of the British Parliament which renounced the last vestiges of imperial control over Canada.

86. Lord Coke held in *Dr. Bonham's Case*, 8 Coke 114a (C.P. 1610), that the courts of common law declare acts of parliament null and void. This doctrine was overthrown on the weight of the principle that the Commons, Lords, and King in Parliament are omnipotent and sovereign, and that, therefore, the judiciary cannot declare an act of Parliament null and void. Even so, the judges can and must construe acts in keeping with the principle that the King can

yet effective principles that Justice Rand became distinguished as a civil libertarian on the bench.

In *Forest Hill*, a provincial law allowed municipal corporations to treat public water supplies so as to make the vended water "pure and wholesome."[87] Justice Rand construed this statute strictly, so as to disallow fluoridation. He protested,

> But it is not to promote the ordinary use of water as a physical requisite for the body that fluoridation is proposed. That process has a distinct and different purpose; it is not a means to an end of wholesome water for water's function but to an end of a special health purpose for which water supply is made use of as a means.[88]

Similar language appears in the concurring opinion of Justice Cartwright, regarding the municipal by-law to initiate fluoridation then in question:

> In pith and substance the by-law relates not to the provision of a water supply but to the compulsory preventative medication of the inhabitants of the area. In my opinion, the words of the statutory provisions on which the appellant relies do not confer upon the council the power to make by-laws in relation to matters of this sort.[89]

Jacobson and *Forest Hill* expound complementary principles of natural law jurisprudence, and thereby supply a cogent idea of health freedom which is inherent in the respected constitutional formulation expressed in *Meyer v. Nebraska*.[90]

Under the Guarantee Clause, the Ninth Amendment, and the Fourteenth Amendment, understood in light of natural law and legal tradition, "police power" to regulate public health includes discretion to compel submission of citizens to medical intervention, but only if three necessary conditions are met. First, legislative judgment underlying the statute may discount responsible professional dissent,

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do no wrong, and thus that all acts of Parliament must be construed, if possible, in keeping with natural law and legal tradition. The judges should do so, even if they must read statutes *quoad hoc* or contrary to their literal meaning in unusual situations. *See, e.g.*, BLACKSTONE, *supra* note 27, at 91, 160, 246.

87. *Forest Hill*, 9 D.L.R. 2d at 114-15.

88. *Id.* at 118. The same distinction appears in the Safe Drinking Water Act, 42 U.S.C. § 300g-1(b)(11), which states, "No national primary drinking water regulation may require the addition of any substance for preventative health care purposes unrelated to contamination of drinking water." This provision was intended by Congress to prohibit the use of the Safe Drinking Water Act as a means of imposing artificial fluoridation of public water supplies throughout the United States.

89. *Id.* at 124.

90. 261 U.S. 390 (1923).

yet must at least rest upon reasonable medical or scientific evidence. Second, it must be fairly justified by grave cause or public emergency, such as the need to prevent the spread of a contagious disease. Third, the intervention prescribed cannot be imposed whenever protesting citizens are able to prove, by a fair preponderance of the evidence, a tangible danger of serious injury to their health. But the legislative power cannot otherwise impose compulsory medication on protesting citizens. This much is the ideal of natural law jurisprudence which is inseparable from the intended meaning of the United States Constitution.

V. THE KEY DECISIONS SUSTAINING FLUORIDATION

It is not our purpose to provide a general review of all judicial decisions that have touched upon the constitutionality of imposing fluoridation on the general public.[91] Suffice it to say that the great majority of cases sustain it, we think wrongly, but there can be no doubt about the clear trend of American jurisprudence.

Our objective here is to note highly important developments in the last twenty-five years, which strenuous efforts have been made to camouflage behind smiling propaganda orchestrated by the ADA and the USPHS to promote fluoridation, as if all were well. In fact an end to this episode of public health malpractice is foreseeable. If we consider scientific and legal revolutions of the past, say from the discovery of the true cause of puerperal fever by Dr. Ignaz Semmelweiss until his eventual posthumous vindication, or in the development of freedom of the press from the founding of the Star Chamber to the adoption of the First Amendment, we should not be astonished to see the passing of considerable time in the rise and fall of fluoridation, and not a little confusion along the way.

Among all others, the most distinguished judgment sustaining the constitutionality of mandatory fluoridation of public water supplies has always been, and still is, *Paduano v. City of New York*,[92] which arose upon a suit brought in 1965 to enjoin the practice in New York City.[93] At that time the clear weight of available medical and scientific evidence, then respectable but long since shown to be

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91. A recent article reviewing many such cases is by Douglas Balog, *Fluoridation of Public Water Systems: Valid Exercise of State Police Power of Constitutional Violation?*, 14 PACE ENVTL. L. REV. 645 (1997).

92. 257 N.Y.S. 2d 531 (S.Ct. N.Y. County 1965), *aff'd* 24 App. Div. 2d 437, 260 N.Y. S. 2d 831 (1965), *aff'd* 17 N. Y. 2d 875, 271 N. Y. S. 2d 305 (1966), *cert. denied* 385 U.S. 1026 (1967).

93. *See id.* at 533.

unfounded,[94] suggested that fluoridation was effective in reducing tooth decay in children.[95] Evidence of potential danger then existed,[96] but it was little known, in an undeveloped state, and effectively concealed by ADA-USPHS misinformation.[97] Most physicians and dentists then believed that fluoridation was beneficial and safe. It is fair to say that most available evidence -at least what could be easily orchestrated into a courtroom appearance of the most available evidence then suggested that fluoridation was beneficial and safe.

True enough, then available evidence suggested the need for caution among the wise. But there were not many in those days who had good credentials, independent means, leisure time for deep study, the persuasiveness to expose the slick sales pitches of ADA-USPHS spokesmen, the capacity to survive assaults on their careers and reputations mounted by fluoridation promoters,[98] an d wisdom besides.

It is wrong to justify fluoridation by reference to *Jacobson*, because fluoridation, unlike small pox vaccinations, does not address a contagious disease, but it is at least understandable that the Supreme Court of New York should have cited it as persuasive legal authority.[99] The court said:

> The question of the desirability of fluoridation is immaterial. In the face of the overwhelming precedents previously cited, and in accordance with general principles of stare decisis, this court sitting at Special Term, feels constrained to deny plaintiffs' application for a temporary injunction and to grant defendants' motion for a dismissal of the complaint. *Until the scientific evidence as to the deleterious effects of fluoridation reaches beyond the purely speculative state now existing*, decisional law mandates the holding that the controversy should remain within the realm of the legislative and executive branches of government. While the courts do not have a right to impose fluoridation upon anyone, judicial restraint requires us to adhere to the uniform decisions holding that the executive and legislative branches of government do -*at least until some proof is*

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94. *See* Kalsbeek & Verrips, *supra* note 8; Ziegelbecker, *supra* note 10; Kumer, *supra* note 8; Imai, *supra* note 9; Colquhoun, *supra* note 11; Yiamouyiannis, *supra* note 12, and accompanying text.

95. *See, e.g.*, Hilliboe et al., *supra* note 4, at 314-24.

96. *See* Taylor, *supra* note 16, and accompanying text.

97. *See, e.g.*, Hilleboe et al., *supra* note 4; HARRIS, *supra* note 18, and accompanying text.

98. Literally volumes could be written on the notorious and ruthless tactics of fluoridation promoters seeking to silence all credible opposition. A sober and factual introduction to this subject of political intrigue can be found in WALDBOTT, ET AL., *supra* note 1, at 258-352.

99. Paduano v. New York, 257 N.Y.S. 2d 531, 539 (S. Ct. N.Y. County 1965).

adduced that fluoridation has harmful side effects and therefore is not in the interests of the community.[100]

The court obviously had in mind the qualifying dictum in *Jacobson* that a public health regulation, obliging a citizen to accept a medical remedy, cannot be extended to a situation in which it is shown with reasonable certainty, or by a fair preponderance of the evidence exceeding speculation or guess, that the remedy will impose a danger of serious injury to the personal health of protesting citizens. Note clearly what the court did not say, should not have said, and, in light of its reliance on *Jacobson*, cannot be interpreted to have said that such danger or injury must be proven by evidence so powerful as to eliminate all reasonable controversy on the subject. Such a burden of proof is legally impossible on any question of public health, nor does it comport with public justice or safety, nor does it have any legitimate basis in legal authority.

Another key judgment sustaining imposed fluoridation merits passing notice because it concerns legal ideals of the type suggested by the natural law jurisprudence of Ivan Rand. In *State Board of Health v. Brainerd,*[101] a mandatory fluoridation law was applied to a community which protested as a whole body politic in a special referendum[102] by a vote of 9 to 1 against implementing the law, and by a vote of 5 to 1 authorizing the city fathers to sit as a convention which met and declared the statute unconstitutional.

The state board of health sued the municipal government which pleaded the express and formal protest of the residents and voters of the city, the want of a public emergency occasioned by a pending epidemic of contagious disease, the existence of a responsible medical and scientific controversy over the effectiveness and safety of fluoridation, the availability of fluoride to persons desiring it by less intrusive means, and, therefore, the invasion of a natural right of the people, protected by fundamental law under these circumstances, to enjoy freedom of choice in maintaining personal health.[103] The Minnesota Supreme Court upheld the constitutionality of the mandatory fluoridation law, and sustained the writ of mandamus

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100. *Id.* at 542 (emphasis added).

101. 241 N.W.2d 624, 626 (Minn. 1976), *appeal dismissed* 429 U.S. 803 (1976).

102. *See* State Board of Health v. City of Brainerd, No. 38183, Respondents' Answer, part VII, plea in avoidance filed Oct. 31, 1974 (Crow Wing County District Court, Minn.). Judge John Alexander Jameson expressed his warm approbation of such citizen assemblies in his classic TREATISE ON CONSTITUTIONAL CONVENTIONS 4-5 (4th ed. 1887, reprint 1972).

103. *See* City of Brainerd, Respondent's Answer, part VIII, plea in avoidance and demurrer, filed Oct. 31, 1974.

ordering city officers to implement the statute.[104] But there was a compelling dissent that speaks to the future.[105]

If it can be established "with reasonable certainty" that fluoridation is dangerous to human health, and has caused massive injury to the health of the American people, two very important legal consequences should ultimately follow: (1) the standard of unconstitutionality set forth in *Jacobson* and *Paduano* will have been met, and fluoridation will be unlawful throughout the United States; and (2) the wisdom of a broader constitutional principle of health freedom, envisioned by the majority in *Forest Hill* and the dissent in *Brainerd*, will then be evident, and its eventual judicial recognition as a blessing of liberty may be anticipated for our children, grandchildren, and great grandchildren.

VI. THE EPIDEMIOLOGICAL EVIDENCE

The question now to be addressed is whether, in keeping with *Jacobson* and *Paduano*, it can be proved with "reasonable certainty" in judicial proceedings that fluoridation is dangerous to public health by causing cancer and other ailments in man. In assessing trends in human cancer, we have two main sources of information which can be used as evidence.

Laboratory studies enable us to view a disease at the molecular and cellular levels, and to consider reactions in living plants, insects and animals. The advantage of laboratory studies is that precise experimental conditions can be designed and implemented to control for known and unknown variables, which is critical in the identification of causal operations in the empirical sciences.[106] Whatever legitimate doubt may once have been voiced on the subject, it is now abundantly clear that a significant body of laboratory research reveals carcinogenic potential in fluoride artificially introduced in water at 1.0 ppm.[107]

The disadvantage of laboratory studies is that some caution is required in extrapolating results to human beings, and here is where

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104. *See* Brainerd, 241 N.W.2d at 629-34.

105. *See id.* at 634-35.

106. Sir Francis Bacon expounded this demand of inductive logic in the third, fourteenth, nineteenth, twenty-second, eighty-second, and ninety-ninth aphorisms in Book I of *Novum Organum*. The meaning of these aphorisms is discussed in 3 COPELSTON, A HISTORY OF PHILOSOPHY, pt. II, 112-22 (1963) [hereinafter COPLESTON].

107. *See, e.g.*, Taylor, *supra* note 16; Taylor & Taylor, *supra* note 20; sources cited *supra* note 21.

epidemiology comes into the picture. Epidemiology is the branch of medicine which studies the diseases of man in his actual environment. If the controls in epidemiological surveys are not as precise, the results are more pertinent to human experience. Therefore, both laboratory studies and epidemiological surveys can profitably be considered together, and, when parallels between them become striking, causal relationships between agents in the environment and human disease can be more readily identified and explained.

Hence the question: Has the carcinogenic potential of fluoride observed in laboratory studies been reflected in human experience? The answer, based on very extensive epidemiological data, is certainly in the affirmative.[108] This fact removes the speculative character of objections previously expressed by physicians and other learned persons when the world first hailed fluoride as a wonder of modern science.

The leader in gathering pertinent epidemiological data and organizing it in a usable form was Dr. Dean Burk, who retired in 1974 as the head of the cytochemistry section of the National Cancer Institute (NCI) of the United States.[109] In his time, he was one of the most famous cancer research scientists in the world. He was well read, highly cultured, disarmingly humble, and had a delicious sense of humor. But standing out above every other trait was his ability to view a problem of empirical observation with clear insight and to give reality, as he put in conversation with those who knew him, "the simplest rational explanation."[110]

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108. The most important versions of the epidemiological data here in question, including reference to related laboratory studies, and conventional adjustments for age, race, and sex, are the following: Dean Burk & John Yiamouyiannis, *Fluoridation and Cancer: Age Dependence of Cancer Mortality Related to Artificial Fluoridation*, 10 FLUORIDE 123 (1977) [hereinafter Burk & Yiamouyiannis]; Dean Burk and J. R. Graham, *Lord Jauncey and Justice Flaherty: Opposing Views of the Fluoridation-Cancer Link*, 17 FLUORIDE 63 (1984) [hereinafter Burk & Graham]; Pierre Morin et al., *Les fluorures versus le cancer et les maladies congentales: l'image globale*, GOURVERNEMENT DU QUEBEC, MINISTERE DES AFFAIRES SOCIALES (1984); Pierre Morin et al., *Fluorides, Water Fluoridation, Cancer, and Genetic Diseases*, 12 SCI. & PUB. POL'Y 36 (1985); Rudolf Ziegelbecker, *Zur Frage eines Zusammenhanges zwischen Trinkwasserfluordierung, Krebs, und Leberzirrhose*, 218 GWF WASSER/ABWASSER 111 (1987); Dean Burk et al., *A Current Restatement and Continuing Reappraisal Concerning Demographic Variables in American Time-Trend Studies on Water Fluoridation and Human Cancer*, 61 PROC. PA. ACAD. OF SCI. 138 (1988) [hereinafter Burk, Graham, & Morin].

109. *See* WHO'S WHO IN THE WORLD 1974-1975 161 (2d ed., Marquis Who's Who, Inc., 1975); *National Cancer Program (Part 2), Hearings Before the Subcomm. of the Comm. on Government Operations*, 95th Cong. 471 (1977) [hereinafter *National Cancer Program*].

110. Dr. Burk's capacity to view and characterize phenomenal reality is illustrated in his trademark paper, Dean Burk & Hans Lineweaver, *The Determination of Enzyme Dissociation Constants*, 56 J. AM. CHEM. SOC'Y 658 (1934), which has been one of the most often cited and discussed papers in biochemstry during the twentieth century..

The epidemiological work here in question was done under the direction of Dr. Burk from his retirement until his death in 1988. As with so much of his work before his retirement, he was years ahead of his time.

On December 16, 1975, the Congressman James Delaney of New York inserted into the *Congressional Record* data gathered and organized under the direction of Dr. Burk, showing a striking association between fluoridation and cancer.[111] It is important to appreciate the basic data, because it was the principal and decisive focus of the judicial hearings that followed.[112]

The year-by-year average observed cancer death rates of ten large central cities of the United States, which served as the control group and remained unfluoridated from 1940 through 1968, were compared for the years 1940 through 1968 with the year-by-year average observed cancer death rates of ten large central cities of the United States which served as the experimental group and remained unfluoridated from 1940 through 1951, but fluoridated between 1952 and 1956, and remained fluoridated through 1968 and thereafter.[113] The experiment came to an end in 1968 because fluoridation was introduced in the control cities step-by-step from and after 1969. The necessary data are available for all years except for 1951 and 1952.

The central cities in question are all very large, comparable in size, and spread out across the whole country. In the control group were: Los Angeles; Boston; New Orleans; Seattle; Cincinnati; Atlanta; Kansas City (Missouri); Cincinnati (Ohio), Newark, and Portland.[114] In the experimental group were: Chicago; Philadelphia; Baltimore; Cleveland; Washington D.C.; Milwaukee; St. Louis; San Fransisco; Pittsburgh; and Buffalo.[115]

Roughly speaking, the comparison is between about seven million people in the ten control cities and about eleven million people in the ten experimental cities over about thirty years.[116]

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111. *See* 121 CONG. REC. 40773-75 (1975).

112. The technical particulars of the selection, derivation, and arrangement of the basic data are precisely described in the method section of Burk & Yiamouyiannis, *supra* note 108, at 103-05, and Burk, Graham, & Morin, *supra* note 108, at 138-39.

113. *See* Burk & Yiamouyiannis, *supra* note 108, at 104; Burk, Graham, & Morin, *supra* note 108, at 138.

114. *See* Burk & Yiamouyiannis, *supra* note 108, at 104; Burk, Graham, & Morin, *supra* note 108, at 138.

115. *See* Burk & Yiamouyiannis, *supra* note 108, at 104; Burk, Graham, & Morin, *supra* note 108, at 138.

116. *See* Burk, Graham, & Morin, *supra* note 108, at 139.

There has hardly ever been a published epidemiological study using so much data, arranged in such powerful experimental design.

The basic data can be expressed as unweighted averages (giving each city equal weight, regardless of size) and as weighted averages (giving each city weight according to size). All cancer death rates here discussed are expressed as so many cancer deaths per 100,000 persons.

The basic data are given in detail in the appendix of this article.[117] For the sake of convenience an observed or crude cancer death rate for all sites in an entire population will be designated as CDRo. It does not matter in this case whether unweighted or weighted averages are used. The pattern is numerically and visibly the same, and the differences emerging from mathematical analysis of the figures for the two types of averages are trivial. Either way the possibility of chance occurrence is far less that 1 in 1000. The weighted averages will be used here because weighted averages have been used by all critics of Dr. Burk's work, and Dr. Burk frequently used weighted averages himself.

The data are arranged in standard experimental design, comparing like along a base line from 1940-50 in which cancer death rates grew equally, then continuing the comparison after fluoridation was introduced in the experimental cities. It was after fluoridation began that there was a pronounced acceleration in cancer mortality in the experimental group (+F) as compared with the control group (-F). The resulting association between fluoridation and cancer can be conveniently quantified by linear regression[118] analysis for the data for 1940-50, also for 1953-68 then extend the resulting lines to achieve values for 1950 and 1970:[119]

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117. The figures and tables set forth in the appendix are taken from Burk, Graham, & Morin, *supra* note 108, at 139-40. The basic data can be recapitulated by any informed and impartial investigator drawing from census figures and vital statistics published by the government of the United States.

118. Linear regression is a standard technique in statistics for characterization of a field of points on a two-dimensional graph as a straight line. This line is also drawn so that the sum of the squares of the several points to the line is the lowest possible number. Such line is assumed in the product moment formula for the linear correlation coefficient, designated "r" to express the degree of association between the two axes. By use of related operations, a statistical confidence level, represented by the coefficient "P" can be derived. P determines the extent to which an observed association may or may not have occurred by chance. The subject is discussed in standard textbooks. *See, e.g.*, SIR AUSTIN BRADFORD-HILL, A SHORT TEXTBOOK OF MEDICAL STATISTICS 161-67, 173-80 (10th ed. 1977); MURRAY SPIEGEL, THEORY AND PROBLEMS OF STATISTICS 218-20, 226-28, 244-45, 253-54 (1961).

119. *See* Burk & Graham, *supra* note 108, at 65; Burk, Graham, & Morin, *supra* note 108, at 142-43.

	1940	1950	1960	1970
CDRo (+F)	154.2	181.8	186.3	222.6
CDRo (-F)	153.5	181.3	183.6	188.8

The size of the association between fluoridation and cancer can be expressed as follows: [(222.6-188.8) - (186.3-183.6)] + [(154.2-153.5) - (181.8-181.3)] or 31.3 excess cancer deaths per 100,000 persons exposed within fifteen to twenty years after fluoridation began in the experimental group of cities. If this figure is multiplied against 130 million Americans who have been drinking fluoridated water over the past fifteen to twenty years or more, an excess of over 40,000 cancer deaths in the United States every year are attributable to fluoridation.

Not long after the foregoing figures were first called to the public's attention, Dr. Burk was called to testify before Congress on April 6, 1976. And testify he did:

> Oliver Wendell Holmes Sr., M.D., of Civil War medical fame, and professor of anatomy at Harvard University, in 1843 and 1855 described then prevailing treatment of puerperal fever in lying-in hospitals as criminal manslaughter. It was only manslaughter, however, not murder because the physicians of that day did not have, and could not have had a sufficiently knowledgeable idea of the bacteriological basis of the doctor-nurse-patient transmission of the disease until the work of Pastuer and Lister decades later.
>
> The scientific and medical status of artificial fluoridation or public water supplies has now advanced to the stage of the possibility of socially imposed mass murder on an unexpectedly large scale involving tens of thousands of cancer deaths of Americans annually.[120]

The shock resulting from this firm statement by a world-renowned cancer research scientist evoked an emergency response from the USPHS. Needles to say, the USPHS did not admit that they had exposed the American people to an environmental hazard which produced "literally tens of thousands of cancer deaths of Americans annually." As night follows day, they claimed that Dr. Burk had failed to take elementary precautions.[121]

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120. *Departments of Labor and Health, Education, and Welfare Appropriations for 1977 (Part 7), Hearings Before a Subcomm. of the Comm. on Appropriations*, 94th Cong. 1063-64 (1976) (statement of Dr. Burk).

121. This protest first appeared in a letter of February 6, 1976, from Dr. Ronald Frederickson, Director of the National Institutes of Health, to Congressman James Delaney of New York. This letter has not been officially published, but the particulars are set forth in the

Their pretext was that he and his associates had not adjusted the basic data for age, race and sex, and that, when such adjustments were done, there was no association between fluoridation and cancer.[122] Their claim essentially was that, among 18 million people in twenty large cities over thirty years, it so happened that the experimental cities grew older faster just as they were fluoridated, at that this aging occurred precisely to the extent necessary to create the shocking appearance of an association between fluoridation and cancer.[123] This association, they held, was merely an illusion deceiving the ignorant. It sounds far-fetched. It was worse than far-fetched.

It is obligatory to note the Dr. Burk and those working with him adjusted for demographic variables on numerous occasions.[124] Beyond his published scholarship, he repeated gave detailed testimony on these questions in public hearings[125] and courts of justice.[126] But his view was that the basic data are best not adjusted in this particular case, because the base line established by the data for 1940 through 1950 already controls for all known and unknown variables.[127]

Cancer incidence and mortality are influenced by countless demographic, environmental, dietary, socio-economic, and other factors, some tending to increase, others tending the decrease the extent of the disease. It is known, for example, that older people tend to experience more cancer than younger people, yet good diet and environment can significantly offset the effects of age. Adjustments

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prepared statement of Dr. Arthur Upton, Director of the NCI, to Congress on October 12, 1977. *See National Cancer Program, supra* note 109 at 104-20.

122. *See id.* at 98-103 (statement of Dr. Guy Newell, Deputy Director of NCI).

123. *See id.* at 80-83 (statement of Dr. Robert Hoover, NCI).

124. Dr. Burk's interest in such adjustments first surfaced at the meeting of the American Society of Biological Chemists in San Fransisco on June 6-10, 1976, where he joined Dr. John Yiamouyiannis in a paper setting forth partial adjustments of the basic data of age and race by the direct method. *See* Dean Burk & John Yiamouyiannis, *Fluoridation of Public Water Supplies and Cancer Death Rates*, 35 FED. PROC. AM. SOC. BIOL. CHEM. 1707, (1976). Dr. Burk's more advanced adjustments of the basic data for demographic variables absorbed twelve years of his life's work and included, among others, articles published by the International Society of Fluoride Research and the Pennsylvania Academy of Science. *See* Burk & Yiamouyiannis, *supra* note 108; Burk & Graham, *supra* note 108; Burk, Graham, & Morin, *supra* note 108. He was the major inspiration of these several articles. His matured views are best expressed in the last, published in 1988 not long before his death.

125. For example, see his formal statement to a hearing panel of the EPA on June 17, 1985, including nineteen tables outlining multiple adjustments by the indirect method for age, race and sex, *reprinted in* NATIONAL FLUORIDATION NEWS, Vol. XXXI, no. 4 (1985).

126. *See* Safe Water Found. of Tex. v. City of Houston, No. 80-52271, Trial Transcript, Jan. 13-14, 1982, at 48-105 (151st Jud. Dist., Tex.)

127. *See id.* at 46-48, 105-07.

for age in particular, and perhaps also for race and sex, may be important in comparing two populations at one point in time, because such adjustments may serve as a control for such demographic variables.[128] Yet a very different situation emerges when, as in the case of the basic data here in question, there is a comparison of trends over time, including a long base line.[129]

There are established principles of inductive logic which are associated historically with William of Ockham[130] and Sir Isaac Newton.[131] They are used in the empirical sciences for the discovery or identification of causes in nature. Given a strong trend or association observed in nature, take the simplest and most fitting explanation as the cause, unless and until the contrary be shown. Likewise, attribute like causes to like effects, unless and until the contrary be shown. Finally, where cause and effect in certain circumstances are fairly ascertained by proper experiment, such cause and effect may be generalized throughout the universe, unless and until the contrary is shown.

Given these principles of natural reason, and given what is known about fluoride, including especially its demonstrated carcinogenic potential,[132] the simplest and most fitting explanation of the basic data is that all cancer-influencing factors counterbalanced each other during the long base line period before 1950; that all these factors continued to counterbalance each other after 1950 except for the one factor known to be knew, viz., fluoridation; and that, therefore, the entire observed association between fluoridation and cancer in the basic data, i.e., 31.3 excess CDs/100,000 after 15-20 years of exposure, is attributable to fluoridation as the cause.[133] It can then be generalized by saying that artificial fluoridation of public water supplies causes an immense amount of cancer in the United

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128. *See, e.g.*, Burk & Graham, *supra* note 108, at 65; Burk, Graham, & Morin, *supra* note 108, at 139-40.

129. *See, e.g.*, Burk & Graham, *supra* note 108, at 65; Burk, Graham, & Morin, *supra* note 108, at 140.

130. Ockham's emphasis on the simplest explanation as the best explanation, often called "Ockham's razor," grew out of his philosophical treatment of universals, relations, causation, and motion. *See* COPLESTON, *supra* note 106, pt. I, at 69-71, 80-81, 83-88.

131. At the beginning of the third book of his PHILOSOPHIAE NATURALIS PRINCIPIA MATHEMATICA, Sir Isaac Newton laid down his "rules of reasoning in natural philosophy" for the identification of causes in phenomenal reality, including the simplicity principle, sometimes called "Ockham's Razor." *See* 5 COPLESTON, A HISTORY OF PHILOSOPHY, pt. I, 162-64 (1964).

132. *See generally* Taylor, *supra* note 16; Taylor & Taylor, *supra* note 20; sources cited *supra* note 21.

133. *See* Burk & Graham, *supra* note 108, at 65; Burk, Graham, & Morin, *supra* note 108, at 139-40.

States, "involving tens of thousands of cancer deaths of Americans annually."

Adjustments for age, race, and sex are here meant to account for demographic factors which have already been addressed by the base line. Such adjustments will therefore tend to control more than once for the same factors and so, in this context, will tend to understate reality. Changes in the demographic composition of the control and experimental cities have in some degree been counteracted by other factors, and the adjusted figures will not reflect this counteracting effect. So again, adjustments will tend to understate reality.

Dr. Burk respected conventional opinion, but he did not adore it. And since conventional opinion demands adjustments for age, race, and sex, not because he thought they clarified the meaning of the basic data, he cheerfully went along. It is ironic that the scientist who thought these adjustments least useful did more than all others to assure that they were properly done. His guiding principle in dealing with the subject was that, if adjustments were to be executed, they should rest upon standard methods, and be carried out as comprehensively and thoroughly as possible, otherwise not at all.

It is no less ironic that the attack against his epidemiological work was spearheaded by the National Cancer Institute which he had served with such distinction before his retirement. The confrontation initially developed in hearings on September 21 and October 12, 1977, in Congress.[134]

In these hearings, the National Cancer Institute came forth with its objections in a definitive, 17-page document.[135] It was presented under the signature of the director Dr. Arthur Upton, and introduced in committee by the deputy director Dr. Guy Newell. This "Upton Statement" was then and still is the official position of the government of the United States. It is reputed to be the irrefutable answer to the thesis of Dr. Burk and his colleagues. The scientific debate since then has turned upon the Upton Statement, which lays down a characteristic adjustment of the basic data for age, race, and sex by the indirect method, an orthodox procedure for this purpose.[136]

In this procedure, we ordinarily compare two populations at a certain point in time in terms of the ratio of the observed cancer death rate (which we have called CDRo) to the "index" or

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134. The key contributions of historic significance on both sides are reprinted in *National Cancer Program*, *supra* note 109, at 3-60, 75-83, 98-140, 181-212, 219-30, 305-18 (1977).

135. *See id.* at 104-20.

136. *See* BRADFORD-HILL, *supra* note 118, at 190-96.

"expected" cancer death rate (which we shall call CDRe) of each population.

In deriving an "expected" CDR, we ascertain from census figures the number of persons in each demographic category of the observed populations. In addressing Dr. Burk's basic data, the staff at NCI used forty such categories, viz., age groups 0-4, 5-14, 15-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75-84, and 85+, each divided into white male, white female, nonwhite male, and nonwhite female.

We must then select a "standard population," drawn from census figures and vital statistics for a certain territory and year: this standard population really consists of a set of known cancer death rates for each category in the population. The choice of this standard population requires some judgment. The staff at NCI selected the United States in 1950,[137] which is not, in our view, an unreasonable choice, because it represents a fair estimate of what cancer experience should be, category by category, in the absence of anything tending to make cancer deaths higher or lower than usual.

For each population compared, the number of persons in each category is multiplied by the corresponding rate in the standard population. Expected cancer deaths so determined are added up, then divided by the total population, and reduced to a common denominator of 100,000. The resulting "expected" CDR will be what may be anticipated for the population in view of its demographic composition.

The fraction CDRo/CDRe is called a standardized mortality ratio or SMR. If based on good judgment, it will indicate the extent to which the observed cancer death rate of a given population is higher or lower than what should be expected under normal circumstances in view of its demographic structure.

The Upton Statement sets forth an adjustment of the basic data expressed in weighted averages. The SMRs are as follows:[138]

	1950	1970	Change
CDRo/CDRe (+F)	1.23	1.24	+.01
CDRo/CDRe (-F)	1.15	1.17	+.02

Using these figures, the NCI asked Congress to believe that, relative to what may be expected in light of the age structure of the

137. *See National Cancer Program, supra* note 109, at 112, 224.
138. *See National Cancer Program, supra* note 109, at 118.

two groups of cities observed, cancer mortality actually grew 1% faster in the unfluoridated cities than in the fluoridated cities.[139]

Dr. Burk and his colleagues had a remarkable answer:[140] The available and pertinent data for the years after 1950, were 1953-1968. Without the trends in these years, nobody would suspect that there is a causal relationship between fluoridation and cancer. In its adjustment, the NCI considered 1950 before fluoridation began the experimental cities, and 1970 after fluoridation had already been initiated in the control cities, and did not consider the years 1953-1968 which were the whole basis of concern. In other words, the NCI simply derived their CDRo values from data reported for 1950 and 1970, and ignored all else, as if 1953-1968 were unimportant.

Having omitted all available and pertinent data in their adjustment, it is not surprising that the NCI came up with the wrong answer. In the same hearings before Congress, it was demonstrated by a colleague of Dr. Burk that, if the adjustment proposed by the NCI is undertaken using all available and pertinent data after 1950, there emerges an impressive association between fluoridation and age-race-sex adjusted cancer mortality.[141]

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139. *See id.* at 81, 112.

140. *See id.* at 64-65. *See also* Burk & Graham, *supra* note 108, at 67-68; Burk, Graham, & Morin, *supra* note 108, at 142-43.

141. Dr. John Yiamouyiannis executed an adjustment of the basic data, using weighted averages and 1950 as the standard population, exactly as stipulated in the Upton Statement. He adjusted only for the years after 1950, deriving CDRo values for 1950 and 1970, by linear regression analysis of the CDRo data for 1950 and 1953-1969, and showed an association in terms of CDRo/CDRe = +.042, and in terms of CDRo-CDRe = 12.4 cancer deaths per 100,00 persons exposed within after fifteen to twenty years after the introduction of fluoridation in the experimental cities. *See National Cancer Program*, *supra* note 109, at 64-65. The main objection to this technique came from Dr. David Newell of the Royal Statistical Society in defense of the Upton Statement. He claimed that, because populations between census years and thus denominators in intercensal CDRs must be estimated by linear interpolation, they are not reliable data, and therefore not suitable for linear regression analysis. *See* Aitkenhead v. Borough of West View, No. GD-4585, Trial Transcript, May 8, 1978, at 72, 72A, 73-76 (Allegheny Court of Common Pleas, Pa). This criticism was exploded by none other than Dr. Guy Newell, Deputy Director of the NCI, who supervised preparation of the Upton Statement and introduced it before Congress. Later speaking as a professor of epidemiology at the University of Texas, he stated emphatically that use of linear interpolation to derive denominators in intercensal CDRs is "accepted procedure" in modern applied epidemiology, and, therefore, perfectly reliable. *See* Safe Water Found. of Texas v. City of Houston, No. 80-52271, Trial Transcript, Jan. 26, 1982, at 1648-54 (151st Jud. Dist., Tex.). The correctness of undertaking a linear regression analysis of intercensal CDRs in which the denominators were estimated by linear interpolation was further confirmed by Dr. Hubert Arnold, professor of statistics at the University of California, Davis. *See National Cancer Program*, *supra* note 109, at 580. The propriety and necessity of such use of interpolated data, based on fundamental principles of inductive logic, is discussed in Burk & Graham, *supra* note 108, at 68-69, and Burk, Graham, & Morin, *supra* note 108, at 143-44.

Dr. Burk developed even more comprehensive adjustments. In doing so, he considered the years before and after 1950, because the observed CDRs portray a change in trends after 1950 and a change from trends before 1950.[142] The data representing 1953-1968 were important, but they were especially important in view of what happened in 1940-1950. The need to consider the years before and after 1950 became clearer from the fact that there were demographic fluctuations before and after 1950: it appeared that these fluctuations both before and after 1950 could materially influence the size the association adjusted for age, race, and sex.

Dr. Burk derived CDRo values for 1940 and 1950 by linear regression analysis of the data for 1940-1950, and for 1950 and 1970 by linear regression analysis of the data for 1953-1968.[143] He derived CDRe values, using 1950 as the standard population, exactly as stipulated in the Upton statement.[144] He used the SMR or CDRo/CDRe, and also the difference between observed and expected CDRs, i.e., CDRo-CDRe, which is also used by conventional epidemiologists.[145] His results can be summarized as follows:[146]

Cities	1940	1950	1950	1970
CDRo (+F)	154.2	181.8	186.3	222.6
CDRe (+F)	128.1	146.9	146.9	174.7
CDRo/CDRe (+F)	1.204	1.238	1.268	1.274
CDRo-CDRe (+F)	26.1	34.9	39.4	47.9
CDRo (-F)	153.5	181.3	183.6	188.8
CDRe (-F)	140.3	155.5	155.5	166.0
CDRo/CDRe (-F)	1.094	1.166	1.181	1.137
CDRo-CDRe (-F)	13.2	25.8	28.1	22.8

142. On the importance of adjusting both for the period before fluoridation was begun in the experimental cities and the period after, then reaching a combined result, see Burk & Graham, *supra* note 108, at 67, and Burk, Graham, & Morin, *supra* note 108, at 142-43.

143. *See* Burk & Graham, *supra* note 108, at 67; Burk, Graham, & Morin, *supra* note 108, at 142.

144. The particulars of the NCI adjustments are laid out more clearly in the paper of the Royal Statistical Society defending the Upton Statement. *See National Cancer Program*, *supra* note 109, at 224-29.

145. *See id.* at 227-28 (Royal Statistical Society).

146. *See* Burk & Graham, *supra* note 108, at 67-68. Dr. Burk preferred another similar adjustment based on the indirect method, using weighted averages and US-1940 as the standard population, then combining the impact of changes both before and after 1950 in "time independent" terms. This adjustment yields the conclusion that 69.2% of the observed association between fluoridation and cancer, as reflected in the basic data, cannot be explained by demographic differences. *See* Burk, Graham, & Morin, *supra* note 108, at 142-43.

There figures can be transformed into coefficients which reflect an association between fluoridation and CDRs adjusted for age, race, and sex, as it developed from 1940 to 1970:

The change in CDRo/CDRe = [(1.274-1.137) - (1.268-1.181)] + [(1.204-1.094) - (1.238-1.166)] = +.088. This coefficient means that, relative to what might be expected in light of the demographic structure of the two populations here in question, adjusted cancer mortality grew about 9% faster in the fluoridated cities.

In terms of CDRo-CDRe, fluoridation is associated with [(47.9-22.8) - (39.4-28.1)] + [(26.1-13.2) - (34.9-25.8)] = 17.6 excess cancer deaths per 100,000 persons exposed after 15-20 years. This adjusted figure, multiplied against 130 million Americans now drinking fluoridated water 15-20 years, works out to something on the order of 23,000 excess cancer deaths every year in the United States.

Whether adjusted or unadjusted figures are preferred, the size of the human casualty is so large and tragic that it is almost indecent to quibble over the numbers. Over twenty years have passed, and the casualty has mounted, since the NCI represented to Congress, on the basis of demographic adjustments which left out all available and pertinent data, that there is no association between fluoridation and cancer.

VII. THE JUDICIAL FINDINGS CONDEMNING FLUORIDATION

In the wake of the hearings in Congress just discussed, litigation seeking to resist or restrain further implementation of fluoridation began in several places in the United States. In Ohio it had recently been held that fluoridation was a constitutional exercise of police power.[147]

But in light of the recent publication of the basic data gathered under the direction of Dean Burk, opportunities for a new judicial hearing vastly improved. When such a hearing was sought, the Ohio Supreme Court commented:

> A more difficult question is raised by the claim that fluoride is a carcinogen based on statistics that the cancer death rate has increased in certain cities with fluoridated water, while remaining the same in certain other cities which do not fluoridate. The evidence for this claim has not been tested by litigation and is disputed by other authorities. This evidence has also been submitted to federal agencies and to the Congress. If scientifically proved,

147. *See* City of Canton v. Whitman, 337 N.E.2d 766 (Ohio 1975); City of Cincinnati v. Whitman, 337 N.E. 2d 773 (Ohio 1975).

> these claims could raise legitimate questions as to the constitutionality of fluoridation as a public health measure, and, since these claims are based upon very recent studies, the purposes underlying the principle of res judicata would probably not be served by barring litigation to determine the validity of these claims.[148]

Reading this statement side by side with *Jacobson v. Massachusetts*,[149] and *Paduano v. City of New York*[150], a suit before the judiciary attacking the constitutionality of mandatory fluoridation should succeed if it could be established by a fair preponderance of the evidence that the measure causes or contributes to the cause of cancer in man. But the court held that the judiciary had no original jurisdiction to consider the question, ostensibly because, in Ohio, the power to find the facts was vested by statute in an administrative agency.[151] The holding seems to have been created post hoc to avoid a touchy question.

It would have been easy for the court to rely on respectable authority to the effect that, where a constitutional question is fairly raised, and the outcome depends on facts, especially where personal rights are involved, exhaustion of administrative remedies is not necessary, and the judiciary can take jurisdiction to hear the evidence and decide the controversy on the merits.[152] No further headway was made in Ohio because the plaintiffs too well understood that impartial consideration by the administrative agency, where fluoridation was institutional policy, was as hopeless as an unbiased attitude by the NCI and other institutes in the USPHS.

A. The Pittsburgh Case

However, it was not necessary to wait very long for the opportunity to be fairly heard on the new evidence in Pittsburgh in the case of *Aitkendead v. Borough of West View*.[153] The case was assigned to Judge John Flaherty who has since become the Chief Justice of Pennsylvania. The suit rested on a theory of nuisance, and

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148. City of Cincinnati *ex rel.* Crotty v. City of Cincinnati, 361 N.E.2d 1340, 1341-42 (Ohio 1977).

149. *See* 197 U.S. 11, 39 (1905).

150. 257 N.Y.S.2d 531, 542 (N.Y. Sup. Ct. 1965)

151. *See* 361 N.E.2d at 1342.

152. *See, e.g.*, United States v. Sisson, 297 F. Supp. 902, 906 (D. Mass. 1969) *appeal dismissed*, 399 U.S. 267 (1970); Bare v. Gorton, 526 P.2d 379, 383-84 (Wash. 1974). This exception to the rule on exhaustion of administrative remedies is ultimately rooted in the "constitutional fact" doctrine in *Ng Fung Ho v. White*, 259 U.S. 276, 282-83 (1922) and *Ohio Valley Water Co. v. Ben Avon Borough*, 253 U.S. 287, 289 (1920).

153. No. GD-4585-78 (Allegheny County Court of Common Pleas, Pa.).

went to hearing on a motion for a preliminary injunction. Expert witnesses from the National Cancer Institute, the National Academy of Sciences, the Royal Statistical Society, an the Royal College of Physicians appeared to oppose the testimony of Dr. Burk and his colleagues, as had occurred in Congress.[154] After many sessions, followed by extensive summations on both sides, Judge Flaherty made his findings on November 16, 1978. He first described the main evidence by stating:

> Over the course of five months, the court held periodic hearings which consisted of extensive expert testimony from as far away as England. At issue was the most recent time trend study of Dr. Burk and Dr. Yiamouyiannis, which compared the cancer mortality of 10 cities which fluoridated their water systems with 10 cities which did not fluoridate over a period of 28 years from 1940 to 1968. The study concluded that there was a significant increase in cancer mortality in the fluoridated cities.[155]

He defined the sole issue of fact as "whether fluoride may be a carcinogen."[156] He then found that "[p]oint by point, every criticism made of the Burk-Yiamouyiannis study was met and explained by the plaintiffs. Often, the point was turned around against defendants. In short, this court was compellingly convinced of the evidence in favor of plaintiffs."[157]

Judge Flaherty entered a preliminary injunction. Since the facts of the case had been fully tried, a motion was prepared for an amended complaint to attack the constitutionality of imposed fluoridation, and for a permanent injunction, based on danger to public health. The motion was about to be filed when raw power showed itself with lightning speed and impressive clout to limit the political

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154. The most critical dispute in the trial was whether the basic data (set forth in the appendix of this article) should be adjusted for age, race, and sex by the methods proposed by Dr. Dean Burk or Dr. John Yiamouyiannis in *National Cancer Program, supra* note 109, at 18-40, 61-72, or by the method proposed in the Upton Statement, *id.* at 104-20, 220-30. The defense of the Upton Statement collapsed when Dr. David Newell of the RSS conceded that he used data only for 1950 and 1970, and considered nothing in between "for the main and simple reason" that he was sent his data from the NCI. *See* Aitkenhead v. Borough of West View, No. GD-4585-78, Trial Transcript, May 9, 1978, at 72-72A, 75-6 (Allegheny County Court of Common Pleas, Pa.). Dr. Marvin Schneiderman of NCI admitted that such intermediate data should be used, but could give no specific alternative to linear regression analysis of intercensal CDRs between 1950 and 1970. *See id.* Trial Transcript, May 9, 1978, at 47-56.

155. *See* No. GD-4585-78, Opinion, Nov. 16, 1978, at 6.

156. *Id.* at 6.

157. *Id.* at 9.

damage.[158] The Chief Judge of the Commonwealth Court of Pennsylvania quickly stayed the preliminary injunction, ignoring the facts judicially found, as if public safety were not an issue.[159]

An administrative agency, which favored fluoridation as institutional policy, quickly and summarily entered "findings" which parroted USPHS propaganda.[160] Another administrative agency, which had a similar institutional policy, then entered an "order" which purported to deny the Borough of West View "permission" to obey Judge Flaherty's injunction.[161] Events thus took bizarre turns to save a sacred cow.

Jurisdiction to enter the findings supporting the preliminary decree of November 16, 1978, was sustained on appeal shortly before Judge Flaherty was elevated to the Supreme Court of Pennsylvania.[162] The Commonwealth Court held that the cause could go no further before the judiciary under the pretext that exclusive jurisdiction belonged to the administrative agency.[163] The was the end of the case, for all understood the notorious bias of the administrative agency which was not about to admit that it had promoted the dumping of carcinogenic agents into the environment. The appellate decisions left the findings of Judge Flaherty untouched, but departed widely from the traditional rule that, once a court of equity takes jurisdiction over the subject matter of a suit, such jurisdiction continues until the final decree, even though a basis for legal or administrative jurisdiction might later appear.[164]

As the USPHS tried to press-release its way out of the crisis in the United States, the findings of Judge Flaherty became highly influential abroad. In the British House of Lords, the Earl of Yarborough accurately summed up the meaning of the case:

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158. The odd appellate history of the cause is summarized in *Aitkenhead v. West View*, 442 A.2d 364 (Pa. Commw. Ct. 1982), and *Aitkenhead v. West View*, 397 A.2d 878, 878-79 (Pa. Commw. Ct. 1979)

159. *See* 399 A.2d at 879-80.

160. *See* Aitkenhead v. Borough of West View, No. GD-4585-78, Exhibit C (Pa. Dept. of Health, Dec. 21, 1978), Plaintiffs' Motion to Dismiss Preliminary Objections, Feb. 21, 1979 (Allegheny County Court of Common Pleas, Pa.).

161. *See id.* Exhibit A (Pa. Dept. of Env. Res., Jan. 8, 1979), Plaintiffs' Motion to Dismiss Preliminary Objections, Feb. 21, 1979. *See also id.* Order Dismissing Preliminary Objections, May 25, 1979.

162. *See* Aitkenhead, 397 A.2d at 880.

163. *See* Aitkenhead, 442 A.2d at 366.

164. The rule can be traced to Lord Eldon in *Eyre v. Everett*, 2 Russ. 381 (Ch. 1826), and *Adley v. Whitstable*, 17 Ves. Jr. 316 (Ch. 1810). *See also* Gulbenkian v. Gulbenkian, 147 F.2d 173, 176 (2d Cir. 1945); Rosen v. Mayer, 113 N.E. 217 (Mass. 1916).

> Already this evening examples have been quoted of what occurred in America. What I read was rather different from the picture painted this evening. It was my understanding if the case quoted was the case in Allegheny [County] in Pennsylvania that it was found proven that fluoride was a danger to health. I know that there was some legal wrangle about jurisdiction but I thought, on the facts presented by a number of experts, that that was the finding and that the facts had not been challenged but merely the jurisdiction of the court.[165]

So important was the meaning of this case that it also attracted the attention of an investigative commission of the Environment Ministry of Quebec, chaired by Dr. Benoît Bundock who had been the principal medical officer for special projects in the Canadian Ministry of Health. The commission had been diligently studying world literature on fluoridation for over a year when Judge Flaherty returned his findings. They obtained the entire record of the proceedings in Pittsburgh.

Dr. Bundock and his colleagues returned a comprehensive report on November 30, 1979, acknowledging the laboratory studies of Dr. Taylor and the basic data of Dr. Burk, specifically concurred with the findings of Judge Flaherty, and recommended executive suspension of all efforts to enforce the mandatory fluoridation law of Quebec.[166] This recommendation was accepted, and the moratorium has now continued almost twenty years through no less than six governments both pequist and liberal. So well regarded is this report that a standard ecology textbook, widely used in the secondary schools of Quebec, forthrightly acknowledges that fluoride in drinking water, as introduced through artificial fluoridation of public water supplies, is an environmental pollutant which causes cancer in man.[167]

B. The Alton Case

One important early case sustaining the constitutionality of imposed fluoridation on sweeping notions of police power came out

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165. 402 PARL. DEB. H.L. (5th ser.) 1446-50 (1979). Another important contribution on the same occasion, including learned discussion on the epidemiological work of Dr. Dean Burk, came from the Deputy Speaker, Lord Douglas of Barloch. *See id.* at 1461-68. See also the recent and informed speeches by the Earl Baldwin of Bewdley in 593 PARL. DEB. H. L. (5th ser.) 1394-99, 1427-29 (1998).

166. *See* Jean-Benoît Bundock et al., *Les fluorures, la fluoruration, et la qualité de l'environnement*, MINISTERE DE L'ENVIRONNEMENT, GOUVERNEMENT DU QUÉBEC, at 1-2, 103-04, 107-08, 116-17, 197-200 (1979).

167. *See* JACQUES VIEL ET PAUL DARVEAU, POUR UNE PENSEE ECOLOGIQUE 35 (1984).

of the Illinois Supreme Court.[168] Some years later a suit was brought to enjoin fluoridation on allegations of new evidence not previously considered. The complaint was dismissed on demurer, but the Appellate Court of Illinois held that, taking the facts alleged as true, res judicata did not bar the suit, because res judicata cannot bar reconsideration of an issue on the basis of evidence which did not exist when the judgment was initially entered.[169] The remand occurred in 1972, and the case floundered in legal horseplay in the circuit court until a trial was forced eight years later in Alton, where Lincoln and Douglas had debated the Dred Scott case before the Civil War.

Illinois Pure Water Committee v. Director of Public Health[170] was tried from April through June 1980 before Judge Ronald Niemann. It was a case of uncommon ferocity with endless dilatory motions and preposterous contentions by the State, causing the trial to move at a snail's pace.

Judge Niemann endured the experience with almost inhuman patience. He had a highly skeptical attitude about the testimony offered on behalf of the plaintiffs and he reacted to the large numbers generated by the basic data with astonishment and disbelief. He discounted much of what he heard, but at length was satisfied that the plaintiffs had at least made a prima facie case of danger to public safety.[171]

Judge Niemann turned to the State and asked it to account for the association between fluoridation and cancer reflected by the basic data.[172] It should be kept in mind that Chicago is the home of the ADA which has at its command every expert in the world to support fluoridation as a public health measure. Even so, no world class scientists appeared to defend fluoridation as in the hearings before Congress and the trial in Pittsburgh.[173]

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168. *See* Schuringa v. City of Chicago, 198 N.E.2d 326 (Ill. 1964).

169. *See* Illionois Pure Water Comm. v. Yoder, 286 N.E.2d 155, 157-58 (Ill. App. Ct. 1972).

170. *See* No. 68-E-128 (Madison County Circuit Court, Ill.). The full record of the proceedings is not available to us, but the final decree entered by Judge Nieman on February 24, 1982, is fairly detailed in describing the procedural history and the scientific evidence presented on both sides. Moreover, the summations of the evidence and the legal arguments on both sides, only slightly abridged, have been conveniently and accurately published by the National Health Action Committee in 2 HEALTH ACTION, NO. 11-12 (1981) [hereinafter HEALTH ACTION].

171. *See* Illinois Pure Water Comm'n v. Dir. of Pub. Health, No. 68-E-128, Final Decree, Feb. 24, 1982, at 9-10, 20-1, 29 (Madison County Circuit Court, Ill.).

172. *See id.* at 10, 29, 33.

173. *See id.* at 10.

A state-hired epidemiologist went so far as to claim that the basic data was invalid because the basic data linking fluoridation with cancer had been selected and organized to meet the requirements of experimental design. In other words, he condemned the comparison of like with like before introducing fluoridation in the experimental cities, then observing the subsequent difference in cancer mortality between the two groups invalidated the data. Instead, he said, it was statistically necessary to select fluoridated and unfluoridated cities of the country at random,[174] which, of course, would have assured no control for known and unknown variables.

The same epidemiologist spoke of the need for adjustments for age, race, and sex, yet the plaintiffs' case in chief was full of detailed demographic adjustments of the basic data by the direct and indirect methods.[175] A large box of original data, rows of government publications, and a thick bundle of sheets of calculations were brought into the courtroom for inspection. The same epidemiologist made generalized claims that his adjustments wiped away any association between fluoridation and cancer, yet he conspicuously offered no specific figures or documented calculations in support of his projections.[176]

"What causes cancer?" asked the attorney general of Illinois in his summation, "Apparently, nobody knows."[177] Judge Niemann pondered the case for almost two years. On February 24, 1982, he entered judgment. He thus stated the law:

> The presumption of the validity of legislation is overcome when the plaintiff makes a prima facie case. The traditional concept of burden of proof resting on the plaintiff, once met, shifts to the government to justify its intrusion into the life and health of the individual. When the State is involved, the traditional view is that the 'King can do no wrong.' Although the King must constantly act for his subjects, certainly he has been wrong a time or two.[178]

Judge Niemann specifically found, "[This legislation] exposes the public to the risk, uncertain in its scope, of unhealthy side effects of artificial fluoridation of public water supplies, is unreasonable, and [is] a violation of the due process clause of the Illinois Constitution of

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174. *See* HEALTH ACTION, *supra* note 170, 16-19 (Plaintiffs' Summation), and 53-54 (Defendant's Summation).

175. *See id.* at 20-26 (Plaintiffs' Summation).

176. *See id.* at 56-58 (Defendant's Summation).

177. *Id.* at 62 (Defendant's conclusion in final argument).

178. Illinois Pure Water Comm. v. Director of Pub. Health, No. 68-E-128, Final Decree, Feb. 24, 1982, at 29 (Madison County Circuit Court, Ill.).

1970."[179] He added with disappointment, "This record is barren of any credible and reputable scientific epidemiological studies and/or analysis of statistical data which would support the Illinois Legislature's determination that fluoridation of public water supplies is both a safe and effective means of promoting public health."[180] Accordingly, Judge Niemann entered a permanent injunction enjoining the State and its subdivisions from further implementation of fluoridation in Illinois.[181]

A direct appeal was immediately taken to the Illinois Supreme Court. Like lightning, the injunction was stayed without any consideration of the evidence, as if power, and not public health, were the name of the game.[182] As night follows day, the Illinois Supreme Court reversed the judgment of the circuit court citing broad notions of police power.[183] Particularly offensive about the opinion were numerous petty and vindictive comments made against the plaintiffs' witnesses,[184] harmful to the dignity of the bench.

There was also dissimulation regarding the record, as may be illustrated. Judge Niemann had specifically found that the statute was "unreasonable," and therefore unconstitutional, because a prima facie case had been made that fluoridation exposes the population to a tangible risk, albeit uncertain in extent, of unhealthy side effects, and that no "credible and reputable" evidence had been given to justify the intrusion.[185] Yet the Illinois Supreme Court attempted to characterize Judge Niemann's position to be "not that the risk was so great that fluoridation was unreasonable, but that the question was shown to be debatable. Under these circumstances the plaintiffs have failed to show an unreasonable exercise of the police power."[186]

C. The Houston Case

A third case arose in the Lone Star State, entitled *Safe Water Foundation of Texas v. City of Houston*.[187] The case brought to trial in January 1982, before Judge Anthony Farris. The petition prayed for a declaratory judgment that a recently enacted city ordinance impos-

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179. *Id.* at 32.
180. *Id.* at 33.
181. *See id.* at 44.
182. *See* Illinois Pure Water Comm. v. Director of Pub. Health, 470 N.E.2d 988-89 (Ill. 1984).
183. *See id.* at 991-92.
184. *See id.* at 989-90
185. *See id.* No. 68-E-128, Final Decree, Feb. 24, 1982, at 29, 32, 33.
186. 470 N.E.2d at 992.
187. No. 80-52271 (151st Jud. Dist., Tex.).

ing fluoridation in Houston was unconstitutional, and it sought an injunction prohibiting implementation of the ordinance within the municipality.[188]

The trial before Judge Farris moved at an energetic pace, not atypical of judicial proceedings in Texas. It was distinguished by polished testimony on both sides. The best available witnesses from several universities defended fluoridation. Cross-examination was crisp and businesslike. The rules of evidence were somewhat relaxed[189] so as to permit practical inclusion of more information in less time. The bench firmly managed the proceedings. The trial was efficient, ample, rigorous, and thorough.

Whereas in Pittsburgh and Alton, the issue was reduced to whether or not fluoridation induces cancer in man, in Houston a larger range of evidence was considered. These issues included, aside from cancer, whether fluoridation induces genetic damage,[190] intolerant reactions,[191] and chronic toxicity,[192] not to mention other disputed points

Counsel and witnesses for the plaintiffs conceeded that a rational controversy exists over the effectiveness and safety of fluoridation.[193] It was so stipulated, because a good measure of knowledge is awareness of both sides of the question. There were a few fanatical pro-fluoridation witnesses who made fabulous claims of Newburgh-Kingston orthodoxy, but they did not do well. Pro-fluoridation

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188. *See id.* at Second Amended Petition, Dec. 3, 1980, at 6-8.

189. *See id.* Trial Transcript, Jan. 14, 1982, at 280-287. Relying on *Urquhart v. Barnes*, 335 S.W.2d 666, 669 (Tex. Civ. App. 1960), Judge Farris held that learned treatises could be marked, introduced and received to prove their existence and the basis of the opinion offered. This ruling was made during the testimony of Doctor Albert Burgstahler, one of the foremost scholars on fluoride and fluoridation. The impact of Judge Farris' ruling was to promote an excellent record for this kind of case, as illustrated by Dr. Burgstahler's testimony on direct examination. *See* No. 80-52271, Trial Transcript, Jan. 14-15, 1982, at 276-429.

190. *See, e.g.*, No. 80-52271, Trial Transcript, Jan. 18, 1992, at 539-59 (testimony of Dr. Pierre Morin). Dr. Morin testified on the laboratory studies of fluoride and mutagenesis noted by Dyson Rose and John Maurier in *Environmental Fluoride*, NAT'L RES. COUNCIL OF CANADA PUBL. NO. 16081 69-70 (1977), as confirmed by epidemiological data linking fluoride in drinking water and mongoloid births. *See* Ionel Rapaport, *Les opacifications du cristallin mongolisme et cataracte sénile*, 2 REV. ANTHROP. (Paris) 133 (1954); Ionel Rapaport *Contribution a l'étude du mongolisme. Rôle pathologénique du fluor*, 140 BULL. ACAD. NAT'L. MED. (Paris) 529 (1956).

191. *See, e.g.*, No. 80-52271, Trial Transcript, Jan. 19, 1982, at 579-96 (testimony of John Lee, M.D., on the work of Dr. George L. Waldbott in *Fluoridation: A Clinician's Experience*. 73 SO. MED. J. 301 (1980), and his own clinical experience.).

192. *See* No. 80-52271, Trial Transcript, Jan. 19, 1992, at 609-14 (testimony of Dr, Lee on the strong association between the fluoride content of public water supplies and dental fluorosis, described by Rudolf Ziegelbecker, *Natürlicher Fluoridgehalt des Trinkwassers und Karies*, 122 GWF WASSER/ABWASSER 495 (1981)).

193. *See* No. 80-52271 (Plaintiffs' Summation), Feb. 4, 1982, at 4.

witnesses who displayed broader understanding were more appreciated.

At the conclusion of the trial, plaintiffs argued that they proved serious injury to the public health by a fair preponderance of the evidence, and that for this reason they were entitled to an injunction.[194] On the other side, counsel argued that there was a reasonable debate, and that for this reason the City was entitled to a judgment of dismissal.[195]

On February 22, 1982, Judge Farris denied the plaintiff's motion for permanent injunction, holding that the plaintiffs "had the burden to introduce overwhelming evidence in this case. Plaintiffs had to prove that no rational relationship exists between fluoridation of city surface water and the public health. Plaintiffs had to prove that no controversial facts exist."[196]

The plaintiffs immediately made a motion for new trial or amended order.[197] The argument on the motion, heard on April 19, 1982, centered on the burden of proof necessary to prevail. Judge Farris stated from the bench that the plaintiffs had proven harm by a fair preponderance of the evidence.[198] "If this were your run-of-the-mill litigation asking for injunctive relief," he said, "plaintiffs would have prevailed, but this is not the run-of-the-mill case."[199]

The question was one of burden of proof, a pure question of law. It was agreed by the court and counsel that "[t]hat is why we have appellate courts."[200] Counsel for the plaintiffs then asked for findings based on a fair preponderance of the evidence to prepare the record for appeal.[201] The court acceded to the suggestion, asking for proposals from both sides.[202] On May 24, 1982, Judge Farris entered his findings which were about as comprehensive and

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194. *See id.* Plaintiffs' Summation, Feb. 4, 1982, at 4, 25.

195. *See id.* Defendant's Summation, Feb. 4, 1982, at 12-13.

196. *See id.*Opinion, Feb. 22, 1982, at 8. Judge Farris relied on *City of Houston v. Johnny Frank's Auto Parts Co.*, 480 S.W.2d 774 (Tex. Civ. App. 1972), which rests squarely of *Ferguson v. Skrupa*, 372 U.S. 726 (1963).

197. *See* No. 80-52271, Plaintiffs' Amended Motion for New Trial, Etc., April 14, 1982, at 1 (stating that, while the evidence at trial "did not eliminate the existence of a rational controversy, and was not intended or claimed to do so, the preponderance of the said evidence tended to show" that fluoridation causes or contributes to the cause of "cancer, genetic damage, intolerant reactions, and chronic toxicity, including dental mottling in man.").

198. *See id.* Hearing Transcript, Apr. 19, 1982, at 11.

199. *See id.* at 10.

200. *See id.* at 12.

201. *See id.* at 12-13.

202. *See id.* at 13-14.

desirable as any judicial findings have been in environmental law.[203] The court found:

> [That] the artificial fluoridation of public water supplies, such as is contemplated by [Houston] City Ordinance No. 80-2530 may cause or contribute to the cause of cancer, genetic damage, intolerant reactions, and chronic toxicity, including dental mottling, in man; that the said artificial fluoridation may aggravate malnutrition and existing illnesses in man; and that the value of said artificial fluoridation is in some doubt as to the reduction of tooth decay in man.[204]

This assessment of the facts, based on a fair preponderance of the evidence, was a reasonable and impartial picture of scientific reality as it was then understood.

If the municipal government of Houston had acted rationally in the face of these findings of fact, effectively a declaratory judgment on the weight of the evidence, the city council would have noted the danger, repealed the ordinance in the public interest, and perhaps established an investigative commission as had occurred in Quebec. But a city councilwoman, smiling broadly as cameras flashed, started the machinery which injected, into public drinking water, a substance judicially found, after an intensive and disciplined trial of the facts to be carcinogenic and mutagenic.[205]

An appeal was taken, based mainly on a venerable old case decided by the Texas Supreme Court which held that, where exercise of police power rests on assumed facts, those facts may be judicially examined and, if upon such inquiry it fairly appears that the means chosen are disproportionate to the end desired, the ordinance should be declared unconstitutional.[206] The principle is typical of the best natural law jurisprudence which prevailed earlier in the twentieth century. Given the findings of Judge Farris, fluoridation was unconstitutional under this principle, because endangering the public with cancer and other ailments cannot be justified by a dubious possibility of reducing tooth decay. The Texas Court of Appeals

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203. The findings of Judge Farris, based on a fair preponderance of the evidence, are similar to the findings of Judge Miles Lord in *United States v. Reserve Mining Co.*, 380 F. Supp 11, 15-17 (D. Min. 1974), and *United States v. Reserve Mining Co.*, 417 F. Supp 789 (D. Minn. 1976), affirmed 543 F. 2d 1210 (8th Cir. 1976). The dumping of taconite tailings was terminated on the principle that, where substantial evidence shows harm to human health, a question of public health should be judicially determined by resolving doubt against the introduction of foreign material into environment.

204. *See* No. 80-52271, Findings of Fact, May 24, 1982, at 1-2.

205. *See id.* at 1-2.

206. *See* Houston & T.C.Ry. v. City of Dallas, 84 S.W. 648, 653-54 (Tex. 1905).

expressly found that a fair preponderance of the evidence showed "the injection of fluoride into the City's water system would be harmful,"[207] but, with the full support of higher tribunals, that such proof of harm was not enough to arrest an exercise of police power.[208]

Therefore, it is evident that, at least for the time, we are saddled with Hugo Black's positivist and anti-libertarian doctrines, and some years must pass before our judiciary see the need for a change of course. Years must pass as surely as years had to pass from the death of Sir John Elliot following his arrest in 1630 for a speech in Parliament, and the grand day in 1667 when the House of Lords reversed the judgment of the King's Bench which denied Sir John release on a writ of habeas corpus.[209] Meanwhile, the findings of Judge Flaherty, Judge Niemann, and Judge Farris have since been quoted to legislative bodies from Montreal to Honolulu and from London to Canbarra. Not always, but occasionally legislators have listened.

There has been other interesting political fallout from these judicial findings. On August 9-10, 1983, a strategic conference of pro-fluoridation activists, most of them deeply involved in ADA and USPHS politics took place at the University of Michigan.[210]

The proceedings began with a presentation by a special counsel of the American Dental Association.[211] The gentleman was introduced as a member of the rules committee of the Illinois Supreme Court, so it is clear that he was a powerful insider.[212] He told the audience that it was he who had secured the stay of the injunction from the Illinois Supreme Court issued by Judge Niemann.[213]

Counsel did not clearly inform his listeners that, from 1978 through 1982, three American judges in courts of superior jurisdiction had fully heard evidence on both sides: the first of these judges, by then a supreme court justice of eminent standing, entered findings undisturbed on appeal, saying he was compellingly convinced

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207. Safe Water Found. of Tex. v. City of Houston, 661 S.W.2d 190, 192 (Tex. App. 1983), *writ ref'd n.r.e.* (Tex. 1984), *appeal dismissed* 469 U.S. 801 (1984).

208. *See id.* at 192-93.

209. *See, e.g.*, HENRY HALLAM, CONSTITUTIONAL HISTORY OF ENGLAND 299-300 (Garland Pub. 1978) (1846).

210. The proceedings were recorded verbatim in *FLUORIDATION: LITIGATION & CHANGING* PUBLIC POLICY, (Michael W. Easley et al. eds. 1983) [hereinafter CHANGING PUBLIC POLICY].

211. *See id.* at 3-11.

212. *See id.* at 3.

213. *See id.* at 5-6; *see also* Illinois Pure Water Comm., Inc. v. Director of Pub. Health, 470 N.E.2d. 988, 989 (Ill. 1984).

of the danger of cancer; the second entered findings of no credible or reputable evidence to redeem fluoridation; and the third had entered comprehensive findings based on a preponderance of the evidence, expressly sustained on appeal, condemning fluoridation as posing a tangible danger of cancer and a good many other human diseases, while expressing doubt even of its capacity to reduce tooth decay.

Another speaker at the University of Michigan announced a significant change of litigation policy to perpetuate and expand fluoridation in future years. Whereas in earlier years it had been standard practice to invite trials, as had occurred in a number of earlier fluoridation cases, a new policy, following the trials in Pittsburgh, Alton, and Houston, was announced: "By avoiding a trial on the merits of fluoridation, we prevent the subjection of what we feel is a purely scientific issue to scrutiny by a judge who is likely not to have proper scientific training with which to make an objective ruling."[214] To recapitulate this interesting phase of legal and scientific history, in the trials in Pittsburgh, Alton, and Houston, one trial judge after another heard the evidence and found that fluoridation appears to be injurious to human health. Therefore, the new ADA-USPHS policy is to avoid, by all means, a trial on the merits.

This policy has been remarkably successful for over fifteen years. No case has ever gotten to trial. No pro-fluoridation witness has been cross-examined in court. Sales pitches continue before legislative bodies with a fair degree of success in the sense that mandatory or imposed fluoridation has considerably expanded. In legislative committees, witnesses usually cannot be effectively held to account for what they say.

We understand that the judicial process is far from perfect. But, now, the "purely scientific issue" mentioned at the University of Michigan ~~and~~ fluoridation is a purely scientific issue until legally imposed ~~is~~ tried in legislative proceedings by frantic political lobbying, maneuvers, ambushes, speechifying, applause, horse-trading, buttonholing, demagoguery, infighting, and posturing.

VIII. THE COMING END OF FLUORIDATION

One of the results of the hearings in Congress on September 21 and October 12, 1977, was a suggestion that the National Toxicology Program (NTP) should investigate fluoride.[215] Over twelve years,

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214. CHANGING PUBLIC POLICY, *supra* note 210, at 84.

215. *See National Cancer Program*, *supra* note 109, at 319.

the NTP sputtered. At last some news was leaked to the press. On December 28, 1989, the *Medical Tribune* reported on the front page:

> Fluoride appears to have caused bone cancer in rodents in a recently completed National Toxicology Program study, and the chemical is now at risk of being classified as a carcinogen, according to internal documents and statements obtained by the Medicinal Tribune from the Environmental Protection Agency.[216]

Press fanfare erupted, and the main feature of this media blitz was the impression that there had been a discovery of something entirely new and previously unknown, as if the work of Alfred Taylor, Dean Burk and many others had never been done. Soon, however, the public was assured that all is well.[217]

The "official" evaluation, while leaving much to be desired, gives a very different impression. The authors conceded that, although the numbers were small, the data gathered by the NTP study reveal a statistically significant dose-response trend of osteosarcomas of bone in male rats.[218] Additionally, the authors cited no less than eleven studies published in good journals, showing that fluoride is capable of inducing genetic mutation in mammalian cells and fruit flies, aggravating chromosomal aberrations in animal systems, and causing morphological transformations in Syrian hamster ovary cells.[219]

The article concludes with the sedate comment that "it would appear prudent to re-examine previous animal studies and human epidemiological studies, and perform further studies as needed to evaluate more fully any possible association between exposure to fluorides and the occurrence of osteocarcomas of bone."[220] We join this recommendation, adding that meanwhile artificial fluoridation of public water supplies ought to be halted across the country pending such review of the evidence, as was recommended by Dr. Bundock and his colleagues in Quebec, and that nobody having any direct or indirect interest in the conclusions ought to participate.

The recommendation for reevaluation has not been fulfilled. There are interesting reasons why.

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216. Joel Griffiths, *Fluoride Linked to Bone Cancer in Fed Study*, 30 MED TRIB., DEC. 28, 1989, 1, 6.

217. *See e.g., Additive approved, Federal study says fluoride no threat*, PITTSBURGH POST-GAZETTE, Feb. 20, 1991, at 1-2.

218. *See* John Bucher et al., *Results and Conclusions of the National Toxicology Program's Rodent Carcinogenicity Studies with Sodium Fluoride*, 48 INT. JOUR. CANCER 733, 734-35 (1991).

219. *See id.* at 736.

220. *Id.*

On May 1, 1990, the acting Director of the Criteria and Standards Division, Office of Drinking Water in the United States Environmental Protection Agency, received a memorandum from Dr. William Marcus, Senior Scientific Advisor in the Criteria and Standards Division.[221] Dr. Marcus reviewed the NTP study and pointed to results suggesting carcinogenic potential of fluoride.[222] He also cited the most recent published version of the epidemiological data gathered and adjusted under the direction of Dr. Burk.[223] Dr. Marcus urgently recommended an independent review by the EPA.[224]

To put it mildly, Dr. Marcus' memorandum did not inspire a warm and friendly response form the management of the EPA. In due course, Dr. Marcus sent his document to the Administrator of the EPA and to his union representative who in turn released it to the press. The public reaction was rather agitated, causing a bureaucrat from the "health effects branch" within the agency to approach Dr. Marcus' supervisor with the suggestion that he memorandum sent "the wrong message tot he public."[225] Shortly thereafter, Dr. Marcus was accused of "violent and aberrant behavior" and discharged.[226]

On December 3, 1992, following extended hearings, an administrative law judge found that Dr. Marcus had been fired on false pretexts because of his warnings against artificial fluoridation of public water supplies.[227] The ALJ ordered Dr. Marcus reinstated with back salary, money damages, and attorney's fees,[228] and, on February 7, 1994, the Secretary of Labor affirmed the reinstatement as ordered.

The simple and blunt meaning of this episode is impossible to misunderstand. The scientists, lawyers, and engineers at the national headquarters of the EPA have since used their union for protection against their administrators who, as the case of Dr. Marcus demonstrates, have a political agenda not necessarily in the public interest, and certainly not in the interest of the professionals at EPA

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221. Dr. Marcus' historic memorandum of May 1, 1990, is a matter of public record. *See* Marcus v. Environmental Protection Agency, No. 92-TSC-5, Complainant's Exhibit 56, mentioned in the Recommended Decision and Order, Dec. 3, 1992, at 5 (U.S. Dep't Labor).

222. *See id.* at 1-3.

223. *See id.* at 3.

224. *See id.* at 4.

225. *Id.* at 5.

226. *See id.* at 6-9.

227. *See id.* at 25-28.

228. *See id.* at 30-31.

who desire the independence required to act honestly for the general welfare.

Under the protection of their union they have made plain that their administrators may set policy, but that they as professionals refuse to conceal the errors of policy set. The subject of fluoridation has come to their attention. On July 2, 1997, the union members, at a duly called meeting,[229] voted unanimously in support of a resolution that read:

> Our members review of evidence over the last eleven years, including animal and human epidemiology studies, indicate a causal link between fluoride/fluoridation and cancer, genetic damage, neurological impairment, and bone pathology. Of particular concern are recent epidemiology studies linking fluoride exposures to lower I.Q. in children. As professionals who are charged with assessing the safety of drinking water, we conclude that the health and welfare of the public are not served by the addition of this substance to the public water supply.[230]

If artificial fluoridation of public water supplies causes cancer in man, as the published laboratory studies and epidemiological surveys indicate, and as judicial findings confirm, then nobody should be surprised to see that it produces a host of other human ailments. Who should be surprised to learn that dumping a

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229. At the time of this resolution, scientists, lawyers, and engineers at the national headquarters of EPA were organized in the National Federation of Federal Employees, Local 2050. These professional people are now organized as the National Treasury Employees Union, Chapter 280.

230. This resolution has been released to the press by the professional union at the national headquarters of EPA, but, not surprisingly, the government of the United States has not seen fit to publish the document. We are indebted to Dr. J. William Hirzy at EPA for our copy. Aside form the material cited in this article, the evidence considered in support of this resolution included, on the question of cancer, PERRY COHN, NEW JERSEY DEPARTMENT OF HEALTH, A BRIEF REPORT ON THE ASSOCIATION OF DRINKING WATER FLUORIDATION AND THE INCIDENCE OF OSTEOSARCOMA AMONG WHITE MALES (1992). This epidemiological survey is particularly important because its finding with respect to human males parallels the NTP study which suggests that sodium fluoride induces osteosarcomas in male rats. To the same effect, is John Yiamouyiannis, *Fluoridation and Cancer: The Biology and Epidemiology of Bone and Oral Cancer Related to Fluoridation*, 26 FLUORIDE 83 (1993). Also considered in support of the resolution of July 2, 1997, on the question of bone pathology was Lawrence Riggs et al., *Effect of Fluoride Treatment on the Fracture Rate in Postmenopausal Women with Osteoporosis*, 322 NEW ENG. J. MED. 802 (1990). Taken into account on the question of neurological impairment was Phyllis J. Mullenix et al., *Neurotoxicity of Sodium Fluoride in Rats*, 17 NEUROT. & TERAT. 169 (1995). Since published to the same effect is Julie Varner et al., *Chronic Administration of Aluminum Fluoride or Sodium Fluoride to Rats in Drinking Water: Alterations in Neuronal and Cerebrovascular Integrity*, BRAIN RES. 784 (1998) 284-98. The epidemiological studies on fluoride exposure and the I.Q.'s of children were done in China. They are abstracted in English as X. S. Li et. al., *Effect of Fluoride Exposure on Intelligence in Children*, 28 FLUORIDE 189 (1995), and L.B. Zhao et. al., *Effect of a High Fluoride Water Supply on Children's Intelligence*, 29 FLUORIDE 190 (1996).

carcinogen and mutagen in public drinking water has not only been accompanied by devastating increases in cancer mortality, but may also reduce human intelligence?

The end of fluoridation will take time, but not because time is necessary to develop essential scientific information. We already know enough to appreciate the enormity of the risk. We knew enough many years ago.

But the end will finally arrive, because, as Aristotle said at the beginning of the *Metaphysics*, all men by nature desire to know.[231] Ignorance cannot be perpetuated forever. The necessary legal and scientific reforms will come in the twenty-first century. Our descendants will look back on us, and they will be amazed.

APPENDIX

TABLE 1. The Basic Data in Unweighted Averages for 1940-1950 and 1953-1968.

Year	CDRo Control Cities (-F)	CDRo Experimental Cities (+F)
1940	158.4	155.5
1941	152.4	155.2
1942	153.9	157.2
1943	159.2	161.6
1944	162.5	162.3
1945	165.6	168.4
1946	168.5	171.6
1947	174.5	172.6
1948	178.0	173.2
1949	179.5	179.4
1950	178.9	179.6
1953	188.2	191.3
1954	185.6	194.1
1955	189.5	196.3
1956	189.1	203.6
1957	188.4	207.1
1958	188.6	203.5
1959	193.0	204.7
1960	191.1	207.0
1961	190.4	209.3
1962	190.2	207.2
1963	189.4	210.9
1964	190.3	212.6
1965	194.3	218.6
1966	193.4	224.8
1967	198.8	224.4
1968	199.4	226.4

FIGURE 1. The Basic Data in Unweighted Averages for 1940-1950 and 1953-1968.[a]

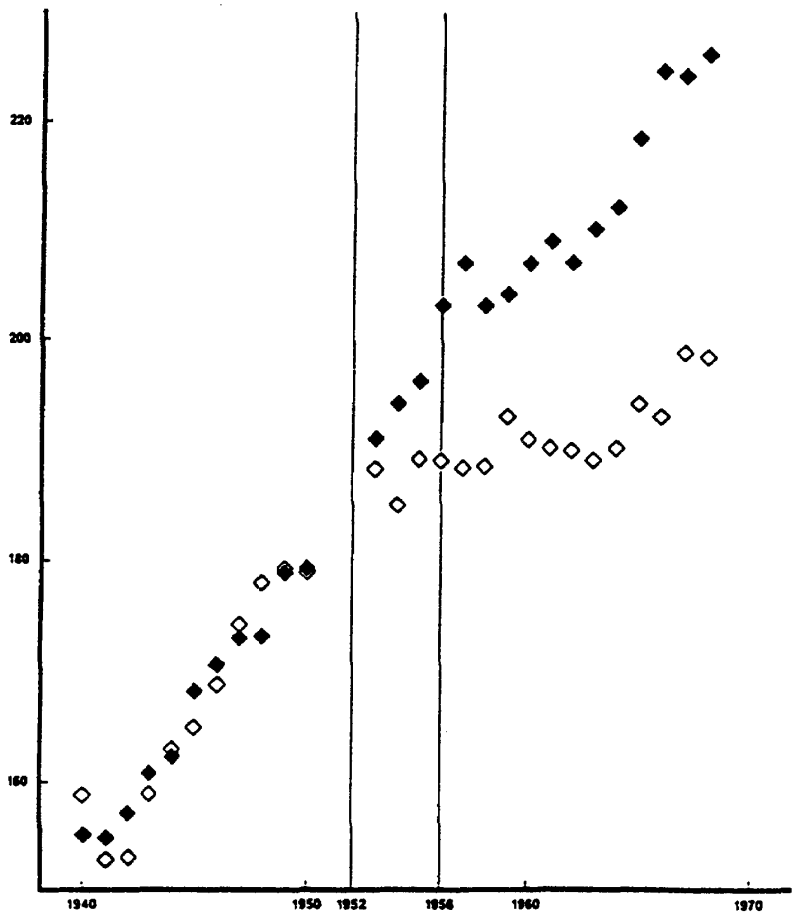
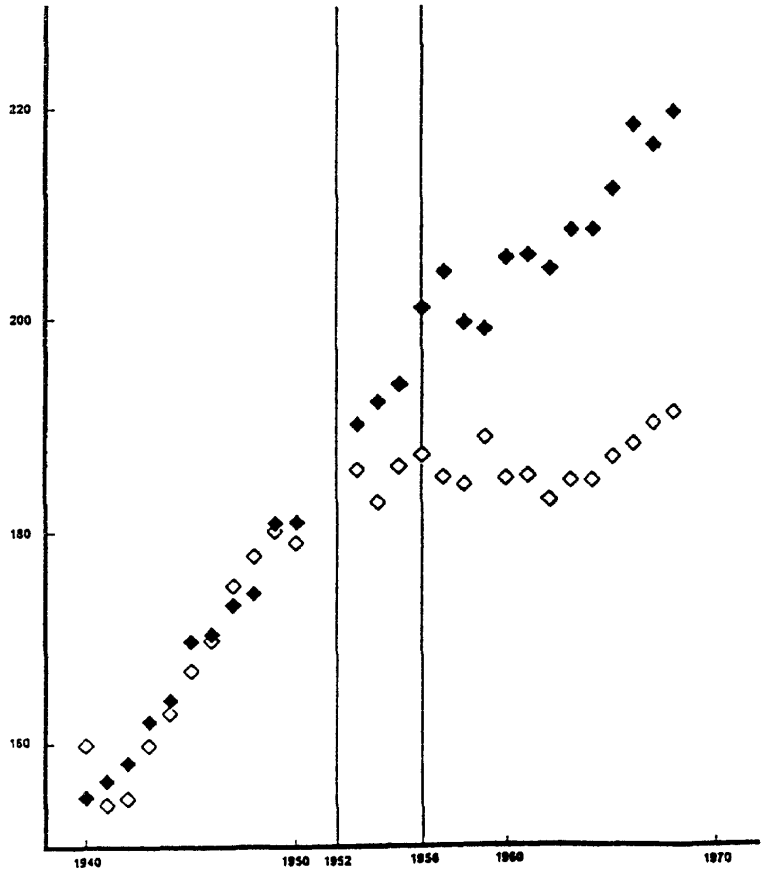


TABLE 2. The Basic Data in Weighted Averages for 1940-1950 and 1953-1968.

Year	CDRo Control Cities (-F)	CDRo Experimental Cities (+F)
1940	159.9	155.6
1941	154.5	156.3
1942	154.7	158.3
1943	159.8	162.4
1944	163.2	164.2
1945	167.0	168.9
1946	169.9	171.8
1947	175.0	173.9
1948	177.8	174.3
1949	180.4	181.1
1950	179.0	180.8
1953	185.9	190.2
1954	182.6	192.3
1955	186.1	193.9
1956	187.6	201.6
1957	185.2	204.5
1958	184.3	199.7
1959	188.8	201.0
1960	185.0	205.8
1961	185.7	206.0
1962	183.8	204.6
1963	184.8	208.6
1964	184.8	208.7
1965	187.0	212.5
1966	188.2	218.5
1967	190.1	218.4
1968	191.1	219.7

FIGURE 2. The Basic Data in Weighted Averages for 1940-1950 and 1953-1968.[b]



RESPONSES BY J. WILLIAM HIRZY TO ADDITIONAL QUESTIONS FROM SENATOR CRAPO

Question 1. If Federal and State regulatory agencies do not prohibit it, is it appropriate for communities to make the determination about whether to fluoridate water?

Response. Since fluoride delivered in drinking water is intended to alter bodily function by changing the structure and composition of a body part, the teeth, it clearly is a drug. (It also unintentionally changes the structure and composition of bone.) For a community to require each and every citizen to take a drug, with no control over dose, with no acknowledgment or accommodation for citizens who may

have adverse effects from the drug, and for the purpose of allegedly minimizing (and not preventing), a non-communicable, non-life threatening condition, is fundamentally wrong.

Vaccination against communicable, serious and/or life threatening conditions, even in the face of objections from some of the vaccinated, is often cited by proponents of fluoridation as a public health analogy that addresses the question of acquiescence of the drug-treated citizen. The analogy is flawed for many reasons, not the least of which are: 1) the types of conditions prevented by vaccination; and 2) the virtual absence of controversy over effectiveness.

Of the advanced nations that do not fluoridate, Belgium, Germany, Japan, Luxembourg, the Netherlands and Norway have stated clearly that one reason for not doing so is the violation of individual rights inherent in forcing medication on the entire population through their public water supplies.

In many communities, the issue of fluoridation is, indeed, put to the community through referendum. What invariably occurs in these cases is that the Federal Government applies enormous and disproportionate influence on the referendum. Money appropriated by Congress to the Department of Health and Human Services is offered through the Public Health Service and Centers For Disease Control as fluoridation grants. These agencies send in speakers, and flood the local media—which often refuse to even acknowledge existence of opposition, let alone grant "equal time"—with pro-fluoride messages. The American Dental Association sends in its hired guns to protect that organization's institutional reputation (and tort liability) through speaking engagements where opponents are pilloried and ridiculed. Such referenda become battles between citizens, who want nothing more than to drink pure water from their taps, and institutions whose interest is in perpetuating and expanding fluoridation and whose resources are virtually limitless and—ironically—drawn in large measure from taxes on those in opposition.

If communities are to be saddled with the ethically inappropriate task of deciding whether to medicate all its citizens, then provision for informed decisionmaking must be made, including decisions on the ethical issues. This is not a partisan political debate in which campaign finance limits and the First Amendment collide. Rather, this is a matter of public health policy in which a full, open and thorough exposition of the issues is clearly required in the public interest.

There is hardly a more appropriate role for Congress to play in such case than to provide a record on the pros and cons of fluoridation through a full airing of this subject. I call again, as I did in my testimony on June 29, 2000, for Congress to provide a forum for developing that record.

Question 2. It has been widely asserted that declining dental decay rates in North America are attributable largely to fluoridation and also generally improved dental health practices by the public. To what do you primarily attribute the improved dental health status in the United States?

Response. There is virtually no dispute, even among those who are concerned by the uncontrolled and increasing exposure of the public to fluoride, that fluoridated tooth pastes are effective in decreasing dental decay by interfering with the metabolic processes of Streptococcus mutans, the organism chiefly responsible for dental decay. This effect occurs because of the high concentration of fluoride (generally about 0.15 percent w/w) in those tooth pastes. In addition, better diet and better dental hygiene in general are factors in deceased dental decay rates in the U.S. Some of the more convincing data come from the 50-year experiment at Kingston and Newburgh, New York. These show that the un-fluoridated city of Kingston has, in fact, a small advantage in dental decay rates among children over the fluoridated city of Newburgh. Furthermore, the data collected during the 1986–7 national survey of 39,000 U.S. school children show that a community's fluoridation status plays no role in determining the percentage of caries-free children or the ranking of the community using the Decayed, Missing and Filled permanent teeth index.

As health and public utility officials in many of the countries of the world that do not fluoridate have gone on record saying, there are more effective, less ethically troubling and safer ways of taking advantage of the fluoride ion's cariostatic propensity than putting it in the public water supply.

Question 3. Is the appearance of dental fluorosis always symptomatic of too much exposure to fluoride? If so, can this be traced to additives in water, fluoride pills, or fluoride in dental products?

Response. By definition, the appearance of dental fluorosis is symptomatic of overexposure to fluoride. All sources of fluoride taken into the body (including, e.g. inhalation) contribute to the body burden of fluoride. In addition to the sources about which you inquire, foods and beverages containing fluoride from fluoridated process water and pesticide residues contribute to the body burden of fluoride.

There is a wealth of literature on the relative contributions by these various sources to the body burden of fluoride. But, once again, the striking simplicity of the summary data from the Kingston-Newburgh experiment are revealing. In non-fluoridated Kingston, in 1995, the prevalence of dental fluorosis in children aged 7–14 years was 11.5 percent, and in fluoridated Newburgh the prevalence was 18. . 5 percent. In 1955, 10 years after the start of the experiment, the data were 0.0 percent fluorosis in Kingston and 7.3 percent in Newburgh.

Proponents like to argue that fluorosis arises from abuse of tooth paste and/or fluoride supplement tablets. But it is not defensible to argue that such abuse is greater across the population of children in Newburgh than it is in Kingston, and that the difference in fluoride exposures due to drinking/cooking water is only a minor factor—across a time span of forty-five years.

Question 4. It is the subcommittee's understanding that national data on the costs of correcting fluorosis are not available; national data on the costs of bonding (a corrective treatment for fluorosis and other conditions) do not include information on the purpose for the bonding. Do you have any information regarding the amount of bonding that is done to correct for dental fluorosis?

Response. I do not have information on the amount of bonding that is done to correct for dental fluorosis. Representative Calvert, Chairman of the Subcommittee on Energy and Environment, posed a closely related question to Jeffrey Koplan, Director of the Centers For Disease Control, and perhaps when Mr. Koplan responds information on that subject may be forthcoming. I am aware that Dr. Hardy Limeback, Head of the Preventive Dentistry Department, University of Toronto, is interested in this subject and has carried out research this field. He may be a source of information. He may be reached via e-mail at <hardy.limeback@utoronto.ca>

Once again, thank you for considering this important public health question and for starting a process that many health professionals hope will culminate in a full Congressional hearing on fluoridation as soon as possible.

Those of us who are very worried about the growing, uncontrolled exposures to fluoride also hope that the Federal Government will soon take corrective action, such as a Congressional ban on the distribution of fluoride through the Nation's public water supplies.

STATEMENT OF ERIK D. OLSON, SENIOR ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL

Good morning, I am Erik D. Olson, a Senior Attorney at the Natural Resources Defense Council (NRDC), a national non-profit public interest organization dedicated to protecting public health and the environment. We have over 400,000 members nationwide. We appreciate the opportunity to testify today on the implementation of the Safe Drinking Water Act.

Drinking water treatment improvements at the turn of the 20th Century advanced public health protection enormously. Much of the nation's drinking water infrastructure, however, has aged, is outdated, and is simply inadequate. We must modernize our water systems to safeguard the nation's water supplies from new and emerging contaminants and the pressure of increased population.

While EPA has estimated that the costs of modernization will exceed $138 billion dollars, many in state and local governments, in the water industry, and the public health and environmental communities believe the true costs of this needed massive upgrade will be many times higher. For example, a report published in March 2000 by a coalition of state and local governments, the water industry, and a water professional trade association called the Water Infrastructure Network (WIN) estimated that the cost of updating our water systems would significantly exceed previous estimates. Specifically, the WIN report found that building new and replacing old drinking water facilities will cost $480 billion dollars (including finance costs) over the next 20 years, and that about $1 trillion dollars is needed for capital, financing, operation and maintenance of the facilities over that period. Consequently, the WIN investigators concluded that there is a funding gap of about $15 billion per year for drinking water infrastructure, operation, and maintenance. Most of these expenses, however, are expected to be necessary irrespective of Safe Drinking Water Act regulatory requirements. Aging pipes in distribution systems, antiquated water treatment plants, water professionals' recognition of the need for infrastructure improvements, public demands for improved water quality, taste, odor, and reliability, growth, and other factors will all drive this investment. While most of these costs will be incurred with or without new EPA regulations, clearly many improvements will be necessary in water treatment and distribution systems in order to meet modern demands for safer tap water. Major new public investments will be needed to

fund this important national priority and significant research initiatives are necessary to support and guide this modernization.

The United States and drinking water suppliers in other developed nations' have begun a "Third Revolution" in drinking water provision. The WIN report recognized this revolution as requiring greater financing. The "First Revolution" occurred when water was initially captured, stored, and channeled or piped for household drinking and other uses. This important advance began in pre-biblical times in Sumaria and other parts of the Middle East, and was expanded and refined by the Roman Empire. The "Second Revolution" was triggered by the steady march forward of medical science, the acceptance of the "germ theory" of disease, and the leadership of public health proponents such as John Snow who, in 1849, linked the London cholera outbreaks to water supplies. This knowledge led to the development of treatment and disinfection techniques such as coagulation, sedimentation, filtration, and ultimately, chlorination. These processes were installed by many major water suppliers beginning in the 19th Century and leading to widespread adoption by the first World War. These technologies have resulted in enormous public health benefits, and have been hailed by the Centers for Disease Control and Prevention (CDC) as one of the greatest triumphs of public health protection in the 20th Century.

The "Third Revolution" in drinking water provision has now been launched by utilities in the U.S. and Europe. This revolution is marked by the culmination and synthesis of the "multiple barriers" approach to preventing disease from drinking water that had long been advocated by Abel Wolman and other 20th Century water industry leaders. In essence, the Third Revolution consists of a three-pronged approach to modern drinking water protection: (1) vigorous measures to prevent contamination of drinking water, through source water protection actions; (2) adoption of modern, highly effective, and broad-spectrum water treatment technologies that can remove a wide array of emerging contaminants simultaneously, such as membranes, ultraviolet radiation disinfection, and granular activated carbon with ozone disinfection; and, (3) the modernization of aging water distribution systems, sometimes over a century old, that often contain lead, frequently cause main breaks, harbor microbial growth, and, according to the CDC, are a significant cause of waterborne disease outbreaks.

Among the challenges now facing the water industry are:

1. Arsenic

The National Academy of Sciences, in a report issued in 1999, recognized that arsenic in tap water poses a significant public health risk in the United States, and that EPA's outdated tap water standard for arsenic, which was set in 1942, "does not achieve EPA's goal for public health protection and, therefore, requires downward revision as promptly as possible." The Academy concluded that drinking water containing arsenic at the 50 parts per billion (ppb) level allowed by the outdated current standard "could easily" pose a total cancer risk of 1 in 100 about 100 times higher than EPA would ever allow for tap water under other rules. For the sake of comparison, the cancer risk allowed by this arsenic standard is about 10,000 times higher than the risk EPA may permit in food under the Food Quality Protection Act of 1996, which Congress passed unanimously. The Academy also found that there was an insufficient basis to find a threshold for arsenic carcinogenesis, and that there was no credible evidence that arsenic was a necessary nutrient in humans. Moreover, the Academy discussed a litany of other adverse non-cancer health effects from arsenic in tap water, including cardiovascular effects, nervous system problems, skin lesions, possible reproductive harms and other effects. Several peer-reviewed, published studies completed in the year since the Academy's report have reinforced the conclusion that a much lower standard for arsenic in tap water is needed to protect public health. For example, a recently published study showed increased cancer rates in Finland among persons who consumed low levels of arsenic (below 5 ppb). Most recently, three studies published in the July 2000 issue of the National Institutes of Health's journal, Environmental Health Perspectives, found that arsenic in drinking water is linked to skin problems and other adverse health effects even in well-nourished populations. Additionally, the studies link the presence of arsenic in tap water to certain reproductive problems in exposed women, and increased cancer risks.

Last week EPA published a proposal to reduce allowable arsenic levels from 50 ppb down to 5 ppb a level that still presents a cancer risk higher than the 1 in 10,000 cancer risk that EPA traditionally allows in tap water. NRDC, along with many public health professionals and organizations, believe that EPA should set the standard at 3 ppb, the level that EPA says is closest to the health goal (Maximum Contaminant Level Goal) and is practical, economically feasible and affordable.

2. Radon

Currently, radon in tap water poses significant cancer risks to over 40 million Americans. Another National Academy of Sciences report, issued last year, found that radon is known to cause cancer, and concluded that a multimedia mitigation strategy should be pursued to deal with the radon problem. The Academy found that while radon can be present in tap water at levels posing substantial risks, generally the vast majority of risks from radon comes from radon seepage into homes from soils.

Congress enacted a provision in the 1996 Safe Drinking Water Act Amendments that allows states or water systems to adopt Multimedia Mitigation (MMM) programs for radon that focus on the highest indoor radon risks. States and public water systems with approved MMM programs do not need to assure compliance with the Maximum Contaminant Level for radon in tap water. Instead, they can meet a less stringent "Alternative Maximum Contaminant Level" (AMCL), because they will be providing greater public health benefits by reducing the overall indoor radon levels through the MMM program than through achieving the MCL for tap water. EPA's proposed rule for implementing this provision could prove to be an important step toward protecting public health from radon, if it can assure that the MMM programs actually will achieve the public health benefits billed.

3. Cryptosporidium, Other Microbial Risks, and Disinfection Byproducts

EPA has engaged in a lengthy, multi-stage process of negotiations over the past 8 years with the water industry, states, local government, water treatment trade associations, public health groups, and environmental organizations in an effort to tackle the complex issue of microbial contaminants and disinfection byproducts. These negotiations have wrestled with how to control the parasite Cryptosporidium (which made over 400,000 people ill and killed over 100 in Milwaukee in 1993, and has led to many smaller outbreaks since 1993).

The negotiations also have sought to improve protection from the class of contaminants known as disinfection byproducts, which are created when chemicals such as chlorine are used to disinfect water. The chemical reactions between the disinfectant and organic matter in the water create unwanted byproducts, which are a potentially toxic soup of chemicals that have been linked in both animal studies and human epidemiological studies to certain forms of cancer and reproductive problems such as miscarriages and birth defects. We are now in the midst of serious negotiations over the "Stage 2" disinfection byproduct rules, and the "Long Term 2" rule for surface water treatment. A proposed rule is anticipated in early or mid-2001.

4. Groundwater Rule

In the 1996 amendments, Congress charged the EPA with issuing a rule requiring that groundwater supplied public water systems disinfect their drinking water, unless such disinfection were to be found unnecessary. EPA recently has proposed a groundwater rule, which is now open for public comment. NRDC has begun to review the proposal and while we believe that the proposal includes several important measures that may improve public health protection, it also has several fundamental flaws that will need to be fixed to prevent the rule from becoming bogged down at the state level and not being implemented.

The 1996 SDWA Amendments encourage better health protection, and the EPA should be commended for the using a generally open public process to implement the majority of this law. Several other important challenges remain:

- Appropriations Acts and a Court Decision Have Effectively Eliminated the Drinking Water State Revolving Fund (DWSRF) Set-Aside for Health Effects Research, Undercutting Funding Assurances.

This committee and the 1996 SDWA Amendments adopted a provision in the DWSRF ensuring $10 million set-aside for health effects research, SDWA .1453(n). The appropriations committees, however, have included provisions purporting to negate this set-aside in the last several appropriations acts. Unfortunately, a court decision reached with the support of the EPA effectively found that the appropriations language overrode the set-aside in the Act. Thus, this committee's effort to assure long-term funding of this research has been nullified by subsequent Congressional action. This committee should fight for the full set-aside for this research.

- A Forum for Open Public Research Planning and Priority Setting is Necessary.

EPA should formalize an open public process for developing its drinking water research plans, similar to the highly successful Microbial and Disinfection Byproducts Council, but with additional assurances of public comment and openness. This is a far more effective approach than the largely closed-door process EPA used in planning its arsenic research, for example.

• A Modest, Dedicated Water Fee, Allocated to a Trust Fund Without Further Appropriation, is Needed to Support Long-Term Drinking Water Research and to Address High Priority Health Risks for Small Systems.

As part of a series of discussions with the water industry and others, NRDC and many in the public interest community (and frankly, even some in the industry), have come to the conclusion that Congress should enact a modest water fee to support a long-term guarantee of adequate research funding for drinking water. The funds raised should be set aside in a trust fund that is available without needing further appropriations. This would prevent the research agenda from being buffeted by the ever-changing winds of the annual appropriations process. In addition, we believe that those funds should be made available for direct funding of the most substantial public health threats posed by drinking water systems, such as grants for emergency repairs, treatment, or consolidation of small systems with serious health standard violations.

• The Need for a National Dialogue on How to Fund the Massive Funding Gap for Drinking Water Infrastructure Improvement and Modernization.

The massive shortfall in resources available for water systems to upgrade, replace, and expand their infrastructure is a problem that must be addressed. NRDC believes there is a serious need for a national dialog on how this funding gap will be addressed. While certainly Federal funding will not itself plug this massive hole, the time has come for a serious discussion of what the respective Federal, state, and local governmental roles are, and what role private industry might play in this overhaul. We believe that there is a need for Federal leadership on this issue, and for significantly increased Federal resources to be dedicated to this crucially important national need.

• Other Research Needs: Assuring More Effective Public Right-to-Know, Better Source Protection, More Affordable Advanced Treatment Technologies, Better Analytical Methods, and Improved Small System Management, Restructuring, and Treatment.

EPA needs to conduct further research about how to build public understanding of tap water challenges. The EPA right-to-know report rules issued in 1998 that required the first reports to be issued to consumers by October 1999, and subsequent annual reports every July, starting July 2000 (next month), are a major step forward. It is critical, however, that methods be developed to improve public understanding of these complex issues. Other important areas of research include: investigations into ways in which source water protection can be made a more effective tool for drinking water protection; research on how modern treatment methods can be improved and costs decreased; development of better, cheaper, and easier analytical methods; and improved approaches to assuring small system compliance through restructuring or treatment upgrades.

• Research to Support Treatment, Occurrence, and Related Issues for Microbes, Disinfection Byproducts, Groundwater, and Distribution System Risks.

New standards will be issued over the next several years for many contaminants, yet EPA resources for research on the availability of treatment and occurrences are inadequate. These rules will be determinative as to whether the "Third Revolution" in drinking water protection involving true multiple barriers to contamination in the form of source water protection, advanced "leap frog" treatment technologies, and modern distribution system management will occur in the early 21st Century, or whether the nation's aging and often outdated water supplies will continue to inadequately address these emerging problems and to deteriorate. A stronger research commitment is needed.

• Compliance Problems that Continue to Plague the Drinking Water Program. Widespread violations of the SDWA, and inadequate state and EPA enforcement against even the most recalcitrant violators continue to be a major problem.

Improved data collection and management and a stronger commitment to enforcement are crucial to assist EPA, states, and the public to address these issues. Compliance problems and data collection and management failures have been catalogued in a USA Today series published in October 1998, in a recent EPA audit discussed in a front page USA Today article in late 1999, and in EPA's own 1998 and 1999 Annual Compliance Reports. The EPA drinking water program and the states need to upgrade their management systems and programs. Routine audits of federally funded state programs are a crucial part of this effort. The new SDWA small system viability provisions could begin to reduce these problems, but substantial additional resources and research are needed to assure that these programs bear fruit. Additionally, small system technical assistance should be granted on a competitive basis, based upon the best available research, so that these assistance providers demonstrate that they can deliver accurate technical assistance to small systems in a

cost-efficient manner. We oppose "earmarked" assistance funding that is non-competitive because it often fails to allocate resources to maximize health benefits.

- Better Leveraging of Other Federal Agency Resources.

The Federal Government has a wealth of expertise and resources directly relevant to EPA's drinking water program that should be better integrated into EPA's efforts. For example, the Centers for Disease Control, Agency for Toxic Substances Disease Registry, and several institutes at the National Institutes of Health, including the National Cancer Institute, the National Institute of Environmental Health Sciences, the National Institute of Allergy and Infectious Disease, National Institute of Child Health and Human Development, National Heart, Lung, and Blood Institute, National Institute of Neurological Disorders and Stroke, and many other institutes and agencies conduct research of which the EPA often is unaware. A better program is urgently needed to assure more information sharing and collaboration among the Federal agencies. Some successful examples of collaboration can be noted such as the waterborne disease estimation research being jointly spearheaded by EPA and CDC, and the joint work on disinfection byproducts by EPA, ATSDR, and NTP. Perhaps more often, however, there is little or no collaboration among many of the agencies while setting priorities and conducting research. This lack of coordination can result in serious lost opportunities and resources through potential duplication of efforts.

In conclusion, NRDC strongly believes that EPA's implementation of the 1996 Amendments to the Safe Drinking Water Act is beginning to show signs of achieving substantial public health gains. Some of the most knotty, difficult issues that have faced EPA and the nation's drinking water supplies for the past quarter century since the original 1974 SDWA was passed, and in many cases for even longer than that, are now being squarely addressed. This process will not be simple, nor will it be cheap. However, this effort is necessary to protect public health and to achieve public demands for a reliable supply of safe, good-tasting tap water for all Americans. A vigorous and well-funded EPA research and regulatory effort is crucial to the long-term success of the drinking water program and the nation's tap water safety. Only a long-term stable source of adequate funding will assure that this is achieved.

RESPONSES OF THE ERIC OLSON TO ADDITIONAL QUESTIONS FROM SENATOR CRAPO

Question 1. Your testimony suggests an arsenic MCL of 3 ppb is appropriate. Do you believe the underlying science supports such a level?

Response. The underlying science does support this level; in fact the underlying science supports a level lower than 3 ppb. According to decades-old EPA policy long supported by Congress, a health-protective tap water standard should allow a maximum lifetime cancer risk no greater than a level presenting a lifetime cancer risk from 1 in 1,000,000 (10–6) to at most 1 in 10,000 (10?) for people who drink about 2 liters of water per day—a level consumed daily by tens of millions of Americans. This would require EPA to set a drinking water standard well below the current 50 ppb standard—in the range of 0.5 to 1 ppb, according to the figures and risk estimation methods used for total cancer risk by the National Academy of Sciences' 1999 report, Arsenic in Drinking Water. Limitations in the analytical techniques widely used for measuring arsenic in water, however, would likely necessitate a standard of 3 ppb, rather than a standard of 1 ppb, because reliably quantifying arsenic at levels below this would be difficult using current standard lab equipment and practices. Based on an extrapolation of NAS's risk estimates, even a relatively skict arsenic standard of 3 ppb would pose a fatal cancer risk several times higher risk than EPA has traditionally accepted in drinking water. This issue is discussed in greater detail in the attached recent NRDC report, Arsenic and Old Laws (2000), which was written as a pro bono professional courtesy by Dr. Paul Mushak, an expert on arsenic and metal toxicity who has sat on several National Academy of Sciences committees. The cost of arsenic removal is quite affordable (at most a few dollars a month per household) for the vast majority of households (>90 percent) affected by arsenic. The relatively small percentage of people served by very small systems where the costs would be greater have several options available under the SDWA, including restructuring or consolidation, availability of Federal funds, point of use or point of entry devices, and other affordable small system technologies, and even state variances or exemptions where none of those other options works.

Question 2. Is it your understanding that the primary exposure to radon is through the air? If so, do you believe that limited community water system re-

sources should be directed to other contaminants that are more readily found in drinking water systems?

Response. Yes, it is our understanding that on average for the nation, the primary exposure to radon is through the air. However, it also is known that in some homes and in some communities, radon in drinking water is a significant radon source, and can even be the predominant source of radon exposure. Moreover, EPA's 1994 report to Congress on radon in drinking water found, using cancer risk figures later confirmed by the National Academy of Sciences' 1999 report on radon in drinking water, that radon presents one of the highest cancer risks of any carcinogen in tap water. People who live in apartment buildings above the first floor or in mobile homes or other homes that are raised above the ground and lack basements, and who use drinking water containing elevated levels of radon, can get more radon from drinking and showering than they would through soil seepage. Furthermore, contrary to the implication of the question above, elevated levels of radon posing cancer risks calculated by the National Academy of Sciences to be in excess of those traditionally accented bv EPA occur in the tan water of tens of millions of Americans. We believe community water system resources should be required to treat for elevated levels of radon, a known human carcinogen, where the levels pose unacceptable cancer risks, because radon in drinking water poses significant threats to human health. In fact, the main reason radon in drinking water threatens public health is due to inhalation during and after water use, though ingestion also contributes to cancer risk. For example, people who take showers soon after someone else in the household are likely to be exposed to very high radon and radon-related cancer risks, because of the buildup of cancer-causing radon decay products in the bathroom. In some cases, the levels found in the shower would exceed Nuclear Regulatory Commission standards for nuclear power plant discharges. Therefore, due to exposure occurring through the air, the risks from radon in water are very high and can have serious health consequences, including lung cancer.

In addition, the treatment for radon in tap water is simple and inexpensive. The only process needed to remove radon from water is aeration—that is, air must be bubbled through the water through treatment equipment to dissipate the radon. Therefore, for a relatively small cost (a few dollars per household per year for the vast majority of affected households), through the centralized application of treatment, a community water system can protect its population against a significant cancer risk. Such centralized, low-cost per household treatment is not possible for radon soil seepage into home basements.

Question 3. Do you believe stakeholders and the public have a meaningful opportunity to influence the ultimate outcome of EPA proposals?

Response. In recent years, EPA has made great strides in improving the public's opportunity to influence EPA tap water regulations. For example, EPA used to rely almost exclusively upon the Administrative Procedure Act's notice and comment rulemaking procedures of publishing a proposal, taking comment for 30 or more days, and then publishing a final rule. However, EPA has in recent years substantially expanded the public's ability to discuss regulatory matters with the Agency, often at the earliest stages of regulatory development. EPA now routinely holds formal and informal "stakeholder" meetings open to all parties. The Agency also holds special meetings with small water systems under the auspices of with the Small Business Regulatory Enforcement and Fairness Act (SBREFA), and with state and local governments pursuant to the Executive Order on federalism and the Unfunded Mandates Executive Order and law. In fact, due to our lack of resources, the public interest community often is unable to take advantage of many of the opportunities for input provided by EPA, resulting in often unbalanced views being presented to the Agency on important regulatory and other matters. This is particularly the case when EPA schedules (as it often does) "public" meetings to discuss regulatory matters to coincide with major industry or state or local government trade association meetings, which may be convenient for those parties, but virtually assures a one-sided meeting.

In some important cases EPA has used a full-blown regulatory negotiation (regneg), in which all interested parties are afforded an opportunity to participate in formulating the rule in a consensus process. For example, EPA has used the regneg process for the Stage 1 disinfection byproduct rule, the Enhanced Surface Water Treatment Rule, the Interim Enhanced Surface Water Treatment Rule, the Stage 2 disinfection byproduct rule, and the Long Term 2 Enhanced Surface Water Treatment Rule.

Unfortunately, despite recent improvements in some cases, we have found that in other cases, the best and sometimes the only way to assure EPA action is to use the judicial process. For example, we have known for decades that EPA's "interim" arsenic standard, first set in 1942, was completely out-of-date. Notably, as early as

1962, the U.S. Public Health Service cited evidence of arsenic's carcinogenicity and low-level toxicity and recommended that arsenic levels in tap water be lowered f?ve-fold, yet EPA has stuck with the standard originally set in 1942. Congress also recognized this problem and required the EPA to revise the arsenic standard on three different occasions. Neither the enormous mountain of scientific evidence of unacceptable risks nor congressional mandates forced the EPA to propose the arsenic standard. The rule was not proposed until we filed a complaint against the EPA to compel its publication. This is just one example where we have had to use the judicial process to either force the EPA to follow a congressional mandate or scientific evidence.

Question 4. Other than funding, what assistance can the EPA provide community water systems and the public to offset shortfalls in infrastructure needs?

Response. EPA can provide technical assistance to community water systems, and can work with states to encourage restructuring and consolidation of smaller or less efficient water systems experiencing financial difficulties. Regionalization, consolidation, or other restructuring opportunities can allow smaller systems to enjoy the economies of scale enjoyed by larger systems, bringing costs down and efficiencies and water quality up. However, the only real option to combat the infrastructure needs in many communities is to either fund some now, or fund much more later. As I explained in my testimony, the Water Institute Network (WIN)' has estimated that there is currently an estimated funding gap of $23 billion a year between the current investments in infrastructure and the investments that will be needed annually over the next 20 years to update the infrastructure to protect the public's health. Most of these costs will be incurred irrespective of any new EPA regulations. Water and wastewater utilities will have difficulty meeting this enormous cost alone. Local solutions, like increasing water rates or operating and treatment efficiencies, can only address a portion of the problem. Financing the full $23 billion a year gap with utility rate increases could significantly increase the rates that some people pay for water and sewage treatment across the nation. This could result in a significant impact for some families, because some people—particularly in small, rural, and low-income communities—may not have disposable income to pay for the expected increases in water and wastewater rates.

Therefore, there is a real need for Federal investment. Accordingly, there is ample precedent for, and clear economic principle supporting, a Federal role in funding water and wastewater infrastructure. The importance of wastewater infrastructure was well understood in the 1960's as the Nation watched the quality of its waters decline precipitously and chose in the 1972 Clean Water Infrastructure Network, Clean and Safe Water for the 21st Century: A Renewed National Commitment to Water and Wastewater Infrastructure (2000).

Water Act, to spend Federal tax collars to reverse this trend. Despite increasing public demand for cleaner surface waters and safer drinking water, despite shifts in population that can strand water and wastewater assets in urban core cities with few ways to pay for needed improvements, and despite the nearly universal need to replace billions of dollars of aging and failing water distribution and wastewater collection systems, the total Federal contribution to water and wastewater continues to decline.

These infrastructure systems, like highways, airports, and transit systems, underpin the U.S. economy broadly and their benefits accrue widely to users without geographic limitations imposed by local political boundaries. Moreover, the water system has network benefits that are felt only after all, or substantial portions, of the network is complete and functional, affording Americans anywhere in the country access to minimum levels of services. Consequently, a Federal solution is necessary. The Water Infrastructure Network appropriately suggests: Federal solutions like direct grants from the General Fund, a dedicated Clean and Safe Water Trust Fund, or other forms of targeted assistance make good economic sense. Each approach has certain advantages and limitations in terms of its ability to provide (1) sufficient funding to meet the water and wastewater investment gap; (2) an equitable distribution of funds; (3) funding stability and long-run predictability of capital; and, (4) financial and administrative innovation. Yet, any of these options would renew the Federal commitment structure investments play in health of all Americans, the welfare of our communities, the integrity of our natural environment, and the strength of our economy.

RESPONSES BY ERIC OLSON TO ADDITIONAL QUESTIONS FROM SENATOR SMITH

Question 1. In your statement, you refer to a study in Finland that supports the need to reduce the MCL for arsenic in drinking water below 5 ppb. What studies have been conducted in the U.S. that support decreasing the MCL for arsenic below 10 ppb? How similar is the Finland population to the U.S. population?

Response. There have been several studies done by U.S. investigators that support decreasing the MCL for arsenic below 10 ppb. The best available, peer-reviewed science supports an arsenic standard below 10 ppb. Most significantly, the National Academy of Sciences' landmark 1999 report, Arsenic in Drinking Water, found that the current arsenic standard of 50 ppb could pose a total cancer risk of 1 in 100, and found that there is not sufficient evidence to depart from the traditional scientific linear, no-threshhold cancer risk assessment method. The NAS committee was not asked to recommend a standard and did not do so. However, using NAS's figures and risk assessment method, in order to achieve a cancer risk for a person consuming 2 liters of water per day of no more than one in 10,000—the highest cancer risk EPA ever allows—the tap water standard should be set at about 0.5 to 1 ppb. (See, Mushak, Arsenic and Old Laws (2000), attached). EPA's arsenic criteria for surface water is in the parts per trillion, and California's draft recommended public health level is 2 parts per trillion—2,500 times stricter than EPA's proposed standard of 5 ppb. California's recommendation was based on studies from University of California experts who found that a person who daily drinks 1.6 liters of water containing arsenic at the current EPA standard is put at about a 1 in 50 risk of fatal cancer of fatal cancer. See Smith et al., "Cancer Risks from Arsenic in Drinking Water," Environmental Health Perspectives, vol. 97, pp. 259—67 (1992); Bates, M.N., Smith, A. H., and Hopenhayn-Rich, C: "Arsenic Ingestion and Internal Cancers: a Review," American Journal of Epidemiology, 135(5): 462—76 (March, 1992). Even more recently, three studies in the July 2000 issue of that National Institutes of Health's journal Environmental Health Perspectives that found that arsenic is linked to skin and other health effects even in populations that are well nourished, that arsenic is linked to certain reproductive problems in exposed women, and that cancer risks are increased among many people consuming tap water containing arsenic.

The data from the Finland study are relevant to the risk the U.S. population faces from arsenic; these results are for a well-nourished population socio-economically similar to the U.S., and simply serve to confirm and reinforce evidence of arsenic's carcinogenicity and toxicity collected around the world. Notably, Dr. Paul Mushak, an expert on arsenic and metal toxicology who has sat on several National Academy of Sciences and other peer review panels, recently directly confronted this question. Dr. Mushak stated in a recent affidavit: "Of particular note is that the increased cancers from As in drinking water are from both Asian (Taiwanese) and a South American, Eurocentric (Chilean) population—populations differing racially, nutritionally, and in life-style behaviors, a fact that effectively demolishes the arguments advanced by certain regulated stakeholders that these studies may have limited regulatory meaning for Americans. Similarly, environmental factors that have been held by some to confound the relevance of an As connection to cancers in foreign populations are spurious and cannot disconnect arsenic as the causative agent in increasing the cancer risks." The studies that Dr. Mushak refers to are particularly noteworthy because they study very large populations; the Taiwanese study population was 40,000 subjects with a control group of more than 7000 individuals and a recent Chilean study population included over 400,000 exposed Chileans. See Smith, et. al, "Marked increase in bladder and lung cancer mortality in a region of Northern Chile due to arsenic in drinking water." Am. J. Epidemiol. 147: 660—669 (1998). Tseng WP. "Effects and dose-response relationships of skin cancer and Blackfoot Disease with arsenic." Environ. Health Perspect. 19:109–119(1977).

Question 2. You mentioned in your statement that NRDC has concerns with the proposed Groundwater rule? What fundamental flaws have you identified and how would you propose to correct these?

Response. NRDC, along with Clean Water Action (CWA) and many other organizations, in the Campaign for Safe and Affordable Drinking Water, have identified our top issues with the Ground Water Rule. The issues/flaws identified in a recent CWA review, which NRDC believes identifies many of the key problems with the rule (listed in no particular order), include:

1. One flaw of the current rule is that disinfection has become the last alternative, even though Centers for Disease Control and Prevention (CDC) data show that most waterborne disease outbreaks occur in groundwater-supplied systems. EPA has chosen to move from a position of requiring disinfection of ground water systems, with

exceptions (where it can be shown that it is not necessary), to a position of not requiring disinfection of a ground water system until all other options have been exhausted. The proposed rule casts a set of complicated and unenforceable measures which are bound to vary widely in quality and oversight from state to state across the nation. We believe the EPA should change this position and have a presumption that the water requires disinfection unless the water system can show otherwise based on sound scientific data.

2. Another problem with the rule is that states do not have to set time limits for ground water systems to fix problems. EPA sets no outer time bounds by which States have to require a drinking water provider with a significant deficiency to take corrective action. This could leave many communities in the situation they now face, according to a General Accounting Office report on the subject—going from sanitary survey to sanitary survey over time, knowing there is a problem, but not seeing any fix ever implemented. This extreme form of "regulatory flexibility" makes any enforcement scheme almost impossible and leaves many people vulnerable to illness or death. Consequently, we believe the EPA needs to set time limits for ground water systems to insure public health is protected.

3. Problematically, ground water systems, under this rule, will not have to test for both pathogens and viruses. EPA is not proposing to require water providers to test for both pathogens and viruses, but allows them to test for either one despite a strong opinion to the contrary from the drinking water committee of the Science Advisory Board (SAB) and EPA's own National Drinking Water Advisory Committee (NDWAC). We think this is a false economy that will leave the public in the dark about real and potential water quality issues, and will pose a significant public health threat.

4. The Sanitary Surveys are too infrequent. EPA will not require sanitary surveys to be done frequently enough to find problems in time to correct them. EPA is proposing that community water systems (COOS) do a survey every 3 years and that non-community water systems do a survey every 5 years. States have been reducing the frequency of surveys over time. For states where the frequency required is more frequent than the proposed rule, we may see significant slippage in frequency of sanitary surveys. Further, EPA is proposing that if a CWS treats their water "to achieve 4-log inactivation or virus removal" or shows an "outstanding performance record," then the survey cycle will be extended from 3 to 5 years. The question of what constitutes an "outstanding performance record" is left up to the States with little or no assurance of national consistency or oversight. We oppose allowing the survey cycle to move to a 5-year periodicity—too much can change over that length of time. Also, we think that the question of what constitutes "outstanding performance record" is too undefined and will have too much variability from State to State. Finally, we believe that a sanitary survey should be done prior to a new ground water system coming on line.

5. States may design Sanitary Surveys that vary widely in quality and oversight. The EPA/State Joint Guidance on Sanitary Surveys and the new EPA "Guidance Manual for Conducting Sanitary Survey of Public Water System" published as technical assistance are non-binding and will not close the gap in the wide inconsistencies in how sanitary survey are performed and how identified problems are corrected. Also, the two guidances do not give the necessary direction to the States on which of the eight elements of the sanitary survey might be more of a priority, treating them all equally. Some of the survey elements require more in depth work or the benefits of the survey element are lessened or lost. Further, States should have to evaluate all eight elements laid out in the Joint guidance and not be allowed to grandfather in surveys conducted under the Total Coliform Rule (TCR) that don't touch on all eight elements. Finally, onsite verification should take place. It's not good enough to have a written certification to verify correction.

6. States are not required to have a cross connection control Program. States should be required to have a cross connection control program. Significant problems in the distribution system may be caused by cross connections. Instituting a cross connection control program would go a long way to ferreting out problems and point to solutions. Waiting for the Long Term 2 ESWTR to begin the process puts off implementation of a critical element for the prevention of a real problem.

7. EPA should establish a baseline list of significant deficiencies which states may exceed. EPA should mandate a minimum cross the board list of significant deficiencies to be evaluated by the States. EPA may want to provide an additional list of significant deficiencies from which the States may pick and choose. We feel that this option will provide both consistency in the program across the Nation and give States the necessary flexibility to tailor its program to local conditions and to innovate or expand its initiatives.

8. EPA should require public participation and Right To Know throughout the Ground Water Rule. EPA should carry over the ethic of public participation and right to know that is ensconced in the 1996 Amendments to the Safe Drinking Water Act. Public Water Systems should be required to hold a public meeting to explain the results of a sanitary survey, including a description of any significant deficiency, potential associated health problems and resultant plans, timetables and capitol budgets for needed corrective actions. A summary of the results of a sanitary survey should be incorporated into the next Consumer Confidence Report and the sanitary survey should be made available in public places like the library, over the net, and through the mail in the next billing cycle. States or their designated sanitary survey technician should work with the water provider to solicit public involvement in doing the sanitary survey just as they would with the source water assessment (SWA). Information provided by the public should be factored into implementation of corrective actions.

9. All Ground Water Systems Should Monitor for Bacterial Indicators and Coliphage Regardless of their Sensitivity. If a ground water systems does not disinfect, EPA proposes that it be required to do a hydrogeologic sensitivity assessment (HSA) to determine if it's source water is vulnerable to contamination. A determination of sensitivity can be nullified by the state if it can be shown that there is a hydrogeolgic barrier (HB) that will stop contaminants from getting into the source water. EPA has determined by definition that ground water system in karst, fractured bedrock or gravel areas are sensitive. EPA has left out sandy soil aquifers from this categorical determination of sensitivity. We agree with the drinking water committee of the Science Advisory Board (SAB) which said that all ground water systems should "be required to monitor for bacterial indicators and coliphage for at least 1 year regardless of sensitivity determinations." Also, we think that sandy aquifers should be included because it is common knowledge that viruses move from septics (and other sources) through sandy coastal plains into ground water. In addition we think that a HB determination and a sensitivity nullification should not lead to a source water monitoring exemption.

10. The SWAP Should Be More Tied Into the Ground Water Rule. Though EPA advises States to take the SWAP process into account, we feel that EPA could do much more to formally tie source water assessments and the sanitary surveys/HSAs together. Where State source water assessment plans (SWAPs) incorporate ground water system assessments that take in all eight elements of the GWR's proscribed sanitary survey scheme and provide the basis for doing a HSA, they may aide the States in rationalizing the two processes, both saving dollars and speeding up the implementation of any necessary corrective actions. If the State's SWAP however does not meet the minimum needs of the GWR then the State must do the SWAP and the sanitary survey/HSA. A mediocre approved SWAP should not be used as an excuse to backslide on all the necessary elements proscribed by the GWR.

[From the Natural Resources Defense Council]

ARSENIC AND OLD LAWS: A SCIENTIFIC AND PUBLIC HEALTH ANALYSIS OF ARSENIC OCCURRENCE IN DRINKING WATER, ITS HEALTH EFFECTS, AND EPA'S OUTDATED ARSENIC TAP WATER STANDARD

EXECUTIVE SUMMARY AND RECOMMENDATIONS

Findings

Arsenic in drinking water poses a significant public health risk in the United States. According to our most conservative analysis of new EPA data covering only 25 states, at least 34 million Americans in over 6,900 communities drank tap water supplied by systems containing arsenic, a known toxin and carcinogen, at average levels that pose unacceptable cancer risks.[1] Our "best" estimate, based on what we believe to be the most reasonable (but less conservative) analytical techniques, indi-

[1] The phrase "unacceptable cancer risk" is used here to mean water containing arsenic at a level posing a lifetime risk of dying from cancers in all internal organs—bladder, kidney, liver, and lung—of over 1 in 10,000, based on the methodologies, estimates, and cancer risk characterizations described in the National Academy of Sciences' recent report, Arsenic in Drinking Water, at 8, 301 (1999), and based on the standard assumption that a person consumes two liters of water per day. A 1-in 10,000 cancer risk traditionally is the highest cancer risk EPA ever allows in tap water when setting standards, although the Agency usually seeks to set standards at a stricter level, posing a lower cancer risk. See Chapters 1 and 2 for details.

cates that 56 million Americans in over 8,000 communities in those 25 states drank water with arsenic at these risky levels. [2]

These newly public figures are based on more than 100,000 arsenic samples collected from 1980 to 1998 by more than 24,000 public water systems in 25 states, which were then compiled by the U.S. Environmental Protection Agency (EPA). The Natural Resources Defense Council (NRDC) obtained the data under the Freedom of Information Act and analyzed them. While arsenic levels can vary with time, when considering cancer risk, the average levels generally are of primary concern. For this reason, NRDC calculated average arsenic levels in the systems evaluated. Because data were available for only half of the states in the nation, these are likely to be significant underestimates of the total U.S. population exposed to arsenic in tap water.

NRDC also has generated maps for this report showing the geographic distribution of arsenic problems for all 25 reporting states. This marks the first time that EPA's drinking water data base has been publicly analyzed using a Geographic Information System (GIS) to generate maps of drinking water problems.

This report includes a summary of the adverse health effects of arsenic in drinking water by an eminent expert on the subject, based upon a 1999 National Academy of Sciences (NAS) report and a review of peer-reviewed literature. The NAS report and other scientific literature discussed here have concluded that arsenic in drinking water is a known cause of bladder, lung, and skin cancer. In addition, the NAS report and many previous studies have found that arsenic in drinking water may also cause kidney and liver cancer.

Arsenic's known noncancer toxic effects include toxicity to the central and peripheral nervous systems, heart and blood vessel problems, and various precancerous lesions on the skin, such as hyperkeratosis (a pronounced scaly skin condition) as well as changes in pigmentation. The NAS report and peer-reviewed animal studies have found that arsenic may also cause birth defects and reproductive and other problems, although some of these effects are less documented than arsenic's cancerous, skin, nervous, and cardiovascular effects.

The NAS concluded in 1999 that EPA's 57 year-old arsenic standard for drinking water of 50 parts per billion (ppb), set in 1942 before arsenic was known to cause cancer, "does not achieve EPA's goal for public health protection and, therefore, requires downward revision as promptly as possible" (NAS, 1999, p. 9). In fact, the academy said that drinking water at the current EPA standard "could easily" result in a total fatal cancer risk of 1 in 100—about a 10,000 times higher cancer risk than EPA would allow for carcinogens in food, for example.

RECOMMENDATIONS

EPA must immediately adopt a strict, health-protective standard for arsenic in tap water. The Safe Drinking Water Act (SDWA) Amendments of 1996 required EPA to propose a revised arsenic standard (to replace the old standard set in 1942) by January 1, 2000, a deadline the Agency has missed. This is the third time EPA has violated a statutory mandate to update the arsenic standard. EPA is required to finalize a new standard by January 1, 2001. We conclude—as did NAS—that EPA should expeditiously issue a stricter Maximum Contaminant Level standard for arsenic. EPA must consider that many Americans also have unavoidable exposure to arsenic in their food, so relatively low levels of arsenic in tap water can cause safety levels to be exceeded. A health-protective tap water arsenic standard should allow a maximum lifetime cancer risk no greater than that EPA has traditionally accepted (a level presenting a lifetime cancer risk from 1 in 1,000,000 to at most 1 in 10,000 for vulnerable or highly exposed individuals).

This would require EPA to set a drinking water standard well below the current 50 ppb standard—in the range of 1 ppb. Limitations in the analytical techniques widely used for measuring arsenic in water, however, would likely necessitate a standard of 3 ppb, rather than a standard of 1 ppb, because reliably quantifying ar-

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[2] As discussed in Chapter 1, the 56 million population exposed figure is our best estimate of the average arsenic exposure levels of consumers in the 25 states included in the new EPA data base analyzed in this report. While this analysis is conservative (it may underestimate the extent of exposure), an even more conservative analysis would suggest that a minimum of 34 million people in these 25 states drank water posing a significant cancer risk. The latter highly conservative low average estimate assumes, when calculating average arsenic levels, that no arsenic was in the water at times when early crude tests with a high reporting limit of, for example, 10 ppb, found none, even though subsequent more sensitive tests found arsenic. On the other hand, the mid-average approach assumes that arsenic was present at half the reporting limit if, in some tests, arsenic was not detected using a high reporting limit, and other more sensitive tests found arsenic. See Chapter 1 for details.

senic at levels below this would be difficult using current standard lab equipment and practices. Based on an extrapolation of NAS's risk estimates, even a relatively strict arsenic standard of 3 ppb could pose a fatal cancer risk several times higher risk than EPA has traditionally accepted in drinking water. EPA data, which the Agency recently said probably overestimate costs, indicate that the cost per household of a 2 ppb standard would be from $5 to $14 per month for the vast majority (87 percent) of affected consumers; users of small systems may have to pay significantly more. EPA's (admittedly high) estimates also project that nationally an arsenic standard of 2 ppb would cost $2.1 billion per year, and a 5 ppb standard would cost $686 million per year.

EPA should reduce its cross-media guidance level for arsenic and should fund improved analytical methods to lower detection limits for arsenic. Health data indicate that EPA's current guidance level establishing the maximum recommended daily arsenic exposure, called a reference dose (which is unenforceable itself, but is used by EPA in developing enforceable standards in all environmental media, including water), is too high and may not protect vulnerable populations, such as children. To protect children, EPA should reduce this reference dose from 0.3 micrograms per kilogram per day (μg-kg per day) to at most 0.1 μg-kg per day, and should immediately reevaluate the reference dose in light of the 1999 NAS risk estimates, suggesting that the cancer risk at this level would still be unacceptable. In addition, EPA should fund efforts to reduce the level at which arsenic can be reliably detected in drinking water, so that it can be found down to levels at which it may pose a health risk (below 1 ppb).

Water systems should be honest with their customers about arsenic contamination and potential health risks. Only if water systems tell their customers the truth about arsenic contamination in their tap water, and about the health threat it poses, will the public support efforts (including possible rate increases) to remedy the problem.

Systems with arsenic problems should work with government officials to clean up their source water. Some systems may be able to reduce arsenic levels by cleaning up or changing the source of their water. For example, some arsenic contamination results from leaching of arsenic from old waste dumps, mines, or tailings, or from past use of arsenic-containing pesticides. Government officials and water systems should team up with citizens to remedy contamination at these sites so water supplies are not arsenic-contaminated. In addition, recent studies have shown that high groundwater pumping rates have increased arsenic levels in some wells. It should be investigated whether reducing pumping rates or reworking wells can reduce some systems' arsenic levels.

Water systems unable to get cleaner source water should treat to remove arsenic; state and Federal funds should be increased to assist smaller Systems in paying for upgrades. As noted above, there is readily available treatment technology that can remove arsenic from tap water, at a cost of about $5 to $14 per month per household for the vast majority of people (87 percent) served by systems with arsenic problems. Very small systems serving a small fraction of the population drinking arsenic-contaminated water, however, will often be more expensive to clean up per household (due to the lack of economies of scale). For these systems, Federal and state assistance to improve treatment is available, and arsenic contamination should be a high priority for these drinking water funds. Additional Federal and state funding through State Revolving Fund (SRF), USDA's Rural Utility Service, and other programs may also be needed. The SRF established by the SDWA Amendments of 1996 should be funded at least to the full authorized amount ($1 billion per year) to help smaller systems with arsenic problems.

EPA should improve its arsenic and other drinking water data bases. EPA should upgrade its drinking water data base, known as the Safe Drinking Water Information System (SDWIS) so that it includes all of these arsenic data, as well as unregulated contaminant data, as required by the Safe Drinking Water Act—and makes them accessible to the public. The SDWIS data base must also be upgraded to include more accurate latitude and longitude ("lat-long") data. The ready availability and low cost of new GPS (global positioning system) units for recording lat-long coordinates—available for a few hundred dollars—should drive EPA to require accurate lat-long data for the distribution systems, treatment plants, and intakes of each public water system. Such data will have a wealth of uses for water systems, state and local officials, EPA, and the public in using GIS systems for protecting source water, for developing targeted and well-documented rules, and for other purposes.

CHAPTER 1

ARSENIC HAS BEEN FOUND AT LEVELS OF HEALTH CONCERN IN THE TAP WATER OF TENS OF MILLIONS OF AMERICANS IN 25 STATES

NRDC has obtained new data showing that tens of millions of Americans are consuming tap water every day that poses unacceptable cancer risks. This chapter summarizes these new arsenic occurrence data, while subsequent chapters discuss in detail the health implications of arsenic contamination of drinking water and the need for a stricter standard for arsenic in tap water.

The source of these new data is an EPA data base not previously made public, obtained by NRDC under the Freedom of Information Act. In preparing to develop an updated standard for arsenic in drinking water, EPA asked all states for data on the occurrence of arsenic in the tap water served by public water systems. Twenty-five states responded (see Figure 1, National Arsenic Occurrence Map), providing over 100,000 arsenic test results taken from 1980 to 1998 from over 23,000 public water systems. These water systems serve a total of about 99.5 million Americans, or 40 percent of the 1990 U.S. population. Because the data base does not cover states in which approximately 60 percent of the U.S. population resides, the estimates of population affected by arsenic in their tap water likely are substantial underestimates. NRDC has deleted from consideration, as potentially unreliable, samples that exceeded 1,000 parts per billion.

These new data reveal startling new details about the extent of arsenic contamination in the tap water. Table 1 shows our best estimate is that over 56 million Americans in these 25 states consumed water from systems containing arsenic at levels presenting a potentially fatal cancer risk above the level that is EPA's highest acceptable cancer risk (1 in 10,000). Even our extremely conservative "low average" analysis approach indicates that at a minimum, over 34 million people in these 25 states drank water posing these elevated cancer risks. Our estimates are based on detailed evaluations of the EPA-collected occurrence data and the National Academy of Sciences (NAS) total cancer risk estimates.[3] Table 2 notes the total potentially fatal cancer risk that would be associated with drinking two liters of water containing arsenic at a given level for a lifetime, based upon the NAS estimates. Chapter 2 includes a further discussion of these data on risks and health effects, and how these estimates were derived.

As is clear from Tables 1 and 2, tens of millions of Americans are consuming tap water every day at levels that may pose a serious potentially fatal cancer risk and other health risks. Appendix A lists each public water system in which arsenic was found in the 25 states reporting data. The national map is intended to show the general areas that are hardest hit by the highest levels of arsenic. However, to determine whether arsenic has been found in a particular public water system, according to EPA's data base, readers should refer to the table of water systems reported in Appendix A. The map cannot be used by itself to identify whether a particular water system has an arsenic problem, because often there are several water systems located immediately adjacent to each other, and the map was generated at a scale that cannot be used to identify precisely which water system contains a given level of arsenic.

Table 1: Arsenic Levels in Tap Water Systems in 25 States

Low and Best Estimates

Average Arsenic Level (in ppb)	Low Estimate* of Number of Water Systems Affected	Low Estimate* of Total Population Served	Best Estimate** of Number of Water Systems Affected	Best Estimate** of Total Population Served
None detected	15,624	40,619,400	15,624	40,619,400
Detected, <1*	2,068	28,017,372	884	5,925,297
≧1 and <3	2,935	19,994,024	3,146	25,711,312

[3] As is discussed in Chapter 3, NAS estimated that, considering lung and bladder cancers death studies, the total cancer risk at the current tap water standard of 50 ppb "could easily" be 1 in 100. NAS, in *Arsenic in Drinking Water*, at 8, 301 (1999). The NAS also noted that while there may be some indication that arsenic may not have a linear dose-response relationship at low doses, these data are "inconclusive and do not meet EPA's 1996 stated criteria for departure from the default assumption of linearity." *Ibid.* at 7. Thus, as discussed in Chapter 2, we assume, as did NAS, that dose-response is linear with no threshold, and that the total lifetime potentially fatal cancer risk of consuming 2 liters a day of arsenic-contaminated water poses the risks noted in Table 2. While NAS did not explicitly calculate risks posed by water with arsenic at levels below 50 ppb, its analysis is used to develop Table 2.

Table 1: Arsenic Levels in Tap Water Systems in 25 States—Continued

Low and Best Estimates

Average Arsenic Level (in ppb)	Low Estimate* of Number of Water Systems Affected	Low Estimate* of Total Population Served	Best Estimate** of Number of Water Systems Affected	Best Estimate** of Total Population Served
≧3 and <5	1,321	7,440,564	1,947	17,494,651
≧5 and <10	1,348	5,033,538	1,652	10,611,259
≧10 and <15	535	1,451,616	566	2,075,157
≧15 and <20	251	243,526	258	340,284
≧20 and <25	171	269,393	173	270,332
≧25 and <50	280	354,802	283	376,542
≧50	66	99,736	66	99,736
Total	24,599	103,523,971	24,599	103,523,970
Total at or above 1 ppb (0.5 ppb presents the highest cancer risk EPA traditionally allows in tap water)	6,907	34,887,199	8,091	56,979,263

*The low estimate is based on the assumption that any nondetect, no matter what the reporting limit, contained no arsenic, even if other samples showed arsenic was present. This highly conservative analysis results in a large number of systems having average concentrations below 1 ppb, because all reported nondetects, no matter what the reporting limit, are averaged as zero. See the discussion in the text for more details on how these averages were calculated.

** The best estimate is the estimated mid-average level of each system, which is the average of the detected levels of arsenic and, for those systems for which there was at least one detect of arsenic, one-half the level of detection for all nondetects. See the discussion in the text for more details on how these averages were calculated.

Table 2: Lifetime Risks of Dying of Cancer from Arsenic in Tap Water

Based upon the National Academy of Sciences' 1999 Risk Estimates*

Arsenic Level in Tap Water (in parts per billion, or ppb)	Approximate Total Cancer Risk (assuming 2 liters consumed/day)
0.5 ppb	1 in 10,000 (highest cancer risk EPA usually allows in tap water)
1 ppb	1 in 5,000
3 ppb	1 in 1,667
4 ppb	1 in 1,250
5 ppb	1 in 1,000
10 ppb	1 in 500
20 ppb	1 in 250
25 ppb	1 in 200
50 ppb	1 in 100

*See note 3 and Chapter 3 for details on how we calculated total cancer risk based on an extrapolation of NAS's risk estimates, which assumed a linear dose-response and no threshold.

WATER SYSTEMS WITH ELEVATED LEVELS OF ARSENIC AND STATE MAPS SHOWING DISTRIBUTION OF ARSENIC PROBLEMS

Arsenic contamination of tap water is not a problem limited to a few pockets of the nation, nor is it limited in scope to small water systems. Tables 3 through 5 present summary data showing some water systems in which the EPA and state data indicate serious arsenic contamination problems may be found.

In addition, using ArcView Geographic Information System (GIS) software, and the latitude and longitude coordinates for public water systems reported in EPA's Safe Drinking Water Information System (SDWIS), NRDC has developed 25 state maps showing the regional variations in arsenic levels in tap water. The larger the dot, the larger the population served water system. In addition, we used graduated red coloration to show the concentration of arsenic found in the water, from light pink (representing low concentrations of arsenic) to bright red (representing mid-level arsenic levels) to dark red (representing severe arsenic contamination). In addition, NRDC wanted to give readers a picture of where arsenic was being searched for but not found. We used separate maps with graduated blue-green coloration to represent nondetects, with light blue-green representing nondetects using low levels of quantification (for example 1 ppb), and darker blue-green representing nondetects using high limits of quantification (for example 10 ppb).

As is clear from these tables and the 25 state maps, although arsenic contamination of tap water has substantial regional variation, no state is immune to the problem. Moreover, many of the nation's larger cities have levels of arsenic that are substantially above the level presenting what EPA would consider an acceptable cancer risk (that is, 1 in 10,000 risk of fatal cancer).

How Average Arsenic Levels are Calculated in This Report and in Appendix A

Arsenic levels can vary with time, and old samples often used cruder analytical techniques that could not detect low arsenic levels (below 10 parts per billion). We found that the so-called reporting limits for arsenic (that is, the lowest level of arsenic in the water that states require to bereported) in many states was 5 to 10 ppb in the 1980's and even in the early 1990's. Figure 3 shows that in some states, such as California, many water systems testing their water for arsenic were allowed to report as nondetected any level of arsenic below the state's relatively high reporting limits.

In many cases, those reporting limits later were lowered, due to improved analytical methods, and arsenic started to be reported in the water of many more communities, as would be expected. This presented a problem for our analysis: when a water system had for years not reported arsenic, and then reported it when the reporting limit dropped, how should we calculate the arsenic level for that system? Additionally, a relatively small number of water systems had very inconsistent reported levels of arsenic over time, and we had to decide how to report their average levels as well. We decided that when a water system conducted multiple tests of its water, we would use two different averaging techniques to estimate the arsenic exposure for consumers of that water:

First, we calculated a very conservative low average, which assumes that when arsenic was not reported as detected, there was absolutely no arsenic in the water at that time, even if the limit of detection was high (for example, 10 ppb), and even if other tests showed that arsenic was present in the water at levels somewhat below the previous reporting limit. For example, if a water system did five tests when the reporting limit was 10 ppb from 1985 to 1990 and found no arsenic, and then tested twice in 1993 to 1995 when the reporting limit was 3 ppb, and it found 8 ppb both of those later times, the low average calculated for that system would be 2.3 ppb (that is, [0 ppb + 0 ppb + 0 ppb + 0 ppb + 0 ppb + 8 ppb + 8ppb] / 7 measurements = 2.3 ppb).

Second, we based our best estimate on a calculated mid-average, which assumes that if at least some arsenic was detected in a water system at some time, then whenever arsenic was not reported as detected, it was present at a level of one half of the reporting limit. Using the same example, if a water system had five tests when the reporting limit was 10 ppb from 1985 to 1990 and found no arsenic, and then tested twice in 1993 to 1995 when the reporting limit was 3 ppb, and found 8 ppb both of those later times, the mid-average calculated for that system would be 5.8 ppb (that is, [5 ppb + 5 ppb + 5 ppb + 5 ppb + 5 ppb + 8 ppb + 8 ppb] ÷ 7 measurements = 5.8 ppb).

CHAPTER 2

AN OVERVIEW OF THE SCIENTIFIC AND HEALTH ISSUES RAISED BY ARSENIC REGULATION: WHAT ARE THE KEY SCIENCE AND HEALTH ISSUES FOR ARSENIC REGULATION IN TAP WATER?

There are several important public health issues raised by the presence of arsenic in America's tap water, including:

1.Why should the public care about arsenic in drinking water?

2.What are some of the environmental and biological characteristics of arsenic that are important to human health?

3.What are the adverse health effects of the various chemical forms of arsenic found in U.S drinking water?

4.Who in America is at special risk for adverse health effects from arsenic?

5.What can we conclude about the adequacy of the U.S. EPA's current drinking water standard for arsenic?

6.What can we conclude about the adequacy of other regulatory guidelines or standards for arsenic, for example the EPA reference dose (RfD) for ingested arsenic?

7.What can we conclude about what a health-protective level of arsenic in American drinking water supplies should be to prevent cancer and noncancer effects in American populations?

8.How can we prevent arsenic from getting into drinking water, or remove it from drinking water once it's there?

ANALYSIS AND DISCUSSION

Why should the public care about arsenic in its drinking water?

Arsenic is an element of the earth's crust that has many economic and industrial uses. However, it also is highly toxic in many of its chemical forms, even at the low concentrations often found in drinking water. Arsenic itself, as the core element in various arsenic compounds, remains unaltered even though it may bind or unbind with other elements or undergo changes in valence, or charge state. This scientific reality has many implications for how the element moves through the human environment and how we can effectively regulate it.

Some drinking water arsenic comes from contamination by human activities. For example, arsenic can be released by industrial or mining waste sites, or can seep from a pesticide dump site into groundwater serving as a community water source. Other drinking water arsenic occurs naturally. Thus, water supplies from wells drilled into groundwater aquifers that can be laced with geochemical arsenic.

In fashioning remedies to the problem of arsenic contamination in drinking water, it may be important to consider the origin of the arsenic. But no matter the source of arsenic, public health concerns dictate that the problem be solved promptly. Where the arsenic contamination is from human activity, waste cleanups (such as Superfund cleanups) may solve the problem, while in other cases the only remedy available may be arsenic removal at the drinking water treatment plant. The bottom line is that as a matter of community and preventive medicine, we must seek to minimize or prevent adverse health effects and risks from arsenic in tap water.

What are some of the environmental and biological characteristics of arsenic that are important with respect to its effects on human health?

Tap water is one important way that people are exposed to arsenic, but they may also encounter arsenic in other environmental media, such as food, dust, soil, and ambient air. Toxic forms of arsenic are harmful to people no matter how they get into our bodies. Water can be the predominant source of the toxic forms of arsenic for many Americans, but in order for arsenic to be a health concern, it is not necessary that drinking water be the sole or dominant source of human arsenic intake. In other words, arsenic levels in our blood increase no matter what the source, so more arsenic in toxic forms from tap water or any other source increases our health risk.

This environmental and biological reality prevents our viewing tap water arsenic in isolation. If we chose to quantify health risks only for drinking water arsenic and did not consider suspected or known contributions from other human arsenic intake sources, we might well be underestimating overall or aggregate health risks. That is, our risk numbers would be at the low end of the likely range of risk numbers with all sources accounted for. This view, however, does not invite the industries responsible for arsenic in one medium to point the finger at other sources as deserving either sole or more regulatory control. For one thing, some media lend themselves more readily to effective control of environmental contaminants and associated human exposures than others. This multimedia, integrated risk concept is particularly critical in the case of drinking water arsenic. Tap water arsenic is more easily controlled through centralized regulation, for example, controls on community water supplies, than arsenic in various dispersed sources and pathways, such as arsenic in soils, arsenic in home remedies popular in certain cultures, contaminated garden crops, or localized air arsenic emissions from smelters. Consequently, the regulatory attention given to arsenic in water is especially critical.

One characteristic of drinking water arsenic of special concern to regulators and scientists is the element's typical occurrence in an especially toxic form, inorganic oxyarsenic. Oxyarsenic occurs in two different charge states (or valences) of importance here: pentavalent, which has five valence electrons (essentially points at which other chemical groups can attach to it), and trivalent, which has three such valence electrons, or attachment points. These forms are associated with a variety of cancer and noncancer toxic effects in humans. A wealth of recent health and scientific data identify trivalent and pentavalent oxyarsenic as equally toxic under the typical long-term, lower-level exposures to these arsenicals sustained by human populations. Earlier, crude studies in which test animals were fed large quantities of either valency form under acute, that is, very short-term, conditions seemed to show some difference in the way the animals' metabolisms reacted, but we now know that result mainly related to the high-dose, short-time conditions of the studies. These conditions do not apply to long-term exposures of human populations to lower, but still toxic, exposure levels.

Most Americans are adept at recognizing visible or "macroscale" acute and chronic (continuing) hazards to their health and readily accept the usual characterizations

of those hazards by experts. Examples include acute injuries from fire and various chronic diseases linked to smoking. But many people are less aware of environmental contaminants and their toxic potentials. Many toxic contaminants such as arsenic occur in the environment at extremely low concentrations, yet these levels still can be high enough to be of health concern because they can be toxic at trace (part-per-million, ppm) or ultra-trace (part-per-billion, ppb and part-per-trillion, ppt) levels. In some cases, the injuries to human health from exposure to contaminants may only be seen after persistent contact with the contaminant for years or even decades; in other cases, complex medical and laboratory tests must be done to establish their presence.

What are the adverse health effects of arsenic in those chemical forms likely to occur in America's drinking water?

The public's perception of arsenic is still largely literary and forensic (stemming from such classics as the Joseph Kesselring play Arsenic and Old Lace and the film it inspired), and is most often recognized as the poison of choice for homicide, suicide, and other nefarious activities. This perception of arsenic toxicity represents only its most severe form. Such poisonings are acute, triggered by ingestion of very high amounts of inorganic arsenic (such as oxyarsenic) over a short time. When arsenic is ingested in large amounts deliberately or inadvertently, it produces a constellation of severe and often fatal injuries to the cardiovascular, gastrointestinal and nervous systems. This report examines the less-dramatic (but perhaps more important overall) dose-response and public health implications of widespread lower-level arsenic exposure of populations or their subsets.

We are concerned with arsenic exposures and toxic responses that are long term, occur at relatively much lower doses than those producing acute, fatal poisoning, and affect entire populations or population segments rather than a toxic outcome reported for a specific individual. In fact, we now know that the levels of arsenic and other elements in the environment that are toxic are so low that scientists could not previously have anticipated adverse effects without the growing scientific data base of human epidemiological, experimental animal, and toxicological mechanistic studies. This large and evolving data base defines significant toxic risks across a wide spectrum of doses or exposures.

The available information on the adverse health effects of arsenic in drinking water and in other media are to be found in various authoritative expert consensus documents listed in this paper's illustrative bibliography. These include documents of Federal agencies such as the EPA, and independent scientific bodies such as the National Academy of Sciences (NAS). These treatises and individual critical reviews and research papers form the foundation of the analyses and conclusions presented in this paper. This analysis and its conclusions about the impact of tap water arsenic on public health are focused on adverse effects associated with the element's toxicological character. Some experimental animal studies of arsenic's biological activity in recent years have suggested a potential role for the element as a nutrient in those animal species tested. Nutrient roles at very low intakes and toxic effects at higher intakes are not uncommon with environmental elements and do not, in any way, ease the need for control of excessive exposures. A nutrient role in humans, within the framework of the battery of widely accepted criteria to establish such roles, has not been determined for arsenic.

Indeed, the NAS's recent report on arsenic in drinking water notes that "studies to date do not provide evidence that arsenic is an essential element in humans or that it is required for any essential biochemical process." (NAS, 1999, p. 259) Any nutrient role would have to be at very low levels, in common with other elements with dual bioactivity. It is highly unlikely that arsenic could ever be regulated to levels so low that any yet-to-be-established human deficiency for the element would occur. This topic was discussed in detail by the author elsewhere (Mushak, 1994).

Arsenic-Induced Skin and Internal Cancers

Long-term exposure of nonoccupational human populations to environmental arsenic is associated with skin cancer and with various internal cancers, such as bladder, kidney, liver, and lung cancer. The NAS's 1999 report on arsenic in drinking water concluded that arsenic is "known" to cause skin, bladder and lung cancer, and noted that there is substantial evidence that arsenic in drinking water is associated with other cancers, including cancers of the liver and kidney.

Workers encountering airborne arsenic in the workplace are known to be at high risk for lung cancer and possibly other cancers as well. Nonworker populations who have been intensely studied for increased prevalence and incidence of skin and internal cancers, and whose cancer histories underlie the calculations of cancer risks for Americans exposed to drinking water arsenic, received their cancer-causing ar-

senic exposures from arsenic in drinking water. Consult the bibliography for further details. Among the key references are the 1984 EPA health assessment document for arsenic, the 1988 EPA assessment of some specific issues for arsenic and human health, the EPA 1996 document for arsenic health assessment, and the 1999 NAS detailed report on cancer and other adverse effects, Arsenic in Drinking Water.

Some of the most compelling evidence for arsenic as a carcinogenic (cancer-causing) substance is to be found in various studies of a large Taiwanese population exposed to arsenic in their drinking water. Also compelling are data showing elevated cancer rates in people who drank arsenic-contaminated water in Argentina and Chile. The Taiwanese study population was huge, numbering more than 40,000 subjects, and included a large control population with more than 7,000 individuals. Study groups of these sizes in the environmental epidemiology of toxic elements are not very common. The earliest cancers appearing in these Taiwanese and in other groups were skin cancers—consisting of various histopathological types—followed later in their lives by cancers of internal organs—bladder, kidney, liver, lung. Arsenic-associated skin cancers occur in specific body areas not exposed to sunlight: the trunk, soles, and palms. Therefore, arsenic cancer lesions can be distinguished from cancers caused by sun exposure.

Additional strong evidence that arsenic in drinking water causes cancer is from Chile, where a larger population was studied than that in Taiwan—more than 400,000 people. Researchers evaluating this Chilean population found marked increases in mortality for bladder and lung cancer in particular. Approximately 7 percent of all deaths over age 30 could be attributed to arsenic (Smith AH et al. 1998).

Some regulators and others have argued that the threat to life caused by arsenic-associated cancers differs between skin cancers and cancers of the bladder, kidney, liver, or lung. They argue that the latter cancers collectively offer a higher mortality risk and are therefore more life-threatening. This distinction is hardly reassuring, nor does it counsel neglect of skin cancer as a public health concern. Only some of the arsenic-associated cancers arising in skin and associated with arsenic are benign (the basal cell lesions) while the squamous cell carcinomas may metastasize to other organs. In any event, the findings of internal organ cancers in reports that are more recent than those for skin cancers have significantly reinforced public health and safety concerns associated with arsenic.

While some regulators have suggested that skin cancer should be downgraded as a health concern because it sometimes is not fatal, is inappropriate to consider only fatal cancers in assessing arsenic's risks to public health. Nonfatal cancers inflict enormous emotional and economic costs to the victims of these cancers, their families, and society as a whole.

Not surprisingly, new findings on arsenic carcinogenesis have generated a number of recent studies, such as ones looking at how representative the Taiwanese population data are for risk analyses in U.S. communities exposed to arsenic in drinking water and other environmental media. Some in industry and their representatives have challenged the Taiwanese data, despite the fact that the Taiwanese data are the most extensive to date, and that rates of cancers associated with drinking water arsenic are proportional, considering varying exposure levels, to those found in other geographically distinct areas, such as Argentina and Chile.

To date, however, no one has successfully challenged the view by U.S. regulators and the NAS that the Taiwanese and Chilean studies provide strong evidence of arsenic's carcinogenicity in humans. Several appraisals of these challenges merit comment and the author noted these in a 1995 paper (Mushak and Crocetti, 1995).

Some attacks on the Taiwanese data have argued that the nutritional status and metabolic aspects of the study population put it at greater risk for toxicity from arsenic exposures than U.S. communities. However, the results of these studies have not produced any convincing challenges to the scientific validity of the data on nutritional grounds (Mushak and Crocetti, 1995). Impaired nutrition as a factor producing increased arsenic toxicity in Taiwanese, even if it were valid, is hardly an exclusionary criterion for comparisons with Americans. The argument of differential nutrition requires that we assume Americans exposed to drinking water arsenic, unlike the Taiwanese, are all well-nourished and at lower risk for arsenic toxicity. This is simply untrue. Undernutrition is a chronic public health and societal problem in America, including for those in the high-risk arsenic groups, the elderly and young children (see below).

Industry and some others have cited additional factors to argue that one cannot compare the Taiwanese exposures to arsenic to American arsenic exposures. They have claimed that other contaminants, such as alkaloids, in the Taiwanese well water are the culprits or at least co-culprits. Again, this argument is unconvincing. For example, arsenic produces cancers and other arsenic-associated effects in a

number of other exposure settings comparable to the Taiwanese situation, but where alkaloidal contaminants are absent.

Others have held that the Taiwanese have genetic determinants that alter arsenic metabolism in the body, resulting in a different likelihood of cancers, but genetic predisposition to arsenic-associated cancers also remains an open issue. Some recent studies suggest that there may be genetic polymorphism (that is, many different human genetic types) in the enzyme pathway which is thought to detoxify arsenic in our body ("detoxifying biomethylation"), but such polymorphism has yet to be linked to risk differences for various cancers. Furthermore, we do not know the range of genetic diversity in Americans with respect to these arsenic methylation enzymes. Nor do we have a good handle on the mechanisms of arsenic carcinogenesis, or the metabolic transformations of the element. Research has also suggested that increased arsenic methylation may be linked to a higher cancer risk. This author first hypothesized in 1983 that the body's metabolic diversion of methyl groups away from needed bodily processes to detoxifying arsenic could be a factor in causing arsenic toxicity (Mushak, 1983). Thus, as NAS's 1999 report concluded, there is no basis on which to rest any argument that the solid body of Taiwanese data associating arsenic in tap water with several cancers, or the confirmatory data from Argentina and Chile, should be rejected.

These studies, taken together, paint a compelling picture. They have lead the NAS and many other august bodies to conclude that arsenic in drinking water is known to cause cancer in humans.

Noncancer Adverse Effects of Arsenic

Low-level arsenic exposure has other toxic effects besides cancer. Inorganic arsenic in drinking water has been associated with toxicity to the central and peripheral nervous systems, the heart and blood vessels, and various precancerous lesions in the skin, including hyperkeratosis, a pronounced scaly skin condition, and changes in pigmentation. These skin changes are so characteristic that the medical literature notes that laypeople could easily identify workers who used arsenic as a sheep-dip pesticide, simply because of their obvious skin lesions.

Ingested inorganic arsenic produces both central and peripheral nervous system effects in exposed humans. Peripheral nervous system effects on both sensory and motor nerve function mainly harm adults, while very young children are more susceptible to central nervous system effects on the brain. The effects of arsenic exposure in children may persist over the long term, based on data described in EPA's 1984 health assessment document (EPA, 1984). Irreversible toxicity must obviously be viewed much more seriously than reversible effects. Once injury has occurred, simply reducing the exposure does not undo the harm.

Exposures to arsenic in drinking water and other media also cause toxic effects on peripheral blood vessels. In its extreme form, vessel toxicity takes the form of a dry gangrene, called Blackfoot Disease, particularly noted in the more heavily exposed Taiwanese. Lower exposures were linked to a very painful peripheral blood vessel disorder in Chilean children exposed to drinking water arsenic, resembling Raynaud's Disease. The latter arises from arterial and arteriolar spasm and contractions leading to impaired blood flow and cyanosis (inadequate oxygen reaching the tissues). Studies also have linked arsenic exposure from drinking water to higher rates of diabetes.

Data from the Taiwanese studies and from studies of other populations reveal that there is a dose-response relationship for ingested water arsenic and several non-cancer toxic effects (NAS, 1999; EPA, 1984, 1996). By dose-response relationship, we simply mean that as the arsenic intake increases, both the frequency and the severity of toxic effects increase in the exposed people. This type of dose-response relationship is one of the most important pieces of evidence that health scientists use to determine that a toxic chemical actually causes a particular toxic effect. For example, scientists have documented a dose-response relationship in human populations showing that increased exposure to arsenic in drinking water causes more frequent and more severe skin lesions and serious vascular effects.

Arsenic also has been linked to injury to the cardiovascular system, a particular concern in the United States where cardiovascular diseases already are a major public health concern. Elevated arsenic exposures should be considered a potential added risk factor in addition to other widely recognized risk factors for cardiovascular diseases.

Who in America is at special risk for adverse health effects from environmental arsenic?

Different people respond to exposure to arsenic or other toxins in different ways. The toxic responses can vary greatly, even when people are exposed to the same amount of a contaminant such as arsenic.

There are many reasons for this variability in toxic response, arising from either intrinsic factors or extrinsic causes. Intrinsic factors are those peculiar to the individual, and over which the individual has little control, for example, gender, age, race, stage of development, or group behavioral traits. Extrinsic factors are those outside the individual's characteristics and include length of exposure to a toxic substance. A general discussion of characteristics that can heavily influence the differential toxicity of toxins to different individuals, in the context of lead, is included in the NAS's 1993 report on populations sensitive to lead exposure (NAS, 1993a), of which the chief author of this report was a co-author. A second NAS report appearing in 1993 (NAS, 1993b) detailed the increased sensitivity of very young children to pesticides compared to adults. As discussed below, many of the basic principles that may lead to higher risks in children from lead or pesticides (for example, children's immature detoxification systems and higher exposure to drinking water per unit of body weight) apply to arsenic.

Variability in the human population's sensitivity to environmental contaminant toxicities is now an accepted principle in scientific, regulatory, and legislative quarters. This acceptance by science is found in numerous documents and individual research papers dealing with environmental contaminants, illustrated in the cited treatises and papers. Agencies such as the EPA regulate environmental metals and other contaminants with an eye to those populations at special risk, not "average" populations. That is, population segments with particular biological sensitivities or enhanced exposures are identified in relevant rulemaking for adequate protection from exposure and associated toxic harm.

In 1996 Congress enacted the Food Quality Protection Act (FQPA), Pub. L. No. 104–170, 110 Stat. 1489 (1996), partly in response to the 1993 NAS report on children and pesticides (NAS, 1993b), Pesticides in the Diets of Infants and Children. The FQPA mandates special protection for young children from pesticides, including a general requirement that an added tenfold margin be included to ensure safety for children, unless reliable data show that such an additional safety factor is unnecessary to protect children. Similarly, Congress adopted the "Boxer Amendment" in the 1996 Safe Drinking Water Act Amendments, which requires EPA to consider children, infants, pregnant women, and other especially vulnerable subpopulations in setting drinking water standards. SDWA §§ 1412(b)(1)(C), (b)(3)(C)(5), 1457(a).

We can readily identify two segments of the U.S. population that are at risk. First, older adults who have sustained elevated arsenic exposures over the long term are at special risk. Both cancer and noncancer toxic effects can occur in these individuals as a result of their prolonged exposure.

Second, very young children can be at elevated risk. The very young, especially infants and toddlers, are more likely to come into direct contact with arsenic. For instance, they often put arsenic-contaminated items in their mouths. In addition, pound for pound they consume more arsenic and other contaminants than adults. A higher arsenic intake rate for children per unit of body weight has been shown, as seen for example in the 1999 study of Calderon et al. evaluating American subjects. Additionally, the very young, being less able to defend against toxicants than are older children or adults. In the case of arsenic, we have to take into account that the very young do not detoxify arsenic as efficiently as adults, as shown in recent studies. Data from a study by Concha (1998a) indicate the fraction of toxic inorganic arsenic found in exposed children's urine is about 50 percent higher than it is in adult women exposed to similar levels. These investigators found that about 50 percent of the arsenic in children's urine was in the toxic inorganic form, while the adults had just 32 percent inorganic form, suggesting that children may be less able to detoxify arsenic and therefore may be more susceptible to its toxic effects. Data from a study by Kurttio et al., (1998) indicate that this differential in biomethylation-detoxification may persist over many years. We also must consider that children are more sensitive to the central nervous system effects of arsenic than adults are, and that children who sustain central nervous system injuries from arsenic may have irreversible injury, as noted above (EPA, 1984).

A third high-risk population, not fully characterized, is fetuses, which can be exposed to arsenic by way of maternal exposure. Arsenic, like a number of other environmental contaminants, crosses the placental barrier in pregnant mammals (for example, NAS, 1999). The fetus is even more biologically sensitive than the infant and toddler. Arsenic intoxication of the conceptus (human embryo relatively shortly after conception) can potentially target both organogenesis (the generation of the devel-

oping vital organs) in the embryo stage and further development in the later, fetal stage. While no in-utero arsenic effects have been documented for human exposures, we do know that oral intake of arsenic in experimental animal studies produced birth defects, impaired fetal growth, and reduced the survival of fetal and newborn animals (see, for example, NAS 1999). Of particular concern here is the recent finding that arsenic enters the fetal circulation in pregnant women by at least the third trimester, and that the level of arsenic in umbilical cord blood approaches the maternal arsenic level (Concha et al., 1998b).

Because of variations in human sensitivity to arsenic, including indications that children may be more vulnerable to this toxin, the NAS (1999) suggested that "a wider margin of safety might be needed when conducting risk assessments of arsenic because of variations in metabolism and sensitivity among individuals or groups"(p. 5). The next chapter, dealing with conclusions about the regulatory status of drinking water arsenic in America, focuses on these risk groups.

CHAPTER 3

CONCLUSIONS FOR SAFE REGULATION OF DRINKING WATER

What can we conclude about the adequacy of the U.S. EPA's current drinking water standard for arsenic?

The present EPA drinking water standard, as an enforceable Maximum Contaminant Level (MCL), is 50 micrograms of arsenic per liter water (50 μg/L, equivalent to 50 parts per billion, or ppb). This value has not changed since 1942, and was promulgated with few scientific underpinnings. There is therefore little scientific support for its regulatory adequacy. This MCL was issued before the accumulation of the large body of scientific and human health data produced over the last 30 to 40 years, a period that included the Taiwanese studies and numerous authoritative treatises on arsenic, including some from the NAS and EPA. As long ago as 1962, the U.S. Public Health Service recommended that water containing more than 10 μg/L (or ppb) of arsenic (one-fifth of the still-current standard) should not be used for domestic supplies.

Congress has directed EPA to update the 1942 arsenic standard three times—in 1974, 1986, and 1996. A court ordered EPA to complete this task in the early 1990's, but several extensions were granted. EPA still has not updated the standard. In a legislative mandate in the Safe Drinking Water Act Amendments of 1996, Congress again directed EPA to publicly propose an updated arsenic standard based on current evidence by January 1, 2000, a deadline that EPA has now, again, missed. EPA is then required to promulgate the final arsenic standard by January 1, 2001.

The current scientific and health risk assessment status of arsenic within that mandate makes it clear that EPA's current MCL of 50 μg/L is grossly inadequate for protecting public health. The extent of that inadequacy is effectively captured in the NAS report, Arsenic in Drinking Water (NAS, 1999). The report focused heavily on risk assessment estimates for human cancer frequencies as a function of drinking water and food arsenic and derived cancer risks for arsenic in environmental media, particularly drinking water. Our analysis concurs strongly with the academy's findings and recommendations as well as the following conclusion:

On the basis of its review of epidemiological findings, experimental data on the mode of action of arsenic, and available information on the variations in human susceptibility, it is the subcommittee's consensus that the current EPA MCL for arsenic in drinking water of 50 μg/L does not achieve EPA's goal for public-health protection and, therefore, requires downward revision as promptly as possible (NAS, 1999, pp. 8–9).

The NAS report did not recommend a specific MCL below 50 that would be fully health protective. It did, however, provide a series of cancer risk assessments for cancers of the skin and internal organs. This approach for bladder and lung cancers employed the traditional straight-line extrapolation from rates at elevated arsenic exposures. Put differently, the NAS assumed—as is usually assumed by scientists based on traditional principles of toxicology, unless there is strong evidence to the contrary—that there is a direct, linear relationship between cancer risk and arsenic exposure. The academy committee members, correctly and conservatively (with respect to the best health protection), noted that low-dose extrapolation models based on available data may or may not be "sublinear" compared to linear extrapolation. That is, arsenic at extremely low doses may, or may not, cause relatively less cancer risk per microgram than it does at high doses. However, the NAS experts concluded, the evidence for such "non-linear" models of arsenic-associated cancer risk is not compelling enough to rule out the traditional linear approach, so the health-protec-

tive linear approach should be used. The NAS scientists then used studies of people who had been exposed to arsenic in their tap water at elevated levels (for example in Taiwan) to model, or estimate, the risks of people exposed to lower levels.

The 1999 NAS report calculated that arsenic consumption in drinking water at the current EPA MCL would produce a male fatal bladder cancer lifetime risk of 1 per 1,000 to 1.5 per 1,000, using a linear extrapolation approach. Factoring in lung cancer risk and its relative robustness compared to bladder cancer (lung cancer risk is about 2.5 times greater than bladder cancer risk), an overall internal cancer risk rate "could easily result in a combined lung cancer risk" of 1 percent, or 1 in 100, according to the NAS's 1999 report (p. 8). The high level of cancer risk from arsenic ingestion in water at the present MCL does not account for concurrent intakes of carcinogenic arsenic from food or idiosyncratic sources (for example, certain prepared ethnic remedies that contain arsenic). In the past, EPA estimated a lower cancer risk from arsenic in tap water than did NAS in 1999. For example, EPA's Integrated Risk Information System (EPA, 1998) estimated about a 10fold lower cancer risk for arsenic than the more recent NAS study (NAS, 1999), apparently in part because EPA evaluated only bladder cancer risks, whereas NAS considered the higher risk of lung cancer as well, based on recent studies. We believe the NAS risk estimates are more reliable and should be adopted by EPA.

The lifetime risks of dying from internal cancers due to drinking water arsenic estimated in this paper based on linear extrapolations in this paper from the NAS 1999 arsenic report are generally supported by studies of people drinking relatively low levels of arsenic in their tap water. For example, a recent study from Finland (Kurttio et al., 1999), found that Finns who drank water containing low levels of arsenic (less than 0.1 ppb) had about a 50 percent lower risk of getting bladder cancer than their countrymen who drank water containing somewhat more arsenic (0.1 ppb to 0.5 ppb). Significantly, people who drank more than 0.5 ppb arsenic had more than a 140 percent increase in bladder cancer rates compared to those who consumed levels less than 0.1 ppb.

The pros and cons of models that characterize cancer risk bring up the role and judgment of risk assessors. The NAS's 1983 seminal document on risk assessment in regulatory agencies and elsewhere in the Federal Government (NAS, 1983) suggested a four-part paradigm for quantifying health risk that is now widely used in various incarnations by governmental agencies and others. The 1983 report also repeatedly made note of the role of judgment in the risk assessment process, a fact too often ignored by interested parties viewing regulatory risk assessment models. Without a totally clear scientific consensus on the guaranteed best scientific approach, or in the face of equally acceptable approaches, we must opt for the scientific approach that provides the maximum protection for human populations. The linear extrapolation approach adopted by the NAS subcommittee is in full accord with this principle, which should apply to assessment of cancer risks for environmental contaminants.

What can we conclude about the adequacy of other regulatory guidelines or standards for arsenic, for example the EPA reference dose (RfD) for ingested arsenic?

EPA issues guidelines for the intake levels of environmental contaminants that the Agency generally considers to be free of toxic risk during long-term, that is, lifetime, exposures. In the case of oral intakes these values are called reference doses, RfDs. They are expressed in milligrams (mg) of contaminant daily intake per unit body weight in kilograms (kg-day). RfDs, being derived for oral intakes, do not usually take account of other routes of intake. Inhalation of contaminants might be a significant exposure route, in which case a reference concentration, RfC, expressed as milligrams per cubic meter of ambient air, may also be used. It is important to note that if more than one exposure route is significant, we must recognize that the RfD is less protective than we would otherwise conclude if we thought that arsenic in drinking water was the sole route of exposure. EPA, in its general description of the RfD approach, notes the need to take account of other intake routes (EPA, 1993).

EPA has set the RfD for ingested inorganic arsenic, the amount viewed as not being linked to any health risk, at 0.0003 mg/kg-day (0.3 μg/kg-day). This value is derived for skin hyperpigmentation and keratosis and potential vascular effects. Analyses in the preparation of this paper, including a review of health effects data for the United States, found no currently valid and convincing reasons to say this value is too low. Thus, no higher RfD is warranted.

EPA's failure to fully consider risks to children in the RfD derivation is of concern. It is true that early childhood is only a fraction of the total lifetime interval considered when deriving an RfD for lifetime effects of arsenic. However, the relatively inefficient detoxification of a potent carcinogen and toxin by children, and the in-

creased sensitivity (and higher exposure per unit of body mass) of children to arsenic-associated central nervous system effects, are serious issues. EPA should revise the current RfD downwards to account for the apparent elevated vulnerability of children; the data certainly do not support any upward revision of the current value.

In addition, EPA has not reconciled the health risks represented by the current RfD value based on noncancer toxic effects with the internal cancer risk estimates calculated for drinking water arsenic in the 1999 NAS report. The current RfD permits a "safe" daily intake by a 70 kg adult male of 21 μg arsenic per day. Risk-characterization estimates in the NAS report for the MCL value permit calculation of a cancer risk for this "safe" 21 μg daily intake that markedly exceeds any acceptable regulatory risk management guideline for cancer. Put differently, the amounts of arsenic intake that may be safe for noncancer risks are unsafe for cancer risks.

To protect children and infants, an RfD at least threefold lower, 0.1 μg/kg-day, is certainly more defensible and more protective of identifiable at-risk populations in the United States. This adjustment is based upon standard EPA use of "uncertainty" factors for the RfD. The current uncertainty factor of three should be increased 10, the next generally permitted level for such a factor, based on concerns about the special susceptibility of children. Even such a lower RfD, it should be noted, would still present a cancer risk higher than EPA would generally consider acceptable. We recommend that the RfD be reduced to at most this level.

What can we conclude about what a health-protective level of arsenic in U.S. drinking water supplies should be to prevent cancer and noncancer effects in the U.S. population?

According to the data, we need a much lower and more protective EPA standard for drinking water arsenic and a much lower and more protective reference dose guidance level for arsenic.

Given the risk estimates for all internal cancers provided in the NAS's 1999 report, the current EPA MCL for arsenic must be revised downward to no higher than a value at the Practical Quantitation Level (PQL) of 3 ppb. EPA completed a thorough review of laboratory capabilities in 1999, and concluded that the PQL is 3 ppb (Miller, 1999). Thus, a new MCL of 3 ppb is reasonable, based on the newest analytical methodology assessment from EPA (which is more current than the 4 ppb figure cited by NAS, 1999, a level based on earlier studies, see, Eaton et al., 1994; Mushak and Crocetti, 1995).

Our conclusion that the MCL should be 3 ppb is driven by practicality, that is, one cannot regulate below what one can measure for compliance. This does not say that values lower than the PQL of about 3 ppb pose no cancer risk; it only recognizes that quantification of these lower levels in drinking water is problematic at this time. While many laboratories can reliably detect arsenic at levels below one ppb, reviews of a variety of laboratories to date have found that many others are unable to reliably detect and quantify the concentration of arsenic at these levels. As the NAS recommended in its 1999 report on arsenic in drinking water, EPA should immediately seek to reduce the PQL for arsenic by developing and standardizing improved analytical techniques for arsenic. The only alternative to setting an MCL at the PQL would be for EPA to establish a "treatment technique" for arsenic, an approach that seems difficult to justify here since arsenic is reliably detectable down to the low ppb range.

There is no scientifically sound reason for increasing the noncancer RfD value from 0.3 μg/kg-day to a higher value. To the contrary, as noted above, there is good reason to adjust the value lower. Adults ingesting the "safe" arsenic dose for noncancer effects will simultaneously be at too high a risk for internal organ cancers. While EPA's risk management guideline for permissible skin cancer risk was changed to 1 in 10,000 in 1988, the guideline for the more dangerous, more often fatal internal cancers should remain at 1 in 1,000,000. One cannot get to anything near this cancer rate guideline with the present RfD value if one assumes significant contribution of carcinogenic inorganic arsenic from food.

For these reasons, an RfD at least threefold lower, 0.1 μg/kg-day, is certainly more defensible and more protective of identifiable at-risk populations in the United States.

How can we prevent arsenic from getting into drinking water, or remove it from drinking water once it's there?

1. Preventing Arsenic From Getting Into Water Supplies.

Arsenic gets into drinking water from a variety of sources. Sources from human activities include:

Leaking of arsenic from old industrial waste dumps. Arsenic is one of the most common contaminants found at Superfund sites, for example.

Leaching of arsenic from mines and mine tailings. Some hard-rock and other mines expose arsenic-bearing rock to the elements, "liberating" the arsenic into the environment, and in some cases causing serious arsenic contamination of ground and surface water.

Runoff or leaching of old arsenic-containing pesticides from sites where they were heavily used. In some cases, the old arsenic-based pesticides remain in the areas where they were applied, manufactured, or disposed of years ago, and can get into water supplies.

Heavy groundwater pumping. Recent studies in Wisconsin and elsewhere have shown that heavy pumping of groundwater has increased arsenic levels in some wells. In some cases heavy pumping appears to have pulled water out of heavily arsenic-contaminated layers of rock that were not the primary aquifer being tapped but had not been sealed off from the well. In other cases, possibly because overpumping appears to have caused groundwater levels to drop, increasing arsenic-bearing rock contact with air and thereby increasing arsenic leaching).

Cleaning up old dumpsites under Superfund and related programs may reduce arsenic contamination in some systems affected by arsenic from industrial sites. Additionally, arsenical pesticide hot spots, and certain mine waste sites, are sometimes covered by Superfund or other cleanup laws and should be addressed in order to reduce water contamination.

Efforts to reduce leaching and drainage from mines and mine tailings by improving reclamation and mining practices should also be undertaken to reduce arsenic loading into many water sources. Furthermore, it is worth investigating whether reworking contaminated wells (for example, using a casing and cement to seal off arsenic-bearing rock layers that may be leaking water into the well) and/or reducing pumping rates may in some cases reduce arsenic levels in systems. Government officials and water systems should work with citizens to remedy these problems so water supplies are not contaminated by arsenic and do not need to be treated for arsenic removal.

2. Readily Available Treatment Technologies Can Remove Arsenic from Drinking Water.

The best way to avoid arsenic contamination from reaching our taps is to prevent it from getting into the environment in the first place. Where prevention is not possible, as when the arsenic occurs naturally, and when no alternative water source is available and the system cannot consolidate with another, cleaner water system, water treatment is readily available. Treatment already in use by some progressive water utilities has been demonstrated to reduce or essentially eliminate arsenic contamination of tap water. Among the effective arsenic treatment options EPA has identified (EPA, 1999; EPA 1994) are:

Modifying Existing Coagulation and Filtration. Large water systems that already have coagulation and filtration technology (as most surface water systems do) can take simple steps to modify these processes to substantially reduce arsenic levels. Changing their use of iron or manganese oxidation, use of ferric chloride or ferric sulfate, and alum coagulation and filtration can reduce arsenic by 80 to 95 percent. These steps are relatively inexpensive.

Water Softening with Lime. Many water systems already use lime to "soften" their water (that is, to reduce water "hardness" by removing the minerals calcium and magnesium). We now know that softening, if optimized, can reduce arsenic levels by 60 to 90 percent. It is about as inexpensive as coagulation and filtration modifications.

Activated Alumina. Activated alumina can be packed into beds through which water is run in a treatment plant to remove arsenic. While this method works well for most waters, if the source water has high levels of selenium, fluoride, or sulfate, it is not as effective at arsenic removal.

Ion Exchange. This technology, already used by many water systems, can remove arsenic effectively in most water. Again, however, if levels of certain other chemicals (such as sulfate, selenium, fluoride, or other dissolved solids) are too high, pretreatment using other technologies is needed to assure that adequate levels of arsenic are removed.

Electrodialysis Reversal. Essentially the same process as used to clean blood at dialysis centers, electrodialysis takes advantage of the charge of particles (like arsenic) and a special membrane under the influence of an electric current, and can remove about 80 percent of arsenic from water.

Reverse Osmosis and Nanofiltration Membranes. RO and NF membranes can remove 90 percent to more than 95 percent of arsenic. These membranes can reject substantial amounts of water, and therefore waste-stream recovery or other actions

may be necessary in the arid West. Also, particularly if arsenic levels in the raw water are high, treatment or disposal of the concentrated brine created by removing the arsenic from the water can increase costs.

Point of Use and Point of Entry Treatment. Under the 1996 Safe Drinking Water Act Amendments, water suppliers are authorized, under strict conditions, to use point-of-use filters (for example, RO units installed under kitchen sinks) or point of entry filters (for example, treatment devices in the basement at the point water goes into the home) to comply with drinking water standards. EPA studies have shown that these devices can be affordable and effective to treat for arsenic, and may be cheaper for small systems than installing centralized treatment. For this to work in a national rule, EPA would have to clarify utilities' utility responsibility in assuring the continued operation and maintenance of such devices.

3. Treatment Costs to Remove Arsenic are Modest for Most Consumers.

For several years, EPA has been evaluating the cost of installing treatment to meet various Maximum Contaminant Levels (MCL) for arsenic. EPA's most recent public analysis (Taft, 1998) found that if the standard were lowered from the current 50 ppb down to 5 ppb, it would cost most households (those served by city systems serving 100,000 people or more) about $2 a month, and would cost up to $14 a month for people living in smaller towns (with 10,000 to 100,000 people). Even a standard as low as 2 ppb would cost city dwellers with arsenic problems about $5 a month, and those living in affected towns as small as 10,000 people would pay about $14 a month.

Systems serving over 10,000 people serve the vast majority of people affected by arsenic contamination. Our analysis of EPA's 25-state arsenic data base shows that about 9 out of 10 people (87 percent) who consume arsenic at a significant level in their tap water (over 1 ppb) are served by these systems serving more than 10,000 customers.

For the 13 percent of consumers who get their water from smaller systems, however, treatment costs can be significantly higher than they are for consumers in cities, because of the lack of economies of scale. Thus, EPA estimates that people drinking water from a system serving 3,300 to 10,000 people may have to pay as much as $20 a month, and the smallest systems (assuming the worst case and that no point-of-use or other devices were allowed) could reach $100 a month (Taft, 1998).

Using these figures, EPA has estimated that a 5 ppb arsenic rule would cost about $686 million per year, and a 2 ppb standard would cost $2.1 billion. However, EPA recently admitted (Taft 1998) that both these national cost estimates and the individual household cost estimates are probably overstatements of the true costs of treatment for several reasons:

Most important, EPA assumed that all systems that exceeded the MCL would install full treatment of all of their water to get it well below the MCL. More recent analysis shows, however, that most water systems would actually treat only some of their water and then would blend it with untreated water, in order to produce water just under the MCL, to keep the costs down.

EPA assumed that if a water system with multiple wells has just one or a few wells exceeding the arsenic MCL, the system will treat all of its wells, including those below the MCL; EPA now understands that this is extremely unlikely.

EPA's estimates did not account for recent advances in treatment technologies, such as the newly understood ability of the relatively inexpensive ion-exchange treatment to effectively treat all but the highest sulfate waters.

EPA's estimates failed to account for improvements in water quality that are expected to be required by other EPA rules, such as the groundwater rule, the Stage 2 Microbial and Disinfection Byproducts rule, and the uranium rule, all of which are expected to drive many water systems to use treatment that will also reduce arsenic.

The older EPA estimates do not consider the availability of point-of-use and point-of-entry devices now authorized by the 1996 SDWA Amendments, technologies that are substantially less expensive than centralized treatment for many small systems.

EPA's cost estimates do not account for expected reductions in treatment costs as more treatment technology is installed.

4. The States and Federal Government Should Assist Small Systems That Cannot Afford Arsenic Treatment.

Even with these reasons to believe EPA is overestimating costs, it is clear that at least some small systems will have to pay relatively high costs per household to have arsenic-safe water. For these smaller systems, Federal and state assistance to improve treatment is available, and arsenic contamination should be a high priority for these drinking water funds. Additional Federal and state funding through State Revolving Funds (SRF), USDA's Rural Utility Service, and other programs may also

be needed. The SRF established by the Safe Drinking Water Act Amendments of 1996, which has not been fully funded since the act's passage, should be funded at least to the full authorized amount ($1 billion per year) to help smaller systems with arsenic problems.

Therefore, even using EPA's high cost estimates,[4] a strict arsenic standard for tap water would be both sound public health policy and affordable for consumers. It is EPA's obligation to protect the American public from arsenic contaminated tap water, by issuing a strict MCL of 3 ppb arsenic.

CONCLUSIONS

Americans should be able to turn on their taps and be sure that their drinking water is safe. Arsenic is perhaps the worst example of EPA's failure to address a serious health risk from a chemical contaminant in drinking water. The Agency has had over a quarter century, since the Safe Drinking Water Act passed in 1974, to adopt a modern tap water standard for arsenic, but has failed to do so. The time has come for the Agency to act. Specifically, we recommend that:

EPA Must Immediately Propose and Finalize by January 1, 2001 a Health-Protective Standard for Arsenic in Tap Water. The National Academy of Sciences (NAS) has made it clear, and we agree, that EPA should expeditiously issue a stricter Maximum Contaminant Level standard for arsenic. Based on available scientific literature and NAS risk estimates, this standard should be set no higher than 3 ppb—the lowest level reliably quantifiable, according to EPA. Even an arsenic standard of 3 ppb could pose a fatal cancer risk several times higher than EPA has traditionally accepted in drinking water.

EPA Must Revise Downward its Reference Dose for Arsenic. EPA's current reference dose likely does not protect such vulnerable populations as infants and children. Furthermore, "safe" arsenic intakes in the RfD present unacceptably high cancer risks. To protect children, EPA should reduce this reference dose from 0.3 micrograms per kilogram per day (μg-kg/day) to at most 0.1 μg-kg/day. For concordance with cancer risk numbers, EPA should reevaluate the RfD in more depth as expeditiously as feasible.

EPA Should Assure that Improved Analytical Methods Are Widely Available to Lower Detection Limits for Arsenic. EPA must act to reduce the level at which arsenic can be reliably detected in drinking water, so that it can be reliably quantified by most labs at below 1 ppb, the level at which it may pose a health risk.

Water Systems Should be Honest With Consumers about Arsenic Levels and Risks. It is in public water systems' best long-term interest to tell their customers about arsenic levels in their tap water and the health implications of this contamination. Only when it is armed with such knowledge can the public be expected to support funding and efforts to remedy the problem.

Water Systems Should Seek Government and Citizen Help to Protect Source Water. Water systems should work with government officials and citizens to prevent their source water from being contaminated with arsenic.

Water Systems Should Treat to Remove Arsenic, and Government Funds Should be Increased to Help Smaller Systems Pay for Improvements. Readily available treatment technology can remove arsenic from tap water, at a cost that is reasonable ($5 to $14 per month per household) for the vast majority of people (87 percent) served by systems with arsenic problems. Very small systems serving a small fraction of the population drinking arsenic-contaminated water, however, will often be more expensive to clean up per household. Assistance to such systems should be a high priority for drinking water funds such as the SRF and USDA's Rural Utility Service programs. The SRF should be funded at at least $1 billion per year to help systems with arsenic problems.

EPA Should Improve its Arsenic, Geographic Information, and Drinking Water Data bases. EPA should upgrade its Safe Drinking Water Information System to include and make publicly accessible all of the arsenic and unregulated contaminant data, as required by the Safe Drinking Water Act. EPA also should require water systems to provide accurate lat-long data using GPS systems, which will have widespread use in GIS systems by Federal, state, and local officials, and the public, for source water protection, developing targeted and well-documented rules, and for other purposes.

[4] The Association of California Water Agencies and the American Water Works Association have charged the EPA has underestimated national arsenic treatment costs. However, EPA has responded in detail to these allegations and thoroughly rebutted these arguments.

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STATEMENT OF DAVID PARIS, WATER SUPPLY ADMINISTRATOR, MANCHESTER WATER TREATMENT PLANT, MANCHESTER, NH, ON BEHALF OF THE AMERICAN WATER WORKS ASSOCIATION

Introduction

Good morning Mr. Chairman. I am David Paris, Water Supply Administrator of the Manchester Water Treatment Plant, Manchester, New Hampshire. The Manchester Water Treatment Plant provides drinking water to 128,000 people in Manchester and the surrounding communities of Derry, Londonderry, Grassmere, Goffstown, Bedford and Auburn NH. I serve on the American Water Works Association (AWWA) Water Utility Council and am here today on behalf of AWWA. AWWA appreciates the opportunity to present its view on the implementation of the Safe Drinking Water Act Amendments of 1996.

Founded in 1881, AWWA is the world's largest and oldest scientific and educational association representing drinking water supply professionals. The association's 56,000-plus members are comprised of administrators, utility operators, professional engineers, contractors, manufacturers, scientists, professors and health professionals. The association's membership includes over 4,2000 utilities that provide over 80 percent of the nation's drinking water. AWWA and its members are dedicated to providing safe, reliable drinking water to the American people.

AWWA utility members are regulated under the Safe Drinking Water Act (SDWA) and other statutes. AWWA believes few environmental activities are more important

to the health of this country than assuring the protection of water supply sources, and the treatment, distribution and consumption of a safe and healthful adequate supply of drinking water. AWWA strongly believes that the successful implementation of the reforms of the SDWA Amendments of 1996 is essential to effective regulations that protect public health.

EPA Drinking Water Program

The Environmental Protection Agency (EPA) drinking water program took on greatly increased responsibilities in the 1996 SDWA amendments. These responsibilities included developing a new regulatory process requiring additional science and risk analysis for regulations, creating a contaminant occurrence data base and methodology to select contaminants for regulation, promulgating regulations for arsenic, radon and microbial and disinfectant/disinfection by-products (M/DBP), identifying new treatment technologies for small systems, administering the newly created drinking water state revolving fund, and developing regulations and guidelines for consumer confidence reports, operator certification programs, source water assessment and monitoring relief.

In satisfying these requirements, EPA has involved the public in the regulatory process to an extent not equaled by any other Federal agency and stands as a model for Federal rulemaking. EPA has involved private citizens, scientists, drinking water professionals, medical professionals, public health officials, economists, and environmental and consumer advocacy representatives, as well as other experts, to provide recommendations on how to carry out these new regulatory responsibilities. The EPA Office of Groundwater and Drinking Water is to be commended for taking this exemplary approach for public involvement that should result in better regulations that protect public health.

However, AWWA does have a major concern that EPA is not conducting essential research and developing new data to support drinking water regulations as expected in the 1996 SDWA Amendments. There is also a long-term concern that the authorizations for the new drinking water state revolving fund will not be adequate to address the needs identified to comply with SDWA regulations and upgrade drinking water infrastructure to ensure that high quality safe drinking water is provided to the American people. In this statement, AWWA will focus on the research and infrastructure funding needs as well as highlight AWWA's concerns with the arsenic, radon, radionuclides and M/DBP rulemaking. Although it is not an SDWA implementation issue, this statement also will address AWWA's concern about MTBE contamination of drinking water an issue that cuts across several statutes and EPA programs.

Drinking Water Research

The use of best-available, peer-reviewed good science as the foundation of the new drinking water standard-setting process under the SDWA amendments of 1996 will require extensive drinking water research—particularly health effects research. Unfortunately, there has been a cycle in which critical drinking water research lags behind the regulatory process. We must break that cycle. This can be done through improved funding and planning.

The nation needs an integrated, comprehensive drinking water research program. EPA must develop research schedules that meet regulatory needs along with a research tracking system so that the researchers and their EPA project officers can be held accountable and Congress must appropriate the funds required to carry out timely research. Only with timely appropriations and Congressional oversight can EPA, the drinking water community and consumers work together to ensure that sound science yields the most appropriate regulations and practices possible for the provision of safe drinking water for all the people in America.

Drinking Water Research Funding

Funding for drinking water research is a critical issue. The 1996 SDWA Amendments require EPA to develop comprehensive research plans for Microbial/Disinfection By-Products (M/DBP) and arsenic as well as other contaminants. An estimated total of over $100 million is needed for the combined arsenic and M/DBP regulatory research plans alone and this figure does not include other needed drinking water research on radon, a whole array of other radionuclides, groundwater contamination, children's health issues, endocrine disruptors, and other new contaminants on EPA's Contaminant Candidates List (CCL) that will require additional occurrence, treatment, and health effects research.

In the past year, AWWA and other stakeholders worked closely with EPA to resolve any future research resource gaps beginning with the fiscal year 2001 budget process. As a result of this cooperative approach to determining drinking water research needs, AWWA believes that the $48,872,500 requested in the President's

Budget for fiscal year 2001 is the absolute minimum necessary for fiscal year 2001, (and may not be enough) to assure that the essential research will be conducted on which to base drinking water regulations as required by the Safe Drinking Water Act (SDWA).

Over the past several years, public water suppliers have worked together with EPA and the Congress to secure increased research funding for the nation's drinking water program. We believe that, through this cooperative effort, essential increases in research dollars have been obtained for drinking water over the past few years after several years of steady decline.

In August 2001, EPA will select at least five contaminants from the Contaminant Candidate List (CCL) and determine whether or not to regulate them. This process will be repeated every 5 years. To determine whether to regulate a contaminant and establish a maximum contaminate level (MCL) or another regulatory approach, EPA will need good health effects research. Recognizing the serious burden this regulatory mandate presents, the drinking water community has offered its time, resources and expertise to work with EPA to develop a research plan for the contaminants on the CCL.

Drinking Water Research Planning

Developing a comprehensive drinking water research plan is necessary. EPA finalized the first Contaminant Candidate List (CCL) in February, 1998, which contained 61 contaminants that could be considered for future regulations. Of these 61 contaminants, only 12 currently have adequate information to move forward in the standard-setting process. The balance of the contaminants (including such important contaminants as MTBE, triazines, and acetochlor) need additional health effects, treatment, analytical methods, and occurrence research. A comprehensive research plan for this large number of contaminants needs to be completed, peer-reviewed, adequately resourced, and then implemented. EPA has been working over the past couple of years to develop such a comprehensive plan. The total funding need for a comprehensive research plan is unknown at this time, but the amount is expected to be substantial.

The vast majority of EPA's ongoing drinking water research is related to the M/DBP Cluster and arsenic. EPA has established innovative research partnerships with the AWWA Research Foundation (AWWARF) and the Association of California Water Agencies (ACWA) that has partially filled the research gap on these two issues. However, very little research is ongoing on other priority regulations such as radon, other radionuclides, the filter backwash rule, etc. While the research on the M/DBP Cluster and arsenic is important, these other priority contaminants and future contaminants for regulatory action cannot be neglected.

Long-range planning is needed to break the cycle of drinking water research lagging behind the regulatory needs. Assume that EPA will finish their overall contaminant research plan and have it peer reviewed by mid-2001. Then, EPA issues a research request, receives proposals, selects specific proposals, and contracts for the research. This process will take at least 6 months, so the research would not start until early 2002. Most research takes a minimum of 2 to 3 years to complete, with an added year for complete peer review, so the results would be available in 2006. The timing of this future research (which is based on a lot of optimistic assumptions)) bumps up against the statutory deadline for the second round of regulatory determinations in 2001. Since EPA has put a strong emphasis on meeting statutory deadlines, the result may be the promulgation of regulations without the good science that was envisioned in the 1996 SDWA Amendments. Long-range research planning efforts must be accelerated by EPA to breaking cycle of research availability only after regulatory decisions have been made.

ADDITIONAL DRINKING WATER RESEARCH IMPROVEMENTS

Recently the National Research Council (NRC), an arm of the National Academy Sciences (NAS) recommended that the position of deputy administrator for science and technology be created within EPA to oversee research throughout the Agency. AWWA has long contended that coordination of research in EPA needed to be improved. While EPA recently has begun to improve the quantity and quality of its science, a higher level of coordination is needed to ensure its effectiveness. The current position of Assistant Administrator for Research and Development does not have Agency wide responsibility or authority to oversee all of the science needed for policymaking. AWWA recommends that the Congress give serious consideration to the NRC proposal.

AWWA also suggests that EPA work closely with other Federal agencies such as the Centers for Disease Control and Prevention (CDC), the National Institutes of Health, the US Department of Agriculture, the US Army Corps of Engineers, etc.,

to leverage resources so that the research efforts can be maximized. The Congress and EPA need to continue to look for innovative research partnerships to get the job done, similar to what was developed for the M/DBP cluster and arsenic. Congress should also consider funding these partnerships for drinking water research independent of other environmental research to give the drinking water program, a public health program that affects every person in the United States, the priority it deserves.

DRINKING WATER REGULATIONS

While timely, best available, peer-reviewed good science is essential to intelligent regulatory decisionmaking, how that science and other data are actually used in decisionmaking is critical. AWWA is concerned about the scientific basis for some regulatory decisions. Incomplete or old science, although it is the "best-available" may still be inadequate science. Making regulatory decisions on inadequate science is not in accordance with the intent of the 1996 SDWA Amendments. The use of cost data and benefit assumptions appears to be arbitrary and capricious in some cases. Most disturbing of all is a perception that researchers may have been pressured into conclusions. The following drinking water regulations, either proposed or under development, illustrate AWWA's concerns.

Arsenic

The 1996 SDWA Amendments required EPA to propose a revised arsenic regulation by January, 2000, and promulgate a final regulation by January, 2001. The National Academy of Sciences' (NAS) conducted a comprehensive review of the arsenic risk assessment that was released last year. The 1996 SDWA Amendments also required EPA to develop a comprehensive research plan on low-levels or naturally occurring arsenic. The objective of the plan was to develop an extensive arsenic research program. The plan has been completed but has not yet been fully executed and the vast majority of the research results will not be ready in time to impact the regulation. The key issue for the arsenic regulation is that the health effects data and the results of the health effects research needed to be available by mid-1999 to meet the deadlines in the SDWA. Only five major arsenic health effects research projects were started by that time. Since EPA had not made a significant start on the bulk of the necessary health effects (which will take several years to complete), it is likely that very little of the necessary research will be completed in time to be used in developing a revised arsenic regulation.

The lack of realistic prioritization of the arsenic research, from the AWWA viewpoint, has minimized the potential for the ongoing research to substantially reduce the uncertainty in the arsenic risk assessment. The ongoing research projects may (or may not) be the specific projects that could have the most impact in reducing that uncertainty, but nobody knows for sure at this point. AWWA is concerned that some of the ongoing research may simply lead to the need for more research rather than give answers that are meaningful for the regulatory process.

AWWA agrees with the NAS that the current arsenic regulation needs to be revised in accordance with the provisions of the 1996 SDWA Amendments. One of the conclusions of the NAS study is that "Additional epidemiological evaluations are needed to characterize the dose-response relationship for arsenic-associated cancer and non-cancer end points, especially at low doses. Such studies are of critical importance for improving the scientific validity of risk assessment." Some of the ongoing research being conducted by EPA (in accordance with the Arsenic Research Plan) and work being conducted by the arsenic research partnership between the AWWA Research Foundation (AWWARF), the Association of California Water Agencies (ACWA), and EPA includes epidemiological studies that will address some of the NAS questions. The research will provide some of the answers for the risk assessment; however, none of these epidemiological studies will be completed until AFTER the arsenic regulation is finalized.

AWWA has grave concerns regarding the scientific basis upon which the forthcoming arsenic regulation will be promulgated. Recently, Inside EPA published a memo from Mr. Andrew Hanson, Office of Congressional Intergovernmental Affairs (OCIR) to Irene Suzukida-Dooley, Office of Ground Water and Drinking Water (OGWDW). In this memo, OCIR indicates that it will not support a proposal of 5 parts per billion (ppb) of arsenic in drinking water. The memo goes on to say that National Research Council (NRC) panelists who participated in the "Arsenic in Drinking Water Study" released this spring "cited numerous specific concerns about methodologies employed in the risk analysis". Through the Freedom of Information Act process, AWWA has obtained notes regarding the discussions with the NRC panelists.

Frankly, the comments of the panelists are quite disturbing. Of the four panelists interviewed, there are three messages that resound. First, these comments indicate that the panel was pressured into creating conclusions that were not "weak", "wimpy", or "less than conclusive". While AWWA highly respects and supports the work of the NRC, this indication of collusion could draw into question (or at least the perception of a question) the very scientific basis upon which EPA is basing this regulation. Although the Executive Summary of NRC report states that "data that can help to determine the shape of the dose-response curve in the range of extrapolation are inconclusive and do not meet EPA's 1996 stated criteria for departure form the default assumption of linearity", the second connotation drawn from the panelist's quotes is that there appeared to be agreement among the panel that the dose-response curve is clearly non-linear. The report goes on to state "Of the several modes of action that are considered most plausible, a sublinear dose-response curve in the low-dose range is predicted, although linearity can not be ruled out." Here the panel considers a sublinear dose-response curve "most plausible". It is AWWA's opinion that this whole issue of dose-response extrapolation adds enormous uncertainty to the standard setting process and makes high cost standards for arsenic in the single digits very unrealistic. What specific research does EPA have planned to address the issue of non-linearity in the dose-response curve? Will this data be available for the 6-year review cycle? The quotes from the panelists further indicate a third most disturbing point; a proposal below 10 ppb of arsenic in drinking water is "not supportable" and "not realistic". This final revelation from some of the panelists begs the question "If the NRC panelists do not feel that an MCL below 10 ppb is supportable, on what basis will EPA base a proposed MCL of 5ppb?"

Earlier this month, in a preliminary draft report, the Drinking Water Committee of EPA's Science Advisory Board (SAB) said that the available scientific evidence on arsenic's health effects could justify a standard of 10 ppb or even 20 ppb under the 1996 SDWA Amendments. This again calls into question the basis for EPA's proposed MCL of 5 ppb. The SAB Drinking Water Committee noted that there are uncertainties associated with the use of old Taiwanese data to estimate the risks from arsenic and concluded that EPA may have misinterpreted the data and overestimated lung cancer risks. According to the draft SAB report, results from the Taiwanese and other studies should not be rigidly extrapolated to the U.S. population. Poor nutritional status in Taiwan, Chile, and India may have influenced the health effects. A 1999 study conducted in Utah found no evidence of either bladder or lung cancer at arsenic levels of 200 ppb, the report said. In addition, the report noted that studies conducted in animals have shown that deficiencies in selenium substantially increases the toxicity of arsenic. Urinary concentrations of selenium in the area of Taiwan were found to be between three and four micrograms per liter, as opposed to 60 micrograms per liter in the United States. The report also noted that other nutritional factors were not taken into account by EPA, nor were rates of infectious hepatitis, which have been associated with cancer.

Clearly the scientific basis upon which to base such a number is questionable at best. In light of the SAB draft report and the quotes from the NRC panelists, the scientific data is not necessarily as strong as previously thought. EPA recognized in the recent abstract of the Utah cohort mortality study that the relationship between health effects and exposure to drinking water arsenic is not well established in the U.S. populations. EPA concluded that further evaluation of potential health effects in low-exposure U.S. populations is warranted. By its own admission, the Agency does not clearly understand the health effects issues as they relate to U.S. populations. Since the science on which to base an MCL of 5 ppb is questionable, how can EPA justify the high cost of the MCL?

EPA invoked the cost benefit provisions of the SDWA to support the choice of an MCL of 5 ppb for arsenic. However, EPA did not employ a marginal analysis to justify this decision. EPA has not therefore performed a proper cost benefit analysis and has not complied with the SDWA. SDWA compliance inherently exhibits diminishing returns. As lower and lower treatment targets are considered, costs increase at an increasing rate while the increment of exposure reduction achieved diminishes with each additional increment of stringency. This relationship implies that there is a balance point where the marginal benefit obtained equals the marginal cost and net benefits are maximized. This is the right way to use cost benefit analysis to justify a decision. However, this is not what EPA did to justify the proposed arsenic MCL.

EPA discussed an aggregate comparison of total costs and benefits to justify its choice of an MCL. In this procedure, the more favorable relationship between benefits and costs from the first increments of additional stringency (i.e., moving from 50 ppb to 20 ppb) are averaged in with the less favorable data relating to the last increments (i.e., moving from 10 ppb to 5 ppb). EPA based its decision on a compari-

son of these aggregates (and other risk criteria of its own making). The SDWA specifically states that the incremental costs and benefits associated with each alternative MCL must be considered. EPA presents such values but provides no discussion of them and does not incorporate them into its justification, relying instead on aggregate cost benefit comparison and analysis of uncertainties on the benefits side. The aggregate comparison performed by EPA embodies a decision rule that is structured such that it will always over-shoot the economically optimal level of stringency that would be prescribed by marginal analysis. EPA's decision rule is arbitrary and has no standing in economic analysis. It is not a cost benefit analysis and does not meet the clear or implied intent of the SDWA.

AWWA also has concerns about the national cost estimate used by EPA. The AWWA Research Foundation did an independent analysis of the costs of implementing the arsenic drinking water regulation at varying MCLs. The differences in estimates were significant, using the same methodology. The differences are:

	5 ppb	10 ppb	20 ppb
EPA Estimate	$378 million/year	$164 million/year	$62 million/year
AWWA Estimate	$1.46 billion/year	$605 million/year	$55 million/year

These widely differing cost estimates need to be reconciled before the final rule is promulgated.

The arsenic drinking water regulation was proposed last week on June 22nd, and comments are due to EPA on September 20th. However, because the rule has been delayed and EPA has a statutory deadline to promulgate the final regulation in January 2001, AWWA is deeply concerned that EPA will not have sufficient time to evaluate comments and that an MCL based on inadequate science and cost and benefit data may be promulgated. AWWA strongly urges EPA to carefully reconsider the body of scientific evidence available and recommends that the proposed arsenic standard be no less than 10 ppb which is the World Health Organization (WHO) standard.

MICROBIAL, DISINFECTANT & DISINFECTION BY-PRODUCTS CLUSTER

This "cluster" of regulations is the most significant and potentially the most costly of all drinking water regulations required in the 1996 SDWA amendments. It includes Disinfectant/Disinfection By-Product Rules, Enhanced Surface Water Treatment Rules, a Filter Backwash Rule and the Groundwater Rule. The regulations in this "cluster" require substantial research, most of which will not be completed by the time indicated in the SDWA.

Research on microbial contaminants and disinfectants and disinfection by-products is a critical need. Each day there are roughly 50,000 deaths in the world attributed to microbial contamination of drinking water. Much of this threat has essentially been eliminated in the United States through disinfection of drinking water. However, it is now known that disinfection of drinking water can produce chemical by-products, some of which are suspected human carcinogens or may cause other toxic effects. Controlling risks from these by-products must be carefully balanced against microbial risks to ensure that when reducing disinfection levels or changing treatment to lower by-product risk, significant microbial risks are not created.

Research on disinfectants and disinfection by-products, as endorsed by the National Academy of Sciences and EPA's Science Advisory Board, is essential. The cost to the Nation of microbial and disinfection by-products regulations under the SDWA will certainly be in the billions and could be as high as $60 billion or more depending on the final rule. An appropriate investment in health effects research will ensure that costs of regulation will be commensurate with the health benefit and not driven to extremes because of the lack of data.

Cryptosporidium is a microbial pathogen of major concern to drinking water supplies. The Centers for Disease Control, in correspondence with EPA, has pointed out that extensive research on the health implications of this pathogen and dramatic improvements in analytical methods for its detection are necessary before it is possible to evaluate the public health implications of its occurrence at low levels and determine the appropriate regulatory response. Adequate funding for research on Cryptosporidium, as well as other emerging pathogens, is essential to protect the health of millions of Americans.

The final Filter Backwash Rule, which will prevent unsafe concentrations of contaminants in the drinking water treatment process resulting from cleaning water

filter beds, is scheduled to be promulgated by August 2000. However, this rule has become a major concern since there is not much data on which to base a regulation and the potential for significant compliance costs.

For the Filter Backwash Rule, EPA assembled a collection of studies that appears to reflect 1,907 individual surface water samples. As presented, this assemblage cannot be directly related to drinking water sources. Few of these individual studies obtained positive samples and large data sets appear to be prone to lower observed occurrence than smaller data sets. Twenty-six of the studies either reported ranges of observation including zero or neglected to provide a range of observations.

Most disturbing is that the assembled studies did not include the most recent and comprehensive survey of drinking water treatment plant influent water concentrations available from the Information Collection Rule (ICR) data collected over 18 months in 1997 and 1998. During that data collection process, public water systems serving greater than 100,000 persons collected monthly protozoan samples using an existing EPA approved method. The resulting data has been available to EPA since December 1999. The raw ICR data suggests that less than 7 percent of large public water systems use source waters that contain Cryptosporidium oocysts. Preliminary estimates from statistical models of this data indicate that the median oocyst concentration to be approximately 0.03 oocysts per liter rather than the values of 4.70 and 10.64 oocysts per liter cited by EPA in their proposal for the Filter Backwash Rule. After all the cost and time involved to collect this information under the requirements of the ICR, why is EPA discounting this most recent information?

EPA correctly points out the difficulties in performing Cryptosporidium analysis for filter backwash samples. Where recovery data are provided in the literature, the rates have been typically low. It is important to point out that the volumes analyzed have been very small due to high turbidity in the samples. It is not uncommon for spent filter backwash samples to have equivalent volumes analyzed of much less than one liter. Therefore, the focus by EPA on high outlier levels of oocysts reported is unjustified. EPA is aware of the uncertainties of individual protozoan measurements and citing these outlier values violates the sound statistics that have been developed by EPA and others over the past several years to better understand protozoan data. The 1996 SDWA Amendments call for the use of "best available" science. EPA does not appear to be following this provision of the law in the Filter Backwash Rule.

RADON

EPA is under a statutory deadline to finalize the radon drinking water regulation by August 6, 2000. AWWA has significant concerns about whether regulating radon in drinking water is cost effective particularly the primary Maximum Contaminant Level (MCL) of 300 picacuries per liter. For the radon drinking water regulation to provide effective public health benefits, it is essential that states adopt a multimedia mitigation (MMM) program to abate radon in indoor air which is the primary threat to public health.

However, AWWA believes that there are some flaws in establishing the primary MCL. AWWA has repeatedly indicated to EPA our numerous concerns regarding the Health Risk Reduction and Cost Analysis (HRRCA) for radon. These concerns cover a wide range of issues such as life years saved estimates, latency times, discounting rates, cumulative costs of regulation, affordability, entry points to the distribution system, and treatment costs. Many of these factors can have a dramatic impact on the benefit-cost ratio. Depending on the assumptions, the cost-benefit ratio can vary from a high of 0.95, indicating a reasonable comparison of benefits to costs, to a low of 0.04, where the costs are clearly extreme compared to the benefits received.

The first and foremost issue is a policy concern in determination of when "benefits justify costs." Some Federal Agencies use a cost benefit ratio to justify an expenditure. The US Army Corps of Engineers, for example, uses a ratio of 1:2. Studies on the lead service line replacement portion of the Lead and Copper Rule show a dismal cost benefit ratio of 100:1. Prudent public policy dictates that federally mandated expenditures at the state and local level should have a ratio where benefits exceed costs.

Costs from the radon HRRCA show that it will have a devastating impact on small water systems, which are the majority of systems expected to take action as a result of the regulation. Simply looking at national costs, in aggregate, allows economies of scale for larger systems to mask the regulations affect on smaller systems. When one looks at the very very small systems category cost benefit ratios range from a disappointing 20:1 to 50:1. To make matters worse, benefits accrue locally in tiny increments. Again in the very very small system size, costs are estimated at $10,000 per year, with a corresponding 10,000–14,000 years between sta-

tistical cancer cases avoided. Clearly the primary MCL should take into account the regulatory impacts on small systems, which it does not.

The accounting of benefits in the HRRCA is inconsistent with common risk assessment and risk management principles. For example, risk assessment and management in the EPA's drinking water program typically assumes a 70-year exposure period. This implies that 1/70 of the benefits will appear in the first year after implementation, 2/70 in the second year and so on. The HRRCA grossly over estimates benefits by assuming that the full benefit of the regulation is realized in the first year, and succeeding years. The HRRCA should be revised to reflect a phase in, or latency period, for benefits.

Also of concern is the failure of the HRRCA to account properly for time in the benefits estimate. The HRRCA discounts costs of a 7 percent annual rate, but does not discount benefits at all. This inflates the benefits estimate. Costs and benefits should be discounted at the same rate and the HRRCA should reflect this. AWWA estimates that the failure to phase in benefits and the failure to consider the timing of benefits shifts the cost benefit ratio from approximately 1:1 an to unfavorable 5:1, or even 9:1.

With the cost benefit ratios for the primary MCL shifting negatively, the multimedia mitigation program that Congress wrote into the 1996 SDWA Amendments becomes critical to providing a public health benefit. The EPA's 1994 Report to Congress placed the dollar cost of saving a life through a radon indoor air program at $700,000. This is almost ten times lower than the cost to save a statistical life through drinking water efforts on radon. AWWA supports the concept of the MMM program; however, AWWA has a significant concern that the MMM program in the statute and in the proposed radon regulation will not work as intended. There is little incentive in the SDWA for a State to adopt a MMM program simply to enforce the alternative MCL for radon rather than the primary MCL. In States that do not adopt a MMM program for radon, the costs to drinking water consumers will be exorbitant with very little public health benefit.

AWWA urges Congress to provide incentives in the Indoor Air Radon Abatement Act for States to adopt a MMM program that would meet the requirements for a State to enforce the alternate MCL for radon. This would put the MMM program and requirement in the air program where it more rightfully belongs and provide resources for the States to successfully implement the MMM program. If all States have a MMM program, the alternate MCL will provide more public health benefit and at a more reasonable cost than the primary MCL. AWWA also believes that there should be a single standard for radon in drinking water based on the MMM since the major health threat is from air. AWWA recommends that the Congress address this flaw in the SDWA as soon as possible before the American people are faced with the exorbitant cost that would result from enforcing the primary MCL in the proposed regulation.

RADIONUCLIDES

AWWA, through its volunteers and contractors, has invested significant time and resources on the benefit-cost analysis (BCA) in the Notice of Data Availability (NODA) that was published on April 21st for the Radionulclides Rule. The BCA components, and the process to fit them together, used in the NODA are critical, as this is one of the first BCA conducted under the new provisions of the 1996 Safe Drinking Water Act Amendments.

At this time, AWWA does not believe that the BCA presented in the radionuclides NODA meets the requirements of Section 1412(b)(4)(C) of the SDWA. EPA simply put the costs in one column, and the benefits in another column to meet this requirement. AWWA believes that a much more robust BCA must be included in the final regulation, and the lack of a more robust BCA in the final regulation would be considered arbitrary and capricious and contrary to the clear SDWA language.

Considerable mention is made in the NODA of the EPA "policy" that MCLs must be established such that individual lifetime cancer risks do not exceed a threshold of 10–4. This notion that a maximum "allowable risk" (of 10–4) is the ultimate binding constraint on EPA rulemaking regardless of what the costs of the rule are, or how the benefits compare to those costs is quite troubling.

Clearly, there is no statutory mandate or authority to have a self-defined and self-imposed Agency policy on an "acceptable risk" floor. The 1996 SDWA Amendments do not impose or envision such a constraint. Consider a case in which the cost of a potential MCL was not justified by its benefits, but where the estimated cancer risk at a less stringent alternative exceeded the 10–4 level. The NODA language appears to clearly state that the Administrator would be obliged to set the MCL at the unjustified level (to maintain a 10–4 risk ceiling) rather than follow the letter

and intent of the statute and set a less stringent MCL that was indeed justified on a reasonable benefit-cost basis. EPA should explicitly clarify whether this indeed is its intent and interpretation of the statute. If this is the case, then the "acceptable risk" floor of 10–4 is more of a rule than a policy, and EPA should publish an "acceptable risk" proposal that allows for public comment on such a critical issue.

DRINKING WATER INFRASTRUCTURE

According to the EPA Drinking Water Infrastructure Needs Survey released on January 31, 1997, $12.1 billion is needed in the immediate future to protect drinking water supplies. Of this amount, $10.2 billion, or 84 percent, is needed to protect water from microbial contaminants which can produce immediate illness or death. According to the needs survey, between 1995 and 2015, a total of $138.4 billion will be needed to upgrade the infrastructure of the nation's water utilities to meet requirements of the SDWA. It is also important to note that this figure does not include other drinking water infrastructure needs, such as replacing aging transmission and distribution facilities, which are not eligible for funding from the Drinking Water State Revolving Fund (DWSRF).

In an independent analysis, AWWA estimates that the total drinking water needs, taking full account of infrastructure replacement needs, is on the order of $385 billion over a 20 year period. The Water Infrastructure Network (WIN), of which AWWA is a member, recently released a report that estimates that the total drinking water and waste water infrastructure needs over a 20 year period approaches one trillion dollars. AWWA will soon release a report that will outline the size and shape of the investment need for drinking water in the United States. The findings illustrate that the size of the need will vary from place to place, reflecting the age, character and history of the community. The AWWA report raises the questions that need to be addressed to determine how best to meet the Nation's drinking water infrastructure needs.

The report concludes that, in the aggregate, after accounting for the potential of best practices in asset management, research and new technologies, efforts to increase ratepayer awareness and support, and possible alternative compliance scenarios, in some utilities there still remains a "gap" between what is needed for infrastructure re-investment and what is practical to fund through water rates. This gap can be expected to grow over the next few decades as a reflection an infrastructure building boom years ago that will begin to reach the end of its useful life.

AWWA remains committed to the principle of full cost recovery through water rates as the essential under-pinning of local sustainability of water infrastructure. Longer term, the objective should be to flatten the replacement function and restore utilities to full cost recovery and financial sustainability.

AWWA does not expect that Federal funds will be available for 100 percent of the infrastructure needs of the nation's water utilities. The DWSRF is a loan program with a state match. Ultimately, the rate-paying public will have to pay for the nation's drinking water infrastructure, regardless of whether financing comes from the DWSRF or other sources. However, AWWA does believe that DWSRF funding is a major issue for congressional oversight to ensure that Federal funding is adequately available to meet the intended purposes of the SDWA. Over the next 20 years, it is clear that SDWA compliance requirements and infrastructure needs will compete for limited capital resources. Infrastructure needs and SDWA compliance can no longer be approached as separate issues. Oversight should take place in the context of the total compliance and infrastructure need and how the needs should be apportioned among the various financing mechanisms and sources.

There are a number of enhancements to the DWSRF that should be considered to increase its effectiveness, such as:

- increasing the authorized DWSRF funding levels to fund SDWA compliance projects and other needs.
- expanding the DWSRF to encompass system rehabilitation and replacement in addition to SDWA compliance as eleigible expenditures, allowing communities to take a more comprhensive approach to providing safe drinking water. As drinking water regulations become more stringent, upgrading the distribution system, like protecting drinking water sources, becomes a larger factor in maintaining the regulated safety level until the water reaches the consumer.
- Examining strategies for streamlining current operations of DWSRFs and strategies to encourage more innovative use of DWSRFs at the state level.

AWWA will provide a copy of the forthcoming report to members of the committee. We look forward to working with you to help resolve the Nation's growing drinking water infrastructure needs.

DRINKING WATER STANDARDS LITIGATION

Within the last several years, lawsuits have been initiated against public water systems for allegedly delivering contaminated drinking water despite the fact that the public water systems were in compliance with Federal and state drinking water regulations. At this time, these cases are concentrated in California and have been subject to a unique California law. However, these type of cases could be initiated nationwide and undermine the SDWA drinking water regulatory program.

Public water systems are regulated under the SDWA. The regulations have been developed over many years based on the health effects of contaminants, measurement capabilities and technical feasibility. The 1996 SDWA Amendments require the use of cost and benefits in setting drinking water standards. The regulatory requirements were the product of extensive congressional debate concerning how best to develop drinking water standards to protect public health. Processes have been developed both at the national and state level to develop regulations based on best available science, costs and benefits.

This type of litigation could result in judges and juries setting drinking water standards that would vary across the nation. Standards could be far different from those set by Federal and state agencies under the SDWA regulatory process. National uniformity of standards and uniformity within a state will be eroded. Public water systems facing uncertainty about which standards to meet will be pressured to follow the most stringent standard set by any judge or jury in the country to avoid liability. This will significantly increase the cost of water to consumers with very little, if any, benefit.

To protect the integrity of the SDWA regulatory program and prevent exorbitant drinking water costs to consumers, the SDWA should be amended to make compliance with Federal and state drinking water standards a defense in lawsuits involving contaminants covered by such standards. AWWA urges this committee to pass such legislation and will work with the committee and others on this issue.

METHYL TERTIARY BUTYL ETHER (MTBE)

Although it is not the subject of this hearing, we believe that we would be remiss to not mention methyl tertiary butyl ether (MTBE) contamination of drinking water. MTBE contamination is an issue that cuts across the Clean Air Act, the Resource Conservation and Recovery Act (RCRA) and the Safe Drinking Water Act. MTBE contamination clearly illustrates the pitfalls of regulating within a statutory "stove pipe" and why coordination across programs is necessary within EPA.

The Clean Air Act of 1990 required that areas of the country with certain air quality problems use reformulated gasoline (RFG) with an increased oxygen content. MTBE is the oxygen additive most commonly used by the petroleum industry to satisfy the RFG mandate. Since MTBE is very soluble in water and does not "cling" to soil well, it has a tendency to migrate much more quickly into water than other components of gasoline. The use of MTBE has created a significant and unacceptable risk to drinking water and groundwater resources. At levels as low as 20 parts per billion, MTBE makes drinking water unfit for human consumption because of taste and odor. It should also be noted that MTBE has been detected in the taste and odor of drinking water at levels as low as 2 parts per billion.

In Santa Monica, California, seven wells supplying 50 percent of the water for the city were shut down because of MTBE concentrations as high as 600 parts per billion. It is estimated that it will cost the city $150,000,000 to develop new water sources. This does not include the cost of remediation and treatment of the contaminated wells. Cases of persistent MTBE plumes extending for kilometer-scale distances in the subsurface have been documented in Port Hueneme, California; Spring Creek, Wisconsin; and East Patchoque, New York. Recent testing conducted by the US Geological Survey (USGS) shows MTBE has been found in approximately 20 percent of the groundwater in RFG areas. As many as 9,000 community water wells in 31 states may be affected by contamination from MTBE. The data was from one-third of the wells in those states and is generally representative of the entire nation. Source water is being impacted from a variety of sources including pipeline leaks, spills, leaking underground storage tanks, and recreational boating on source waters.

For example, at my own utility in Manchester, we are finding low levels of MTBE in Lake Massabesic. While the levels are relatively low as shown below, the increases in the summer due to boating are clear. Additionally, Lake Massabesic is a well-protected watershed, with Manchester owning about 95 percent of the shoreline. Recreational use is limited, as there is not overnight docking allowed, and there are only 3 boat ramps with about 100 parking spaces total. Although these levels are relatively low, as previously mentioned in this statement, consumers with

acute taste and odor sense may detect an objectionable taste and odor at the single digit level.

According to the report of the EPA Blue Ribbon Panel on Oxygenates in Gasoline, a major source of groundwater MTBE contamination appears to be releases from underground gasoline storage tanks. The EPA Blue Ribbon Panel on Oxygenates in Gasoline recommended enhanced funding from the Leaking Underground Storage Tank (LUST) Trust Fund to ensure that treatment of MTBE contaminated drinking water supplies can be funded. The LUST funds could only be used for contamination resulting from leaking underground storage tanks. Since leaking underground storage tanks appear to be the major source of MTBE contamination in ground water, the LUST Trust fund is an existing option to consider as a source of potential funding assistance for some cases of MTBE contamination of drinking water supplies in circumstances that meet the criteria of the law. As part of MTBE legislation, AWWA recommends that Congress amend RCRA to clarify the use of the LUST Trust Fund to provide alternative drinking water supplies or treatment for drinking water sources contaminated by MTBE from leaking underground storage tanks. AWWA is very pleased that Senator Smith has addressed this issue in draft legislation circulated on June 13, 2000. We thank Senator Smith and other Senators and staff for their assistance on this issue.

In testimony before the House VA, HUD, and Independent Agencies Appropriations Subcommittee and in a similar statement submitted to the Senate VA. HUD, and Independent Agencies Appropriations Subcommittee, AWWA recommended that Congress appropriate at least $100,000,000 for LUST to accelerate the clean up of LUST sites with priority for MTBE contaminated sites to prevent contamination of water supplies. There is a backlog of about 169,000 LUST site clean ups. EPA and the States have put increased emphasis on monitoring for MTBE as part of the Underground Storage Tank (UST) program so the number of MTBE contaminated sites may increase. Eliminating leaking tanks is an immediate remedy to protect drinking water supplies from further contamination until MTBE is phased out or eliminated.

Congress appropriated $70,000,000 for the LUST program in fiscal year 2000. The fiscal year 2001 President's budget requests $72,100,000 for the LUST program. AWWA strongly believes that the requested increase is not sufficient to accelerate cleanups of LUST sites that are difficult to remediate because they are contaminated by MTBE. EPA's goal for fiscal year 2001 to complete 21,000 LUST cleanups is commendable but not adequate to address the immediate needs of millions of Americans who no longer can drink the water from their wells. An aggressive, high priority effort is necessary to cleanup sources of MTBE from leaking underground storage tanks as quickly as possible. AWWA is pleased that the House Appropriations Committee increased the LUST appropriation to $79,000,000 for fiscal year 2001; however, we hope that $100,000,000 can be appropriated in the Senate.

Numerous bills have been introduced in Congress and draft legislation circulated that would amend the Clean Air Act to ban or phaseout MTBE as a fuel additive. EPA has recently called for Congress to amend the oxygenate requirement in the Clean Air Act to ban or phaseout the use of MTBE as a fuel additive. The EPA Blue Ribbon Panel on Oxygenates in Gasoline recommended action to amend the Clean Air Act to remove the oxygenates requirement and to clarify Federal and state authority to regulate and/or eliminate the use of gasoline additives that threaten drinking water.

AWWA has developed the following legislative principles that will address the contamination of drinking water sources by MTBE:

1. Amend the Clean Air Act to significantly reduce or eliminate the use of MTBE as a fuel additive.

2. Ensure that air quality gains are not diminished as MTBE use is reduced or eliminated.

3. Require adequate research to be conducted on any replacement fuel additive for MTBE to ensure that a replacement will not contaminant drinking water sources.

4. Provide Federal funding assistance to public water systems that have MTBE contaminated water sources for treatment or alternative water supplies.

AWWA recommends that Congress take swift action on legislation necessary to prevent further contamination of water supplies by MTBE or other fuel additives and provide assistance to public water systems that have MTBE contaminated water supplies. We look forward to working with Senator Smith and others to advance legislation addressing this critical issue.

CONCLUSION

We have covered a lot of issues in our statement today. Although much of the statement appears critical of EPA, we want to emphasize that EPA has made a good faith effort in other areas to implement the 1996 SDWA amendments. The Agency's outreach and involvement of stakeholders in the regulatory process is to be commended. However, our concerns raised in how EPA uses science and cost benefit analysis in regulations are valid and are issues that bear watching by the Congress.

We look forward to working with the committee on MTBE and drinking water infrastructure issues. We thank you for your consideration of our views.

This concludes the AWWA statement on the implementation of the 1996 Safe Drinking Water Act Amendments. I would be pleased to answer any questions or provide additional material for the committee.

RESPONSES OF DAVID PARIS TO ADDITIONAL QUESTIONS FROM SENATOR CRAPO

Question 1. What does AWWA estimate to be the shortfall in research funding for the regulatory activities of the EPA under the SDWA?

Response. It is difficult to estimate the total drinking water research needs as EPA has failed to develop an overall drinking water research plan for all contaminants that could potentially be regulated under the SDWA. While individual research plans have been developed for M/DBPs and arsenic, EPA has consistently failed to develop an overall drinking water research plan that clearly lists each research project with a budget and a timeframe (start date and completion date). While EPA has developed a process for conducting the Contaminant Candidate List (CCL) research, this process plan doesn't even estimate when this research might start or be completed. For example, twentytwo contaminants need a suitable analytical method to be developed and validated before the health effects and treatment research can begin. Six of these contaminants are microbials (primarily specific virus strains), and reliable microbial analytical methods are particularly difficult to develop. The analytical method for Cryptosporidium has been researched extensively for over a decade, and continues to be elusive. A determination cannot be made if a specific treatment technology is removing a specific contaminant if a suitable analytical method is not available to measure removal. The proper dosing for health effects research cannot be completed without a suitable analytical method. Therefore, it is impossible to estimate the total cost for the health effects, treatment, and analytical method research for the research priority contaminants on the Contaminant Candidate List (CCL).

Question 2. What level of research funding for each of the following proposed rules or priority contaminants does AWWA believe is the absolute minimum: 1) arsenic, 2) radon, 3) M/DBP cluster of rules, 4) other priority contaminants such as MTBE?

Response. As stated in the answer to the previous question, it is difficult to estimate the needs of individual drinking water contaminant research, as EPA has failed to develop an overall drinking water research plan for all contaminants that could potentially be regulated under the SDWA.

Question 3. Your testimony is fairly critical of the research being used to support the proposed arsenic rule. Do you believe that EPA should delay promulgation of the rule until additional epidemiologicaland other studies are complete?

Response. AWWA believes that the schedule for the promulgation of the arsenic regulation should allow for 1 year between the proposal and the final regulation so that EPA can assimilate the many public comments that they will receive on the proposal, and incorporate these comments into the final regulation. AWWA supports the conclusion of the National Research Council (NRC) report that the current arsenic regulation needs to be revised in a timely manner. Additional research, such as epidemiological studies, is always ongoing, and at some point, EPA needs to use the best available research and make its regulatory decision. However, AWWA believes that EPA needs to take another look at the Utah epidemiological study conducted by its own researchers. This study does not show the same bladder and lung cancers as the studies from Taiwan, Chile, and Argentina that are being used as the basis for the proposal. The Utah study is the only epidemiological study that has been conducted in the U.S., and, therefore, should be accorded more weight in EPA's risk assessment.

Question 4. If the scientific research does not support an arsenic MCL below 10 ppb and if the EPA is precluded from revising standards upward (even if future science supports such a decision) should the Agency establish a standard at 5 ppb?

Response. AWWA believes that EPA should establish an arsenic standard at no lower than 10 ppb at this time due to the uncertainties as to the arsenic health effects at very low levels. While the NRC report gave one example of an arsenic risk assessment, the NRC recommended that "the final calculated risk should be supported by a range of analyses over a fairly broad feasible range of assumption". In the proposal, EPA has not conducted this range of analyses and has simply relied on the one NRC example.

Question 5. Do you have any concerns with the EPA's estimate of costs and benefits for the proposed arsenic rule?

Response. AWWA has extensive concerns with both EPA's costs and benefits in the arsenic proposal. On the cost side, the feasibility of operating large scale arsenic removal facilities (ion exchange, activated alumina, or coagulation/microfiltration) has not been adequately addressed in the proposal. Although small scale arsenic removal facilities exist at this time, large scale arsenic removal facilities have not been tested in the field. AWWA also believes that EPA has overestimated the number of treatment facilities that will be able to dump their waste streams into a sanitary sewer system that feeds into a Publicly Owned Treatment Works (POTW).

Additionally, AWWA believes that EPA has painted a much more positive picture of the costs at a local level than is the reality. For example, Albuquerque, New Mexico, is one of the larger cities with potentially significant financial impacts from the arsenic proposal. Even with their larger rate base, Albuquerque has estimated that their rates will increase by 40 percent to comply with the proposed arsenic standard of 5 ppb.

EPA touts the Drinking Water State Revolving Loan Fund (DWSRF) as a funding solution, while the reality is that the DWSRF is dwarfed by the capital costs for compliance with the arsenic proposal. For example, the State of Utah has estimated the capital costs for all of systems to comply with the proposed arsenic standard of 5 ppb to be approximately $170 million. The past 4 years (FY97—FY00) of Utah's DWSRF allotment totals $34 million. The water utilities in Utah also need the DWSRF to comply with other drinking water regulations in addition to arsenic.

On the benefits side, AWWA believes that the arsenic proposal does not contain a true incremental Benefit-Cost Analysis (BCA) as required by Section 1412(b)(3)(C) of the 1996 SDWA Amendments. EPA has not published and sought comment on the incremental costs and benefits with each alternative MCL considered. In this proposal, EPA simply puts the costs in one column, and the benefits in another column to meet this requirement.

Other flaws are apparent in the benefits analysis. EPA incorrectly assumes that the benefits from the arsenic regulation begin to accrue immediately, as EPA does not take into account the cancer latency period. Regulations don't save lives, per se; rather, life expectancy is extended due to cancer avoided and these benefits start in the future. Therefore, EPA needs to take into account the cancer latency period and discount these future benefits back to present value to match up with the present value of the costs for the treatment technology. The Environmental Economic Advisory Committee (EEAC) of the EPA Science Advisory Board (SAB) supports the adjustments to benefits based on the timing of the risk. (An SAB Report on EPA's White Paper Valuing the Benefits of Fatal Cancer Risk Reductions, July 2000)

Additionally, unintended consequences will likely play a significant role in the implementation of the arsenic proposal. These items will likely lead to negative benefits, and will likely result from the implementation of the arsenic proposal. These items have not yet been identified by EPA and need to be incorporated into the final regulation as potentially negative benefits. The following list is not intended to be comprehensive, but rather a list of examples:

- Risk of acute exposure to arsenic and/or nitrate due to chromatographic peaking of anion exchange technology;
- Environmental risks associated with the generation, storage, and handling of arsenic treatment waste streams;
- Environmental risks associated with discharge to Publicly Owned Treatment Works (POTW) of liquid waste streams;
- Public health risks associated with the transport, storage, and use of chemicals and waste products at groundwater treatment facilities located in community neighborhoods;
- Solid waste disposal in non-hazardous landfills (arsenic and salt contamination plumes, availability of space, etc.);
- Viability of small communities to continue to provide public sources of drinking water;

- Opportunity cost, i.e., removing capital from the pool available to U.S. communities and misguided use of public health funds;
- Loss of water availability;
- Groundwater storage and recharge operation impacts;
- Indirect/Direct Additive Approvals; and
- Water quality degradation issues due to arsenic control.

Question 6. At what public water system size does AWWA believe costs outweigh the benefits of the proposed radon rule?

Response. AWWA believes that the benefit-cost analysis for the radon rule should not be based on system size, as even large groundwater systems are made up of several wells. It is the number of wells per system that have to be treated that increases costs.

Question 7. What level of involvement have AWWA and other stakeholders had in the final EPA proposals for radon, arsenic, and other contaminant standards?

Response. AWWA, along with many other stakeholders, have been extensively involved in the development of the proposals for radon, arsenic, and the filter backwash rule. EPA has done a respectable job in conducting stakeholder meetings for these proposals. However, we are concerned that EPA only conducted a single stakeholder meeting for the arsenic proposal in Reno, Nevada on August 8th, The location of this single stakeholder meeting precluded many impacted systems in the upper Midwest and the Northeast from participating in this stakeholder meeting.

Question 8. Given the conclusion of the WIN report on infrastructure needs, from where does AWWA expect the shortfall of resources needed to meet costs of current and upcoming regulations to come?

Response. The cost of replacing aging infrastructure and the cost of compliance are two issues that are raising affordability questions for some communities and can no longer be approached as separate issues.

The WIN report identifies the size of the infrastructure replacement need. The size of the gap between the cost of that need and what local communities can afford to pay to meet the need is an issue that is currently being examined by AWWA and other stakeholders. We know that the gap, if there is one, will vary from community to community. Some communities may be able to fund the need through existing and projected rate revenues, best practices for asset management, new technologies and other improved operations/management practices. Other communities may not be so fortunate for a variety of economic and social reasons.

The cost of compliance with future regulations compounds the affordability question. While many individual regulations may be affordable, the cumulative affect of several vary expensive regulations such as radon, arsenic, groundwater and the Microbial/Disinfectant Byproducts (M/DBP) cluster of regulations may raise significant affordability problems in smaller communities and in a few large urban water systems.

AWWA does not expect the Federal Government to fund 100 percent of the need or the gap. A large portion will come from local rate increases, best practice asset management, improved technology and improved operations. More efficient regulations may also contribute to reducing the gap.

AWWA is engaged in a process with other stakeholders to determine the size of the gap, the appropriate role of the various levels of government in funding the gap for communities that have reached the affordability ceiling and how best to fund the gap. Later in the year or early next year, AWWA and the other stakeholders may be in a better position to provide this information to the committee.

Question 9. Beyond financial assistance, what support can the EPA provide public water systems in addressing infrastructure resource gaps?

Response. EPA can help educate the American people concerning the need to invest in drinking water infrastructure to assure the highest quality safe drinking water. EPA should also examine ways to streamline the current operations of the drinking water state revolving fund (DWSRF) to make the program more efficient for states to administer and utilities to obtain loans. The cost of compliance, which is competing for infrastructure dollars at the local level, can be reduced by doing thorough research on regulations to ensure that the consumer is getting a benefit commensurate with the cost of the regulation as required in the Safe Drinking Water Act. The contaminant-by-contaminant regulatory approach needs to be revamped to get a more cost-effective means of providing safe drinking water. EPA needs to make broader use of risk analysis and regulate by classes of contaminants that can use the same treatment techniques and not have competing regulatory requirements.

Question 10. What is AWWA's view on the EPA's current approach to assessing the feasibility of drinking water standards and regulations?

Response. AWWA is concerned with EPA's continued use of a format for Benefit-Cost Analysis (BCA) that doesn't meet the requirements of Section 1412(b)(4)(C) of the 1996 SDWA Amendments. EPA's BCA in past proposals would be considered marginal, at best. AWWA believes that a much more robust BCA must be included in final regulations.

Additionally, AWWA believes that EPA needs to look at the combined affordability from the combined effects of all of the new drinking water regulations. EPA looks at the affordability of each regulation one at a time, and that is not the reality for a drinking water utility. Many small systems will be impacted by arsenic, radon, the Groundwater Rule, and the Stage 1 and Stage 2 Disinfectants/Disinfection By-Products Rule (D/DBPR). Complying with these regulations will likely require the installation of more than one treatment technology where none may have existed before. EPA cannot continue to look at each regulation one at a time, and must analyze the combined impacts of all of its regulations.

Question 11. What are AWWA's views on the EPA's proposed method of accounting for new regulations in its affordability criteria for identifying small system variance technologies as proposed in the arsenic rule? (65 FR 38926, June 22, 2000)

Response. AWWA believes that EPA's proposed method for accounting for new regulations in its affordability criteria is oversimplified for such a complex issues for several reasons. First, EPA's method doesn't take into account the impacts to lower-income households. On an system-wide basis, the installation of arsenic removal treatment technology may be affordable while creating severe economic hardships for households at the poverty level or facing a large rate increase. Second, an increase of $500 per year (the difference between the "affordable" threshold of $750 per year and the average of $250 per year) is significant for any household. A tripling of water rates is going to create rate shock anywhere. Third, EPA again touts the Drinking Water State Revolving Loan Fund (DWSRF) as a solution to disadvantaged communities. As discussed previously, there is not enough money in the entire DWSRF to comply with the proposed arsenic standard of 5 ppb.

American Water Works Association
Government Affairs Office

July 11, 2000

Senator Michael D. Crapo
Subcommittee on Fisheries, Wildlife, and Water
Committee on Environment and Public Works
SD-410 Dirksen Senate Office Building
Washington, DC 20510-6175

Re: Supplemental Oversight Hearing Materials

Dear Senator Crapo:

The American Water Works Association (AWWA) would like to again thank you for the opportunity to present testimony at the SDWA oversight hearing on June 29th. AWWA hopes that the Senate continues to conduct oversight hearings to ensure successful implementation of the 1996 SDWA Amendments.

Based on the discussions at the hearing, AWWA would like to include additional analyses on two critical issues on the proposed arsenic regulation for the hearing record. The first issue is the cost benefit analysis for the proposed arsenic regulation. Enclosed is a copy of a "regrets" analysis for the proposed arsenic regulation that presents radically different conclusions than EPA's cost benefit analysis. A "regrets" analysis is a tool that EPA has utilized in the past to look at incremental costs and benefits as increasingly lower standards are considered. As lower and lower standards are considered, costs increase at an exponential rate while the increments of exposure reduction diminish. A "regrets" analysis calculates total societal costs by combining treatment costs with an estimate of residual medical costs left over after the treatment is installed. Obviously, the goal should be to minimize total societal costs, and the proposed arsenic regulation provides an opportunity to take a hard look at how EPA calculates costs and benefits.

EPA has developed a wide range of estimated benefits, based on the inherent uncertainties in its risk assessment. Assuming that all of the benefits exist at EPA's high end of the range of estimated benefits (with all of the inherent conservative risk assessment assumptions), and using EPA's cost estimates (which are likely low), the minimal societal costs would occur at an MCL of 10 ppb. The minimal societal costs would occur at 50 ppb (the current standard) if the low end of the range of estimated benefits is used (using both EPA's cost estimate and AWWARF's cost estimate [*Cost Implications of a Lower Arsenic MCL*, www.awwarf.com/research/as_mcl.htm]). The minimal societal costs would occur at 20 ppb if the high end of the range of estimated benefits is used along with AWWARF's costs estimate.

The second issue is the potential affordability of the proposed arsenic regulation. You made several good points in questioning EPA's affordability critieria, particularly the point that the average annual water bill could triple from $250 per year to $750 per year and still be considered "affordable". Enclosed is a copy of an affordability study developed for the proposed arsenic regulation that analyzes the impacts to low-income households in certain communities. Affordability for a low-income household would likely be quite different than the $500 per year increase inherent in EPA's affordability criteria.

This study assumed that an impact of $100 or more per year could raise serious affordability concerns, which might require a low-income household to make a tradeoff that would be detrimental to its members' health or welfare. This study concluded that at an MCL of 5 ppb, 45% of all households, and 51% of households with incomes below the poverty threshold, would have increases in their water bills greater than $100 per year. These numbers drop dramatically as different MCL levels are considered. At 10 ppb, 13% of all households, and 15% of poverty households, would have increases in their water bills of greater than $100 per year. At 20 ppb, these percentages drop to 5% and 6%, respectively. Clearly, affordability needs to be looked at from the perspective of low-income households, not just the "average" household.

Again, we would like to thank you for the opportunity to present testimony and this additional material on these important issues.

Yours Sincerely,

Thomas W. Curtis
Deputy Executive Director

Cost Benefit Analysis of Proposed Arsenic MCL

EPA's "Cost Benefit Analysis"

EPA has for the first time invoked cost benefit provisions of the SDWA to support the choice of an MCL of 5 ug/l for arsenic. However, EPA does not employ a marginal analysis to justify this decision. EPA has not therefore performed a proper cost benefit analysis and has not complied with the Act. AWWA asks that EPA's analysis in support of the proposed arsenic MCL be peer reviewed by the SAB Environmental Economics Advisory Committee.

SDWA compliance inherently exhibits diminishing returns. As lower and lower treatment targets are considered, costs increase at an increasing rate while the increment of exposure reduction achieved diminishes with each additional increment of stringency. This relationship implies that there is a balance point where the marginal benefit obtained equals the marginal cost and net benefits are maximized. This is the only right way to use cost benefit analysis to justify a decision. But this is not what EPA does to justify its proposed arsenic MCL.

EPA discusses an aggregate comparison of total costs and benefits to justify its choice of MCL. In this procedure, the more favorable relationship between benefits and costs from the first increments of additional stringency (i.e., moving from 50 to 20) are averaged in with the less favorable data relating to the last increments (i.e. moving from 10 to 5). EPA bases its decision on comparison of these aggregates (and other risk criteria of their own making).

The real intent of the statute is clear from the fact that EPA is compelled to compute incremental costs and benefits. EPA presents such values, but provides no discussion of them and does not incorporate them into its justification, relying instead on aggregate cost benefit comparisons and analysis of uncertainties on the benefits side.

Economics focuses on marginal costs and benefits because the marginal dollar that regulation takes out of a household budget is significant. If low-income households are deprived of medical care due to utility bills (as evidence suggests), the effects on health (especially of sensitive subpopulations) could far outweigh the effects of trace levels of most contaminants. Marginal expenditure matters. Without a marginal analysis, the attention due to the health of sensitive subpopulations under the Act is incomplete. The aggregate comparison performed by EPA embodies a decision rule that is structured such that it will always over-shoot the economically optimal level of stringency that would be prescribed by marginal analysis. EPA's decision rule is arbitrary. It has no standing in economics. It is not cost benefit analysis. It has no standing under the SDWA. Marginal analysis was the intent of the cost benefit provisions. Why else would EPA be compelled to compute incremental costs and benefits?

Regrets Analysis

EPA has presented marginal analyses on numerous occasions in support of rulemakings under the prior statutes. In support of the Stage 1 Disinfection By-Products Rule, EPA's rationale was summarized in terms of a regrets analysis. Regrets analysis is equivalent to marginal net benefits analysis. Instead of maximizing net benefits, the perspective is to view everything as a cost and minimize the total social cost. The procedure adds compliance costs to residual health costs (i.e., health damages remaining after compliance) to obtain the total social cost.

The table below presents a regrets analysis of arsenic MCL options. The left half of the table presents the analysis using inputs taken directly from EPA's analysis. The right half presents the same analysis substituting compliance cost estimates taken from a recent AWWA Research Foundation study.

Regrets analysis is particularly useful when there is substantial uncertainty over health effects, as is usually the case in drinking water regulation. The procedure is intended to help the decisionmaker evaluate which choice would leave the least to regret if all the assumptions and all the beliefs about the pure unknowns turned out to be wrong.

The first step is to compute the total social cost for each regulatory option. This is the sum of compliance costs and residual health damages. The second step is to determine within each column (representing low vs. high-end estimates of health risks) the regulatory option that has the lowest estimated total social cost. In the third step, the regret for the lowest total social cost option is set to zero. The regret for each of the other options is set equal to the difference between the total social cost for that option and the total social cost of the lowest cost option. The final

step is to look across the regrets rows to compare the entries in the low-end and high-end health risk columns to see which regulatory option will minimize the maximum regret. In other words, which option will leave the decisionmaker with the least highest social cost to regret regardless of what turns out to be true about health risks.

The results indicate that an MCL of 20 μg/L is the best of the options considered. EPA notes there is a need to weigh also the unknowns beyond the quantified bladder cancer and lung cancer risks. Regrets analysis provides a marvelous framework for examining such imponderables. By adding another set of rows for "unquantified" residual health damages to each option in the table, the analyst can "what-if" the significance of these unknowns.

Modification of the table in this manner (not shown below) reveals that justification of an MCL of 10 μg/L requires a belief that the "unquantified" health damages are worth about half as much as the quantified health damages (bladder and lung cancer), assuming also EPA's compliance cost estimates. Using the AWWARF compliance cost estimates instead, it must be believed that the "unquantified" health damages are worth about five times as much as the quantified health damages in order to justify an MCL of 10 μg/L.

Similarly, justification of an MCL of 5 μg/L requires a belief that the "unquantified" health damages are worth about as much as the quantified health damages (bladder and lung cancer) using EPA's compliance cost estimates. Using the AWWARF compliance cost estimates, it must be believed that the "unquantified" health damages are worth about eight times as much as the quantified health damages in order to justify an MCL of 5 μg/L.

Regrets analysis is an appropriate framework for implementing the cost benefit analysis provisions of the SDWA. It provides a means of making it very clear what has to be believed about quantified and unquantified health risks in order to justify a decision. Another use that EPA should consider is applying regrets analysis to contaminants very early in the rule development process in order to provide a quantitative framework for developing data quality objectives for research needed to minimize uncertainties.

	EPA Costs (@3%)		AWWARF Costs	
MCL = 50 μg/L (No Action)	**Low Benefits**	**High Benefits**	**Low Benefits**	**High Benefits**
Compliance Cost	0	0	0	0
Residual Health Damage (Bladder Cancer)	44	104	44	104
Residual Health Damage (Lung Cancer)	47	448	47	448
Total Social Cost	91	552	91	552
Regret	**0**	111	**0**	**103**
MCL = 20 μg/L				
Compliance Cost	63	63	55	55
Residual Health Damage (Bladder Cancer)	36	74	36	74
Residual Health Damage (Lung Cancer)	38	320	38	320
Total Social Cost	137	458	129	449
Regret	**47**	17	**38**	**0**
MCL = 10 μg/L				
Compliance Cost	165	165	605	605
Residual Health Damage (Bladder Cancer)	26	52	26	52
Residual Health Damage (Lung Cancer)	28	224	28	224
Total Social Cost	218	441	658	881
Regret	**127**	**0**	**568**	**432**
MCL = 5 μg/L				
Compliance Cost	379	379	1,460	1,460
Residual Health Damage (Bladder Cancer)	12	14	12	14
Residual Health Damage (Lung Cancer)	12	64	12	64
Total Social Cost	403	457	1,484	1,538
Regret	**312**	**16**	**1,393**	**1,089**

DRAFT – DO NOT CITE

Estimating the Effect of Different Arsenic Maximum Contaminant Levels on the Affordability of Water Service

Scott J. Rubin
Attorney * Consultant
3 Lost Creek Drive
Selinsgrove, PA 17870
(570) 743-2233 * scott@publicutilityhome.com

Prepared under contract to the American Water Works Association
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Introduction

The Safe Drinking Water Act (SDWA) requires the Environmental Protection Agency (EPA) to consider the effect of new drinking water regulations on the affordability of water service in smaller communities.[1] In addition, Executive Order 12898 requires federal agencies to consider whether their actions will have a disproportionate effect on minority and low-income communities.[2]

EPA is considering a change in the maximum contaminant level (MCL) for arsenic from its current level of 50 micrograms per liter (μg/L)[3] to a more stringent level. EPA has proposed an MCL of 5 μg/L, with a request for comments on alternatives of 3, 10, and 20 μg/L.[4]

The purpose of this paper is to estimate the effect on the affordability of water service of a more stringent MCL for arsenic. Data will be analyzed from EPA's Arsenic Occurrence and Exposure Database, which contains the results of more than 100,000 arsenic samples from more than 1,100 counties in 25 states. The affordability analysis will be conducted at the county level, after aggregating estimates of compliance costs for individual water systems within each county.

Background[5]

Examining the affordability of a new drinking water regulation is an important undertaking. It is not simply a legal or regulatory requirement. Rather, it is directly related to ensuring that the regulation will, in fact, achieve a public health benefit.

A potentially significant unintended consequence of a new regulation is that low-income households will make tradeoffs in order to pay their water bill. The literature is replete with studies that show that low-income households already are forced to make serious tradeoffs that affect the health and well-being of their members – including foregoing food and medical

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[1] SDWA § 1412(b)(4)(E), 42 USC § 300g-1(b)(4)(E)
[2] Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 *Fed. Reg.* 7629 (Feb. 16, 1994).
[3] 40 CFR § 141.11(b).
[4] [insert cite to Federal Register]
[5] This section is taken, almost verbatim, from the author's paper evaluating the effect of the proposed radon regulation on the affordability of water service. Scott J. Rubin, "Assessing the Effect of the Proposed Radon Rule on the Affordability of Water Service" (AWWA Dec. 1999).

care.[6] [7] [8] [9] By diverting needed funds from these other necessities, a new drinking water regulation could adversely affect public health. Thus, the goal of an affordability analysis is not to compromise the safety of the water supply, but to ensure that any increased public health benefits from the water regulation are not negated by the tradeoffs that low-income households will make in order to pay for the regulation.[10]

In theory, any new regulatory requirement that increases the cost of water service might raise an issue about the affordability of water for some low-income households in certain communities. If the impact is limited to a few communities because of their unusual characteristics, then the provisions of the SDWA allowing for variances and grants based on affordability criteria can be expected to address the problem.[11]

In contrast, if the costs associated with complying with a new regulation will create affordability concerns for many low-income households in many communities, then the effects should be addressed through the process of establishing the regulation. To do otherwise would lead to a the requests for affordability-based variances negating the effect of the rule as a whole.

There are no hard and fast standards for determining whether the effects of a proposed rule would lead to affordability concerns. It does not appear necessary to have a "bright line" test for whether a proposed regulation raises affordability concerns, but there must be some sense for whether costs are relatively affordable. An additional cost in the range of $4 to $5 per month ($48 to $60 per household per year) would seem to be affordable for even the lowest-income households. One comprehensive study of low-income household expenditures and strategies found that even at the lowest income levels where serious tradeoffs were being made, households spend an average of $3 per month on lottery tickets.[12] While the authors of that study properly note that such expenditures might be necessary for the psychic well-being of the individual, it is reasonable to conclude that expenditures of this magnitude could be diverted to paying the water bill without imposing serious public health consequences on the household.

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[6] Kurt Bauman, Direct Measures of Poverty as Indicators of Economic Need: Evidence from the Survey of Income and Program Participation, U.S. Census Bureau Population Division Technical Working Paper No. 30 (Nov. 1998), http://www.census.gov/population/www.documentation/twps0030/twps0030.html, as of Sept. 29, 1999 (showing that more than one-third of households with incomes under $10,000 were unable to meet at least one basic need).

[7] Kurt J. Bauman, Extended Measures of Well-Being: Meeting Basic Needs, U.S. Census Bureau Current Population Reports, P70-67 (June 1999) ("In 1995, ... about 1 person in 5 lived in a household that had at least one difficulty meeting basic needs. These included households that didn't pay utility bills, didn't pay mortgage or rent, needed to see the doctor or dentist but didn't go, had telephone or utility service shut off, were evicted, didn't get enough to eat, or otherwise didn't meet essential expenses.")

[8] Kathryn Edin and Laura Lein, *Making Ends Meet: How Single Mothers Survive Welfare and Low-Wage Work* (Russell Sage Foundation 1997).

[9] U.S. Department of Agriculture, *Household Food Security in the United States in 1995: Summary Report of the Food Security Measurement Project* (1997).

[10] See also Frederick W. Pontius, "Environmental Justice and Drinking Water Regulations," *Journal American Water Works Association* 92:3:14-20 (Mar. 2000).

[11] SDWA § 1412(b)(15), 42 USC § 300g-1(b)(15); SDWA § 1415(e), 42 USC § 300g-4(e); SDWA § 1452, 42 USC § 300j-12.

[12] Edin and Lein, *Making Ends Meet, supra.*

On the other hand, expenditures that approached $8 to $10 per month or more ($96 to $120 per household per year) could raise serious affordability concerns for a low-income household. For example, Edin and Lein write that single mothers receiving welfare payments reported spending only $18 per month on medical care. So an increased expenditure for water of $8 to $10 per month would represent nearly half of the household's budget for medical care. Similarly, they reported that the average telephone bill was $31 per month, but "about one-third of the welfare-reliant mothers had their telephone disconnected or went without any phone service throughout the previous year." An $8 to $10 expenditure would represent one-quarter to one-third of the telephone bill which already is seriously at risk of going unpaid for many low-income households.

Another approach to evaluating affordability is to examine the effect on median household income in a community. Rather than focusing on the effect on the lowest-income households, this approach evaluates the impact on the community as a whole. Under this approach, if the total cost for water is on the order of 1.5 percent of median household income in the community, then water service should be affordable (Beecher and Shanaghan indicate that some states use other figures, ranging from 1.0 to 2.0 percent of median household income). [13]

For purposes of this study, it will be assumed that an impact of less than $50 per household per year is affordable for a low-income household, while an impact of $100 or more per year could raise serious affordability concerns which might require a low-income household to make a tradeoff that would be detrimental to its members' health or welfare. As noted, these are not hard and fast numbers, but they should provide an indication of the potential scope and magnitude of the effects of a proposed regulation on low-income households.

Alternatively, using the community-wide approach, it will be assumed that a regulation that increases the cost of water by 0.5 percent of median household income in a community might raise an affordability concern. This percentage is selected based on the author's previous work which showed that the typical water bill, for a household with median income, was 0.9 percent of income in 1989, with water rates increasing faster than the rate of growth in income. [14] Thus, an increased cost of 0.5 percent of median income would be more than a 50% increase in the water bill and would bring it close to 1.5 percent of median income overall.

The selection of these ranges also is based on other considerations, including the fact that many low-income households do not pay directly for water. The author's previous study has shown that the percentage of low-income households that pay directly for water (rather than having it included in the rent) varies tremendously from one state to another. For example, nationwide about one-half of households with incomes less than $10,000 pay directly for water, but in some states the percentage exceeds 70%, while in others it is less than 15%.[15] Selecting target ranges for affordability on a per-household level recognizes that many of the lowest-income households will not be directly affected, though they do run the risk of paying these costs indirectly (through

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[13] Janice A. Beecher and Peter E. Shanaghan, Water Affordability and the DWSRF, *Journal American Water Works Association*, Vol. 90, No. 5, 68-75 (1998).
[14] Scott J. Rubin, A Nationwide Look at the Affordability of Water Service, *Proceedings 1998 Annual Conference of the American Water Works Association*, Water Research Vol. C, 113-129.
[15] *Id.*

increases in rent or through landlords changing their policy and beginning to charge separately for water).

Methodology

Data Selection

EPA's Arsenic Occurrence and Exposure Database provides a data set of more than 100,000 arsenic samples from more than 24,000 water systems. These systems are located in approximately 1,172 counties in 25 states.[16] A subset was created from the database containing only those samples from community water systems (CWS) that detected arsenic greater than or equal to 3 μg/L. This smaller data set (containing approximately 16,000 records) was then examined in detail and "cleaned" to ensure data consistency and completeness. This process included filling in missing entries for county and population served from EPA's Safe Drinking Water Information System (SDWIS) database, where possible. Entries where county and population data could not be obtained were deleted from the database. In addition, county names were edited to precisely match U.S. Census Bureau county names.[17]

This process was very successful, resulting in the loss of data for fewer than 4% of the water systems. The most significant loss was of systems in the state of Oklahoma which all were excluded because SDWIS does not contain county identifiers for that state.

Finally, the data set was further restricted to include data only from systems that use groundwater. The analysis is restricted to groundwater systems because of differences in the technologies (and costs) that would be used to remove arsenic from groundwater systems as opposed to surface water systems. In addition, it is very difficult to generically estimate the cost of arsenic removal in surface water systems because of different types of treatment that are already in place for those systems. Table 1 summarizes the effect of this data extraction and "cleaning" process.

Table 1: Summary of Data Extraction and "Cleaning"

	Records	States	Counties	Systems	Population Served (x 1,000)
All observations	100,595	25	1,172*	24,599	103,856
CWS only	92,498	25	1,162*	19,527	102,464
Arsenic μ 3 μg/L	16,388	25	702*	5,305	50,057
County and population	15,826	24	1,022^	5,121	50,796^
Groundwater	12,639	24	856	4,491	21,143

* Includes blank counties
^ Population and number of counties are higher because missing data were filled in from SDWIS.

As shown in Table 1, the data set to be used for further analysis includes data for nearly 4,500 groundwater systems serving a population of more than 21 million people. These systems are located in 856 counties in 24 states.

[16] This figure is approximate because several entries in the database do not have a county listed.
[17] All U.S. Census Bureau data on counties is from U.S. Bureau of the Census, *City and County Data Book 1994*, [http://fisher.lib.virginia.edu/ccdb/].

Compliance Cost

The cost of complying with various possible arsenic MCLs was estimated based on the population served by each water system. The system-level compliance cost was derived in two parts: annual capital cost and annual operating & maintenance (O&M) cost. In order to develop the capital cost, it is necessary to estimate the capacity, in million gallons per day (MGD) of the treatment facility that the water system would construct to comply with the proposed regulation. In order to derive the O&M cost, it is necessary to estimate the average daily consumption of water within the water system, also in MGD.

Average daily consumption was estimated using actual per capita water consumption in each state during 1995, as reported by the U.S. Geological Survey (USGS).[18] Average consumption was calculated for each water system using Equation 1.

Equation 1: $$\text{Average use } (MGD_{avg}) = \frac{\text{Population served x per capita use}}{1{,}000{,}000}$$

Plant capacity was estimated using the relationship between capacity and average flow. Equation 2 was developed in the author's previous work dealing with the proposed radon regulation.[19]

Equation 2: $$\text{Plant capacity } (MGD_{cap}) = MGD_{avg} \times 6.3302 \times \text{Population}^{-0.1025}$$

Both capital and O&M costs were calculated using equations developed by Frey, *et al.*, that provide cost estimates in 1999 dollars.[20] Systems with design flows of less than 1.0 MGD are assumed to use activated alumina with throw-away media at a level of 7,000 bed volumes, as well as pre-oxidation. Systems with a design flow of 1.0 MGD or larger are assumed to use coagulation-assisted microfiltration with solids separation and recycled waste flow.[21] The O&M and capital cost equations are shown as Equations 3-6.

Design flow < 1.0 MGD – Capital Cost

Equation 3: $1{,}744{,}515(MGD_{cap}) + 11{,}862 + 7{,}277$ [7,277 is pre-oxidation cost]

Design flow < 1.0 MGD – O&M Cost

Equation 4A: $14{,}136(MGD_{avg}) + 1{,}162$ [pre-oxidation cost]

Equation 4B: $-22{,}529(MGD_{avg})^2 + 542{,}552(MGD_{avg}) + 1{,}961$ [activated alumina]

Design flow ≥ 1.0 MGD – Capital Cost

Equation 5: $1{,}021{,}846(MGD_{cap}) + 1{,}923{,}097$

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[18] U.S. Geological Survey, National Water Use Data (by state) for 1995, [http://water.usgs.gov/watuse/spread95]

[19] Scott J. Rubin, "Assessing the Effect of the Proposed Radon Rule on the Affordability of Water Service" (AWWA Dec. 1999).

[20] M.M. Frey, J. Chwirka, R. Narasimhan, S. Kommineni, and Z. Chowdhury, *Cost Impacts of a Lower Arsenic MCL* (AWWA and AWWARF 2000).

[21] These assumptions were provided by M.M. Frey of McGuire Environmental Consultants, Inc., through personal communication.

Design flow μ 1.0 MGD – O&M Cost

Equation 6: $74{,}928(MGD_{avg}) + 113{,}121$

The resulting capital cost, which is a total construction cost, was then annualized using the same assumption that EPA used in its analysis of the proposed radon rule; specifically, that the costs would be repaid over 20 years at a 7% interest rate, which is equivalent to a capital cost recovery factor of 9.33% per year.[22] [note: change this to refer to arsenic proposal in Federal Register]

The sum of annual capital costs and O&M costs provides an estimate of the annual, system-level arsenic compliance cost for each water system in 1999$.

Aggregation by County

The compliance cost and population data for each water system were then aggregated by county. This provides an estimated compliance cost for each county, as well as the population served by the water systems in the data set in each county. In order to conduct an affordability analysis, it is necessary to have some level of confidence that the demographic data are applicable to the population that will pay the cost of compliance. In order to provide this confidence, further analysis was restricted to counties where the population served by the water systems in the data set was equal to at least 50% of the population of the county according to the 1990 census. Table 2 shows the number of counties, and other information, remaining for analysis after this population screen was applied.

Table 2: Counties After Application of Population Screen

	States	Counties	Systems	Population Served (x 1,000)
Data set before screen	24	856	4,491	21,143
Data set after population screen	18	199	1,437	11,679

It should be emphasized that water systems in counties that failed to meet the population screen will face compliance costs, and potential affordability concerns, that may be comparable to those in counties where the screen was met. The screen is being used only as a method to ensure that readily available demographic data relate to the population served by community water systems.

Finally, an average per-household compliance cost was developed for each county by dividing the total compliance cost by the population served divided by the average number of people per household in the county, as shown in Equation 7.

Equation 7: $$\text{Cost per household} = \frac{\text{Total Cost}}{\text{Population Served} \;/\; (\text{Population/Household})}$$

[22] EPA, National Primary Drinking Water Regulations; Radon-222, Notice of Proposed Rulemaking, 64 *Fed. Reg.* 59246-59378 (Nov. 2, 1999), at 59276.

Income and Demographic Data
The relevant census data – including population, number of households, household income distribution, median household income, and number of people in poverty, among others – were taken from the U.S. Census Bureau's *City and County Data Book*.[23] Income and poverty data are for calendar year 1989. Population and household data are as of March 1990.

All income amounts were then inflated using the change in the Consumer Price Index from the annual level for 1989 to the annual level for 1999 (an increase of 34.35%).[24] This placed all income amounts in 1999$, the same units used for the compliance cost estimates. For example, assume that the 1990 census reports that 100 people in County X had an income in the range of $15,000 to $24,999, which has a midpoint of $20,000. For purposes of this analysis, the midpoint was inflated by 34.35% to $26,870 and it was assumed that all 100 people had that level of income in 1999. Similarly, the median household income that is reported by the Census Bureau was inflated by the same 34.35%.[25]

Finally, before conducting any further analysis, the characteristics of the counties that met the population screen were compared to all counties in the United States[26] and to the approximately 595 counties in the USGS arsenic database.[27] Table 3 shows that the group of 199 counties is reasonably representative of the United States as a whole and the USGS database, in terms of income, incidence of poverty, and household size. Figure 1 plots the income distribution curves for the data set, the counties in the USGS database, and all U.S. counties. While it cannot be concluded that the characteristics of the data set's 199 counties precisely mirror those of the entire country or the counties in the USGS database for all possible demographic characteristics, it appears reasonable to use data for the groups to provide additional information that will be used to establish national drinking water policy.

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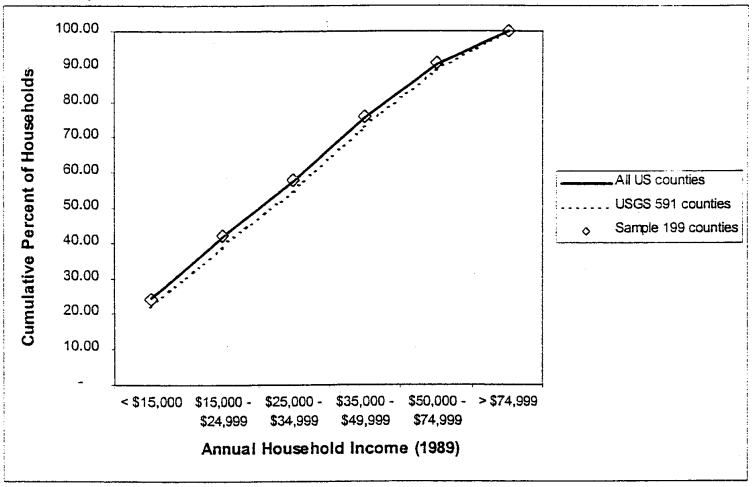
[23] U.S. Bureau of the Census, *City and County Data Book 1994*, [http://fisher.lib.virginia.edu/ccdb/].
[24] U.S. Bureau of Labor Statistics, Consumer Price Index-All Urban Consumers, Base Period 1982-1984=100, as of May 2000 [http://stats.bls.gov/cpihome.htm].
[25] Neither income distributions nor poverty distributions changed significantly between 1989 and 1997, the most recent year for which a complete analysis is available, as discussed in the author's radon paper. It is not known whether significant changes occurred between 1997 and 1999, but it in the absence of information indicating a change in the trend from 1989 to 1997, it appears reasonable to assume that income distributions have remained fairly constant. As a result, it appears reasonable to increase 1989 income data by the Consumer Price Index to estimate income levels and income distributions in 1999. Similarly, it appears reasonable to use 1989 data for the number of people in poverty to estimate the number of people in poverty in 1999.
[26] Data for all counties are slightly different from data for the entire United States because of the exclusion of the District of Columbia and territories. Data for all counties are from the *City and County Data Book 1994*.
[27] M.J. Frazio, A.H. Welch, S.A. Watkins, D.R. Helsel, and M.A. Horn, *A Retrospective Analysis of the Occurrence of Arsenic in Groundwater Resources of the United States and Limitations in Drinking-Water Supply Characterizations*, USGS Water Resources Investigations Report 99-4279 (1999); the database supporting this study was publicly released in May 2000 at [http://co.water.usgs.gov/trace/data/arsenic_may2000.txt].

Table 3: Comparison of Data Set to United States and USGS Database

	All Counties	USGS Database (591 counties)*	199 Counties
Number of households (1990)	91,697,776	37,288,257	5,269,066
Population (1990)	248,102,973	101,717,473	14,949,814
Avg. people per household (1990)	2.7	2.4	2.8
Median household income (1989)	$30,725	$32,381	$30,418
Percent of people in poverty (1989)	13.1%	12.4%	14.6%
Percent of households with income less than $15,000 (1989)	24.3%	22.1%	24.0%
Percent of people age 65 and over (1990)	11.9%	11.2%	10.7%

* The USGS database contains five or more arsenic samples for 595 counties; however, a match of the county code to the *City and County Data Book* was obtained for only 591 of the counties.

Figure 1: Comparison of Income Distribution for Data Set, USGS Database, and all U.S. Counties



Results

The potential impact of changing the arsenic MCL on the affordability of water service can be evaluated in terms of the effect on counties, households, and people who are living in poverty. While each of these points of view relies on the same underlying data – the estimated cost of compliance – each presents a slightly different picture of any potential affordability concern.

County Impacts

Table 4 and Figure 2 show the county-wide impacts of the various potential arsenic MCL levels. These results show that at an arsenic level of 5 µg/L, only 35% of the counties have an average

compliance cost below $50 per household per year, which is the level that we assume is affordable. In fact, more than 60% of the counties will have a compliance cost that is more than $100 per household per year, which is the level at which serious affordability problems could arise. Moreover, approximately 50% of the counties will face an average compliance cost that is more than 0.5% of median household income. As discussed previously, this equates to a likely increase in water rates of more than 50% and is likely to bring the total cost of water above the threshold affordability level of 1.5% of median household income.

Table 4: County Impacts

	3 µg/L	5 µg/L	10 µg/L	20 µg/L
Counties with compliance cost < $50 per household per year	0 (0%)	69 (35%)	140 (70%)	174 (87%)
Counties with compliance cost $50 to $100 per household per year	13 (7%)	10 (5%)	9 (5%)	5 (3%)
Counties with compliance cost $100 to $200 per household per year	54 (27%)	49 (25%)	28 (14%)	10 (5%)
Counties with compliance cost >$200 per household per year	132 (66%)	71 (36%)	22 (11%)	10 (5%)
Counties with compliance cost < 0.5% of median household income	37 (19%)	101 (51%)	160 (80%)	185 (93%)
Counties with compliance cost 0.5% to 1.0% of median household income	98 (49%)	68 (34%)	26 (13%)	9 (5%)
Counties with compliance cost > 1.0% of median household income	64 (32%)	30 (15%)	13 (7%)	5 (3%)

Figure 2: County-Level Compliance Cost as a Percentage of Median Household Income

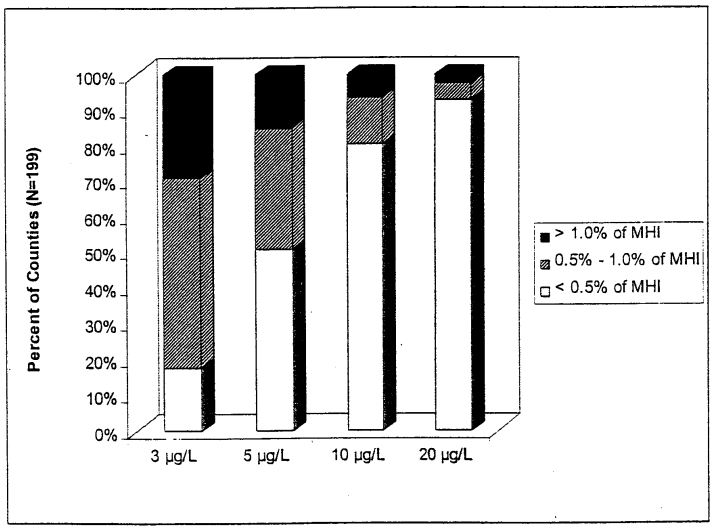


Table 4 also presents results at even higher cost levels – more than $200 per household per year and more than 1.0% of median household income. These figures represent cost levels that are at least *twice as high* as the level that is expected to raise affordability concerns for the county as a whole. These results show that if the MCL is set at 5 μg/L, more than one-third of these counties would face average household compliance costs of more than $200 per year, while 15% of the counties would see water rates increase by more than 1% of median household income. This represents an approximate doubling of water rates to a level that is likely to be more than 2.0% of median household income. Water rates at this level would raise affordability concerns under every affordability criterion of which the author is aware.

Table 4 and Figure 2 also show that most of these potentially serious affordability concerns can be alleviated if the MCL is set at a higher level, while lowering it to 3 μg/L would greatly exacerbate these concerns. Establishing the MCL at a higher level mitigates these impacts, potentially to the point where any remaining affordability concerns can be alleviated through existing grant programs or the establishment of variance technology.[28] For example, at an MCL of 20 μg/L, approximately 10% of the counties would see household compliance costs exceed $100 per year or 0.5% of median household income.

Household Impacts

The household impacts are summarized in Table 5 and Figure 3. That table and figure show that at an MCL of 5 μg/L, 77% of households are estimated to spend more than $50 per year. Further, 16% of the households are in counties where the estimated compliance cost will exceed 0.5% of median household income.

Table 5: Household Impacts

	3 μg/L	5 μg/L	10 μg/L	20 μg/L
Households with compliance cost < $50 per year	0 (0%)	1,231,455 (23%)	2,789,597 (53%)	4,140,851 (79%)
Households with compliance cost $50 to $100 per year	1,890,017 (36%)	1,685,923 (32%)	1,809,368 (34%)	861,708 (16%)
Households with compliance cost $100 to $200 per year	2,659,627 (51%)	1,926,973 (37%)	580,762 (11%)	231,874 (4%)
Households with compliance cost >$200 per year	719,422 (14%)	424,715 (8%)	89,339 (2%)	34,633 (1%)
Households in counties with compliance cost < 0.5% of median household income	3,697,433 (70%)	4,444,539 (84%)	4,892,638 (93%)	5,124,268 (97%)
Households in counties with compliance cost 0.5% to 1.0% of median household income	1,398,597 (27%)	735,079 (14%)	335,656 (6%)	129,155 (3%)
Households in counties with compliance cost > 1.0% of median household income	173,036 (3%)	89,448 (2%)	40,772 (1%)	15,643 (0%)

[28] [add footnote and citation on EPA's failure to propose variance technology and the effects that could have; alternatively, I could add a short section to the paper that discusses ways to mitigate any affordability problems that remain—use of SRF and variances]

Once again, it can be seen that establishing the MCL at a higher level would alleviate most of these potential affordability concerns, while lowering the MCL to 3 µg/L would significantly worsen these concerns. For example, at an MCL of 3 µg/L, 65% of the households would face compliance costs of more than $100 per year (compared to 45% at 5 µg/L), but this figure declines to just 5% of households if the MCL were to be established at 20 µg/L.

Figure 3: Range of Household-Level Compliance Costs

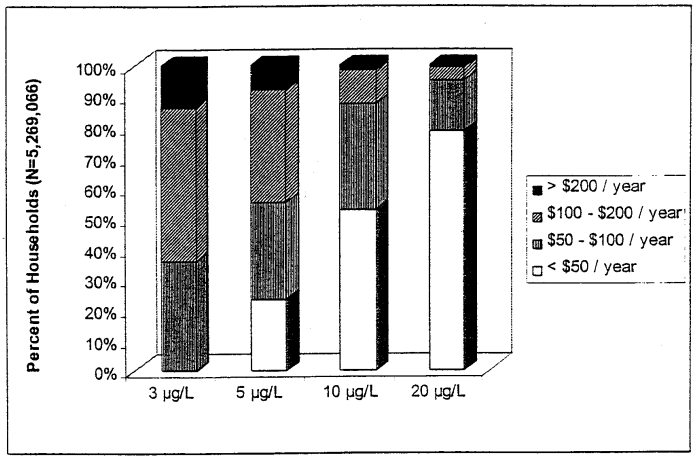


Table 6 and Figure 4 provide another measure of the impact of different arsenic MCL levels on households. This table and figure compare the compliance cost to the actual distribution of household incomes in each county. Rather than examining a percentage of median household income, this table and figure are based on an analysis that applies the estimated compliance cost to the actual income distribution in each county (using the midpoint of income ranges, escalated to 1999$, as described above). This analysis provides another perspective on the affordability question. Rather than just examining the magnitude of cost increases, it evaluates those cost increases as a percentage of household income across the range of incomes.[29]

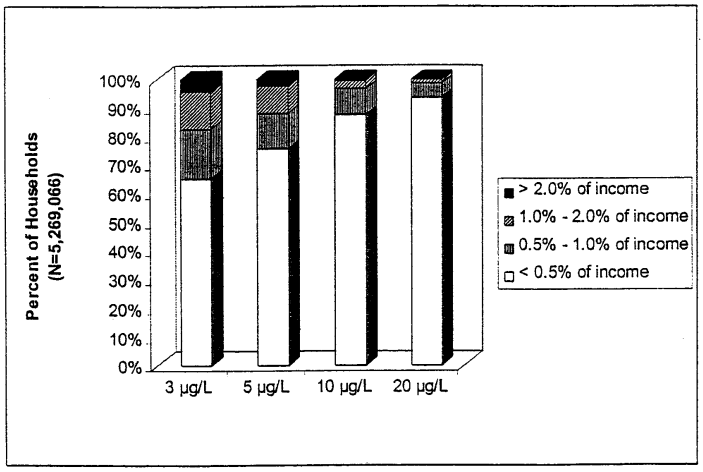
[29] The income ranges used in this analysis, which are taken directly from the *City and County Data Book*, are $0 to $14,999, $15,000 to $24,999, $25,000 to $34,999, $35,000 to $49,999, $50,000 to $74,999, and over $75,000 in 1989 dollars.

Table 6: Impacts on Households by Percentage of Income

	3 µg/L	5 µg/L	10 µg/L	20 µg/L
Household cost < 0.5% of income	3,425,134 (65%)	3,969,723 (75%)	4,595,477 (87%)	4,913,132 (93%)
Household cost 0.5% - 1.0% of income	921,301 (18%)	667,251 (13%)	486,019 (9%)	273,379 (5%)
Household cost 1.0% - 2.0% of income	691,791 (13%)	500,455 (10%)	160,660 (3%)	71,968 (1%)
Household cost > 2.0% of income	230,840 (4%)	131,637 (3%)	26,910 (1%)	10,587 (0%)

The results shown in Table 6 and Figure 4 are consistent with the tables discussed above. They show that the lower MCL levels are likely to cause serious concerns about the affordability of water service. For example, setting the MCL at 5 µg/L would result in 25% of the households in this data set having their water bill increase by more than 0.5% of their household's income. In fact, about one in every eight households would see their water bills increase by 1.0% of household income or more. As has been discussed above, higher MCLs would mitigate this impact, such that setting the MCL at 20 µg/L would see only 6% of households have their water bills increase by more than 0.5% of their income, with less than 2% of households seeing increases equivalent to 1% of household income. Similarly, setting the MCL at 3 µg/L would exacerbate these concerns, such that 35% of households would see an increase of more than 0.5% of household income, with one in six households seeing increases of more than 1.0% of household income.

Figure 4: Distribution of Household-Level Compliance Cost as a Percentage of Household Income



Poverty Impacts

Finally, Table 7 and Figure 5 summarize the estimated impacts of different MCL levels on people who live in households that have incomes below the poverty threshold. Here again,

Conclusion

From the available data, it is reasonable to conclude that establishing a new arsenic MCL at a level of 5 µg/L (or lower) will raise serious concerns about the affordability of water service for a majority of affected groundwater systems. This conclusion is supported by an examination of:

- county-level impacts, based on the percentage increase in water costs for households with median income in each county;
- household-level impacts, based on the percentage of households that would see water costs increase by more than 0.5% of their income; and
- impacts on people with incomes below the poverty level, based on the percentage of people who would face increased expenditures for water of more than $100 per year.

These impacts are a function of the cost of treating groundwater for arsenic, the size of the affected water systems (the smaller the system, the higher the cost per household to treat the water for arsenic), and the demographics of the affected population. Due to the sheer number of systems that would face affordability concerns, it is believed that existing variance and grant programs would not be adequate to alleviate the affordability concerns raised by establishing the MCL at 5 µg/L.

Establishing the MCL at a higher level, particularly at 20 µg/L, alleviates most, but not all, of this adverse effect. The remaining impact, at the 20 µg/L level, however, should be sufficiently small to be mitigated through existing variance and grant programs. This assumes, of course, that EPA designates variance technologies and permits primacy agencies to grant variances. [insert statement and citation to proposal in Federal Register on this issue]

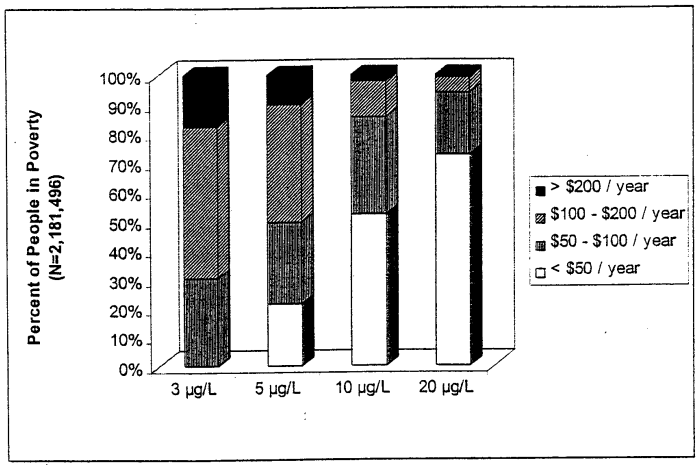
These conclusions appear to be robust, in that they are based on a data set encompassing nearly 1,400 water systems of various sizes in 199 counties in 18 states. The data from these counties appear to be reasonably representative of the United States as a whole. It is reasonable to conclude, therefore, that the types of affordability impacts that have been determined for the counties in the data set would be replicated throughout the United States where a groundwater system would be required to install treatment to meet a new arsenic MCL.

setting the MCL at 5 µg/L would raise serious affordability concerns for people whose incomes are below the poverty level. More than 50% of these impoverished people would face increases in their water bills of more than $100 per year, with one in ten facing an increase of more than $200 per year. Increases of this magnitude for people that already are living in poverty could result in serious tradeoffs that could affect the health of those individuals, as discussed above.

Table 7: Impacts on People in Poverty

	3 µg/L	5 µg/L	10 µg/L	20 µg/L
People in poverty with compliance cost < $50 per household per year	0 (0%)	466,955 (21%)	1,134,093 (52%)	1,584,550 (73%)
People in poverty with compliance cost $50 to $100 per household per year	656,209 (30%)	606,546 (28%)	726,889 (33%)	464,065 (21%)
People in poverty with compliance cost $100 to $200 per household per year	1,141,885 (52%)	886,753 (41%)	273,118 (13%)	112,889 (5%)
People in poverty with compliance cost > $200 per household per year	383,402 (18%)	221,242 (10%)	47,396 (2%)	19,992 (1%)

Figure 5: Distribution of Compliance Costs for People with Incomes Below Poverty Level



As has been seen from other measures of affordability, setting the MCL at a level of 10 or 20 µg/L greatly reduces (but does not completely eliminate) these effects. It should be noted that setting the MCL at 3 µg/L results in 70% of the people with incomes below the poverty level facing increased water costs of more than $100 per year, with one in five impoverished households facing an increase of more than $200 per year.

STATEMENT OF J. RICHARD TOMPKINS, MIDDLESEX WATER COMPANY, ON BEHALF OF THE NATIONAL ASSOCIATION OF WATER COMPANIES

Good morning, Mr. Chairman. My name is J. Richard Tompkins. I am the President of Middlesex Water Company, an investor-owned community water system serving a population of more than 200,000 in northern New Jersey. I am also the President of the National Association of Water Companies (NAWC), a non-profit trade association that exclusively represents the nation's private and investor-owned drinking water industry. I am offering this testimony on behalf of NAWC's member-

ship over 300 companies in 43 states that provides safe, reliable drinking water to over 23 million Americans every day.

Mr. Chairman, NAWC commends you and your subcommittee for conducting these oversight hearings on the implementation of the 1996 Amendments to the Safe Drinking Water Act (SDWA), the second such hearings by your subcommittee in as many years. With its emphasis on public participation and right to know, and the requirements for sound science and cost-benefit analysis in the regulatory process, the 1996 Act represents a new paradigm for environmental legislation of which this committee and Congress can be justly proud.

Although our statement expresses some concerns over current and future issues regarding the Act and the drinking water industry, NAWC believes that overall EPA has made a good faith effort to comply with the letter and spirit of the Act. In particular we wish to commend EPA for its timely implementation of the Consumer Confidence Reports (CCR) rule; its efforts to seek increased funding for scientific research through the fiscal year 2001 appropriations process; its positive response to complaints about its SDWIS compliance data base (although much still needs to be done); and its efforts to implement the new Drinking Water State Revolving Loan Fund (DW-SRF) in an equitable manner.

Areas of concern that we wish to address today include the proposed radon rule, the proposed arsenic rule, MTBE contamination of drinking water sources, inequitable implementation of the DW-SRF by some states, the threat to national drinking water standards posed by tort litigation, and drinking water infrastructure needs.

EPA's Proposed Radon Rule

NAWC does not believe that EPA's proposed MCL of 300 pCi/L, or any level below 1000 pCi/L, can be justified by cost-benefit analysis, especially for small companies. NAWC's California chapter, the California Water Association, has prepared a statement that documents in detail the deficiencies of EPA's cost estimates, and we would like to submit CWA's statement for the record of this hearing.

The cost differences between compliance with the proposed alternative MCL (AMCL) of 4000 pCi/L and 300 pCi/L can be huge. NAWC's largest company, American Water Works Company, estimates capital costs of $1.3 million for a treatment level of 4000 pCi/L compared with $134 million for a treatment level of 300 pCi/L, a 100-fold difference.

NAWC supports state-sponsored Multimedia Mitigation (MMM) programs as the most cost-effective way to achieve substantial health benefits through reduction in exposure to radon in indoor air. Furthermore, we believe that the prospect of water systems implementing local MMM programs in the absence of state programs is unrealistic. It is highly doubtful that the nation's public water systems, especially small systems, will have sufficient resources to achieve the goals of multimedia mitigation by themselves without state assistance. Tracking new home construction and remedial venting of existing homes is far removed from the chartered objectives of community water systems, not to mention the added burdens that would be placed on water ratepayers.

In summary, NAWC believes that nationwide implementation of effective state MMM programs is essential for the Radon Rule to achieve its intended goals. Otherwise systems will be faced with the very unattractive alternatives of implementing local MMM programs or meeting a very costly MCL which cannot be justified by cost-benefit analysis. We urge Congress to consider legislation that would place the requirements of the MMM program in EPA's air program where it belongs and to provide states with sufficient resources to implement it. Effective MMM programs implemented in every state plus a drinking water AMCL of 4000 pCi/L will provide far greater public health benefits at a more reasonable cost than a drinking water MCL of 300 pCi/L standing alone.

EPA's Proposed Arsenic Rule

NAWC agrees with the National Academy of Science that the current arsenic standard of 50 ppb needs to be revised in accordance with the provisions of the 1996 SDWA Amendments. However we are not convinced that EPA's proposed standard of 5 ppb, announced June 22, 2000, can be justified.

- Earlier this month, in a preliminary draft report, the Drinking Water Committee of EPA's Science Advisory Board (SAB) concluded that the available scientific evidence on health effects could justify a standard of 10 ppb or even 20 ppb.
- The World Health Organization has an arsenic standard for drinking water of 10 ppb.
- According to the AWWA Research Foundation, the cost of compliance with a standard of 5 ppb is 2 1/2 times that of compliance with a standard of 10 ppb.

NAWC urges EPA to reconsider the available body of scientific evidence and to consider a final standard of no less than 10 ppb.

MTBE Contamination of Drinking Water Sources

The use of Methyl tertiary butyl ether (MTBE) as an oxygen additive in reformulated gasoline has created a significant and unacceptable risk to drinking water surface and groundwater sources in many areas throughout the United States. Recently EPA recommended that Congress amend the Clean Air Act to significantly reduce or eliminate the use of MTBE as a fuel additive.

On May 4, 2000, NAWC joined three other drinking water Associations in urging Congress promptly to consider legislation that would:

- Amend the Clean Air Act to significantly reduce or eliminate the use of MTBE in gasoline.
- Ensure that air quality gains are not diminished as MTBE use is reduced.
- Require adequate research to be conducted on any replacement fuel additive to ensure that such a replacement will not contaminate drinking water sources.
- Provide assistance to public water systems that have MTBE contaminated sources for treatment or for alternative water supplies.

We urge Congress to take swift action to resolve this threat to our nation's drinking water supplies in accordance with these principles.

State Revolving Loan Funds

When NAWC testified before this subcommittee in March, 1999, we observed that 19 states had declared privately owned drinking water systems to be ineligible for DW-SRF assistance through their constitutions, statutes or official policies. This unfortunate consequence is a clear, and in many cases deliberate, violation of Congressional intent that SRF loans should benefit customers of all public water systems, regardless of ownership. In fact, this intent was made explicit in this committee's report accompanying the 1996 Amendments. Unfortunately, the most recent data from EPA reveals that, 15 months later, the numbers of states ignoring Congressional intent has been reduced by only two.

Mr. Chairman, EPA's state-by-state allocation of SRF funding is based on infrastructure needs surveys that include the needs of all utilities regardless of ownership. Those 17 non-complying states are accepting Federal funds based in part on the needs of privately owned utilities in their states while refusing to allow those same utilities to apply for SRF assistance. Plainly put, this is discriminatory not just against the companies but also against their customers, both of whom pay the taxes that make these funds available in the first place.

Some argue that privately owned companies, even those serving the public, should not receive Federal assistance not even loans. Congress considered that argument in 1996, and concluded that regulation by state public utility commissions would assure that the interest savings from SRF loans would benefit customers not company shareholders. In fact the National Association of Regulatory Utility Commissioners (NARUC) has joined us in criticizing the failure of these states to comply with Congressional intent.

We have urged EPA to base its SRF allocations on the needs of those customers that the states are actually willing to help. The funds forfeited by those states that refuse to comply would be reallocated to those who do. If EPA cannot, or will not, take this step, we believe that Congress should intervene to end this discrimination.

Water Contamination Tort Litigation

NAWC continues to be concerned about a new kind of lawsuit which we believe seriously threatens America's drinking water industry and the regulatory system under which it has successfully operated for many years. In California, the plaintiff's bar has organized and commenced more than a dozen mass tort lawsuits against several community water systems (both public agencies and private companies) for allegedly delivering contaminated water, even though those systems claim to be in full compliance with state and Federal standards. As you know, these standards have been developed by regulatory agencies over many years based on the health effects of contaminants, measurement capabilities, and technical feasibility. They are the product of extensive Congressional debate over both the need to protect the public health and the cost of treatment.

If 12 jurors conclude that these national standards are inadequate to protect the public health, water systems across the country will need to consider whether to comply with uniform national standards or the relatively arbitrary and unpredictable standards set by random juries. Furthermore, the costs of defending these lawsuits as well as increased insurance coverage will place upward pressure on water rates and charges. Ultimately, the substantial judgments that could result from

these lawsuits could threaten the financial stability of water systems across the country.

In September 1999, a California appellate court that had consolidated 11 of these cases ruled that the complaints against regulated systems should be dismissed because they were preempted by the authority of the California Public Utilities Commission. However, the complaints against the public agencies were ordered to proceed. In December 1999, The California Supreme Court accepted petitions for review of the intermediate court's decision.

Regardless of the ultimate outcome in California, water systems all over the country remain vulnerable to the threat of this kind of litigation. Given the widely acknowledged success of the SDWA since its enactment more than 25 years ago, we believe that it would be most unfortunate, if not potentially disastrous, if the heart of the Act uniformly enforced national drinking water standards were to be eroded or destroyed by litigation.

Accordingly we have been working with other drinking water groups to draft legislation that would:

- Make compliance with drinking water standards a defense in civil lawsuits against water utilities.
- Cover unregulated contaminants as well by requiring proof of negligence (as opposed to strict liability).
- Give deference to compliance determinations by state primacy agencies (without requiring those agencies to go beyond current requirements).
- Protect all utilities (public and private, large and small) from frivolous lawsuits which are expensive to defend.
- Preserve, through a standard "savings clause," defenses already available under Federal or state law.

Mr. Chairman, we look forward to working with the Members of this committee as we proceed with this endeavor.

Drinking Water Infrastructure Needs

A 1997 EPA report estimated that the drinking water industry must invest $138 billion over the next 20 years to replace failing infrastructure. At that time, this amount actually exceeded EPA's total estimate of existing water industry assets. A recent analysis by the American Water Works Association estimated total infrastructure needs to be $385 billion. When wastewater needs are added, that number more than doubles.

The private sector stands willing and able to help with these infrastructure financing challenges. Creative partnerships should be encouraged and pursued so that municipalities can tap and pursue the private capital markets. If such partnerships were fully pursued, many cities and towns all across the country could successfully address many of their infrastructure financing shortfalls.

However, some have responded to this challenge by calling upon Congress to consider massive Federal grant or trust fund programs. NAWC believes such a call to be, at best, premature. In addition, if the water industry cannot meet the infrastructure challenge substantially on our own over the long run, we will have admitted that our utility models are not self-sustaining. In other words, NAWC believes that the supply and delivery of potable water should be cost effective and should pay for itself as is the case with the electric, gas and telecommunication utilities. Consequently, we need to find solutions that will assure that water utilities are economically viable in the future, without subsidy.

In summary, if it is demonstrated that Federal assistance is warranted, NAWC will be prepared to support narrowly targeted solutions that:

- Are economically efficient and equitable.
- Include all water utilities regardless of size or ownership.
- Support innovation.
- Assure that utilities are self-supporting over the long term.
- Provide special assistance to economically depressed areas based on consumer needs.

These are long-term challenges, and we look forward to working with this committee to achieve long-term solutions that will allow the industry to stand on its own two feet.

In conclusion, Mr. Chairman, NAWC very much appreciates this opportunity to present our views, and I would be happy to respond to any questions.

RESPONSES BY RICHARD TOMPKINS TO ADDITIONAL QUESTIONS FROM SENATOR CRAPO

Question 1. What does the NAWC believe to be the per household cost implications of a radon rule of 300 pCi/L, either generally or for your membership?

Response. It is always difficult to talk about costs per household with drinking water regulations because usually the costs are not spread out evenly over all households. In the case of radon talking about average cost per household is so misleading as to be virtually useless. Radon is only found in very specific parts of the country. Furthermore, radon only shows up in the source water of groundwater facilities, which tend to be small, thus concentrating the costs even more. To illustrate the wildly differing costs different utilities face, one of NAWC's members surveyed its utilities and found that the cost per household of a 300 pCi/L rule ranged from $7 per household to $200 per household.

We agree with the comments to EPA from American Water Works Association, which stated "the proposed MCL would not give rise to an affordability concern for most water systems serving 500 people or more. However, there are indications that low-income households served by smaller water systems. . . might be faced with serious tradeoffs that could adversely affect the occupants' health".

Also, costs per household for radon should not be viewed in isolation, but considered together with costs of other pending regulations such as arsenic, M/DBPs and groundwater.

Question 2. The EPA's cost estimates per household for the treatment for arsenic do not vary considerably for systems below 1 million customers irrespective of the proposed MCL. Does this conclusion match findings of NAWC's analyses?

Response. On June 22n? EPA proposed a new arsenic standard of 5 ppb, and has asked for comments on standards of 3, 10, and 20 ppb. In the proposed regulation EPA endeavored to answer this very question:

"Costs per household do not vary dramatically across MCL option. This is because of the fact that once a system installs a treatment technology to meet an MCL target, costs do not vary significantly based upon the removal efficiency it will be operated under. "

However, the AWWA Research Foundation has found that the cost of compliance with a standard of 5 ppb is 2 I/: times that of compliance with a standard of 10 ppb. AWWARF also sharply disagreed with EPA's national cost estimates. They estimated that compliance with a standard of either 5 or 10 ppb would about 4 times more expensive than EPA estimated. NAWC is on record urging EPA to reconsider the available body of scientific evidence and to consider a final standard of no less than 10 ppb.

Question 3. State SRF allocations are based on infrastructure needs for both private and public systems. However, several states, by their own determination, preclude private systems from accessing the SRF. Should the EPA prepare future allotment formulas based on the needs of systems eligible to receive funds from that state?

Response. Yes. Fairness and consistency require that EPA take into account State eligibility determinations when preparing the State allotment formulas.

Thus far, EPA officials have been even-handed and persistent in their efforts to implement the DW-SRF equitably. However, they have been resisted by about 17 States which do not allow access to the DW-SRF by privately owned systems, despite the clear intent of Congress.

Presently, EPA is considering implementing a policy that would base a state's SRF allocation only on those infrastructure needs that the state has determined to be eligible. (The funds subtracted from States that do not comply with Congressional intent would be redistributed to those States that are in compliance.) This makes perfect sense. Why award a state an allocation for infrastructure needs which the state has no intention of assisting? NAWC believes that such a revised policy would be fair and proper for all community water systems and their customers, as well as the states.

Also, If EPA concludes that it lacks legal authority to make such a policy, we urge Congress to make such authority explicit and to require its implementation.

Question 4. Is it your expectation that additional states will extend DW-SRF eligibility to private systems in the future?

Response. Not without specific direction from EPA or Congress.

Since the establishment of the DW-SRF many states have changed their laws or practices to extend SRF eligibility to private systems, thus fulfilling Congressional intent. However, in the 15 months since NAWC last testified before this committee the number of states denying private system access to the SRF has only been fur-

ther reduced by 2, to 17. (Illinois, Indiana and North Dakota have included private utilities. West Virginia has gone the other way, excluding privates. Note: of the states represented on the subcommittee, only Wyoming excludes privates. On the full committee only Montana and Oklahoma exclude privates.)

When Congress established the DW-SRF in 1996, it recognized that all benefits from low interest loans are passed on to the utilities' customers (in fact, the State Public Utilities Commissions require it). To deny such loans to private and investor-owned utilities penalizes the customers of such utilities. Therefore, NAWC believes that EPA and Congress should continue encouraging all States to implement the SRF as intended.

Question 5. Tort litigation in California has raised the issue of liability of water systems to unregulated contaminants. Is this an isolated problem?

Response. No, the California litigation is not an isolated problem. There have been toxic tort actions filed in other states, but have thus far been settled, including the Milwaukee cryptosporidium lawsuit. The California suits, on the other hand, are the first in which trial lawyers have apparently mounted an organized effort to target the water industry. Over the last several years a dozen different suits, with hundreds of plaintiffs, were filed in California. If the plaintiffs are successful we believe a wave of lawsuits could be set loose all across the country. Should this happen the following problems will be presented for the water industry, Congress, and Federal and State regulators:

1. Undermining Water Quality Regulations. This litigation could result in 12 jurors in a state courtroom setting national drinking water standards—standards far different from those set by the Federal and state agencies under the regulatory process. Those jurors will have heard "scientific" testimony that those standards do not protect public health. Water suppliers, facing uncertainty about which standards to meet, will be pressured to follow the most stringent standards set by any jury in the country to avoid liability. National uniformity (and uniformity within the states) will be eroded.

2. Water Cost Increases. Such litigation will place upward pressure on water prices due to the costs of defense (which could be substantial given the expert testimony and multiple plaintiffs) and the unexpected expenses of new water treatment technologies -technology beyond that required by Federal and state regulations to avoid potential liability. This economic burden will fall most heavily on working class families where water—a necessity of life—will take a bigger share of their paychecks.

3. Threat to Financial Stability of Water Agencies. Mass tort litigation can result in catastrophic judgments against utilities and public agencies and—if Superfund has taught us anything—insurance may not be available to cover these new liabilities. Most water suppliers do not have reserves for damages of this magnitude and have limited access to outside sources of funds. Sudden and substantial rate increases are likely.

STATEMENT OF RANDY VAN DYKE, PRESIDENT, CLAY REGIONAL WATER, ON BEHALF OF THE NATIONAL RURAL WATER ASSOCIATION AND THE IOWA RURAL WATER ASSOCIATION

Good morning Chairman Crapo and Members of the committee. My name is Randy Van Dyke. I am the general manager of the Clay Regional Water, a rural water system in Iowa and President of the National Rural Water Association which represents over 17,000 small and rural communities. On behalf of all these small communities I would like to thank the committee for this opportunity.

I will focus my comments today on a review of three of the key principles of the Safe Drinking Water Act of 1996—one, the use of sound science and cost/benefit in rulemaking; two, input from stakeholders in the process; and three, an emphasis on flexibility in the law to reduce bureaucracy.

Small communities embraced these principles, hoping they would limit Federal drinking water rules from wasting local public health resources. Unfortunately, this has proven not to be the case across the board and I will briefly explain.

First, sound science and cost/benefit. The EPA has not taken the initiative to obtain adequate data, and sound science, including the use of the most recent accurance information, reasonable health affects studies, and compliance cost information when promulgating new rules. Frequently, good scientific studies are started too late and research data collection lag behind the timing for EPA to write and finalize new regulations. Consequently, old information and inadequate science is utilized as "best available science" creating weak or wholly inaccurate conclusions, placing a devastating financial impact on small water systems across this nation.

Without anyone holding EPA accountable, only a strong emphasis on statutory deadlines is accomplished. Selective science and data is used instead of the good science and that cost/benefit analyst that was envisioned in the 1996 SDWA amendments. Here are some examples:

EPA's proposed ground water rule is incredibly broad in scope, and it based on one private utility funded occurrence study that the science community considered inadequate. Compliance cost have not been accurately calculated, and EPA disregarded rural water's request to study the possibility of designing a simple monitoring method that would have greatly simplified the rule.

EPA failed to use the best available science to set requirements under the LTlESWTR. Independent analysis of the Cryptosporidium occurrence data from the Information Collection Rule (ICR) survey indicated actual mean occurrence levels (considering recovery and viability) are likely to be an order of magnitude different (or less) than the figures used by EPA . Opposite the conclusion reached by EPA the ICR figures indicated that the cost far exceeded any benefit, "If the facts don't fit the theory, change the facts." Albert Einstein (1879–1955)

Disinfectant/Disinfection byproducts—The small systems have withdrawn from two prior Federal Advisory Committee Act (FACA) on D/DBP because there was not adequate science to justify a standard to a level that was affordable by small systems. We are now participating in a third FACA where the science is still inadequate and data is lacking for small systems.

Arsenic—There is very uncertain scientific evidence of the health effects of arsenic at levels proposed by EPA. Recently, EPA's own Science Advisory Board expressed concern that EPA proposal for a MCL of 5 parts per billion may be a precipitous action and that a less extreme proposal made until new studies are completed. Any decision by EPA to go below the current 50 parts per million standard will place an enormous cost on small systems without the public health benefits to justify such an action. The unintended consequences of regulating small communities in the absence of public health and cost information can be deleterious, causing much more harm than benefit to the customers. The problem with the current approach is best articulated by consumer expert Scott Rubin, who said: "Public health protection is notiree. Whether it's medical care, sewage treatment, clean drinking water, AIDS prevention, prescription medicine, food, heat, or shelter—it costs real money. And we don't have enough to go around. So, yes if we're setting public health policy, and that's what drinking water regulation is, we better make sure that we're getting our money's worth. Because if we're not buying meaningful public health protection, all we've done is take away money that people need to put food on the table, pay for a doctor, and keep the house warm. . . . My point is simple: Whenever we do anything to increase the price of water, we areforcing millions offamilies to makeyet another tradeoff which will directly affect their health. And, at the same time, we take a family that was barely squeaking by and we push them over the edge. "

Five major arsenic scientific studies are started at this time. The bulk of the health effects information necessary to appropriately set a rule will not be completed during the time of the regulatory rulemaking process.

To paraphrase Mark Twain, there is nothing as pesky as a good anecdote. What should be done in the City of Lidgerwood North Dakota, a very small city with just over 400 homes, an agriculture based economy with a high concentration of retired person, 70 miles south of Fargo. The city spent the better part of 1 million dollars to comply with the current arsenic standard which brought their levels from 56 parts per billion to 17. To comply with a 5ppb standard they would have to completely rebuild the treatment system for a cost over 1.5 million dollars.

Variances and Determining URTH (unreasonable risk to health): The SDWA contemplated that standards would be become affordable for small systems through the use of variances as described by Senator Baucus [Senate—November 29, 1995]

The bill provides special help to small systems that cannot afford to comply with the drinking water regulations and can benefit from technologies geared specifically to the needs of small systems. Here is how it would work. Any system serving 10,000 people orfewer may request a variance to install special small system technology identif ed by EPA. What this means is that if a small system cannot afford to comply with current regulations through conventional treatment, the system can comply with the act by installing affordable small system technology. Small systems that seek a variance will be protectedirom f nancial penalties while their application is being reviewed, and they would have 3 years to install the affordable technology. States approve the variance, but only if the technology provides adequate water quality and public health protection. So small systems are not forced to use big city treatment. But they must fully protect public health.

For a variety of reasons, EPA has not granted any variances. However, more concerning, is that EPA has not determined a criteria for who will be granted vanances.

This failure to determine a simple (or any) policy on what cost/benefit principal will be used to grant variances or what URTH levels of contaminants will force small systems to comply with the same standards as large systems. This was the problem the SDWA of 1996 was attempting to remedy. We urge the committee to require EPA to publish any numerical levels (ranges) for all regulations that will not result in an unreasonable risk to health as contemplated in the SDWA and the methodology for determining URTH levels so small communities can plan for the future. Also, we would request that the committee ensure that when any standards that are set using the criteria that is affordable for a large city, there is a corresponding level identified under the variance provisions based on either (1) public health or URTH or (2) the affordability of venous systems sizes identified in the small system technology provisions.

This information would be very beneficial for small communities to use in explaining—to their constituents—the need and public health benefits from compliance.

Occasionally, EPA is being held accountable tor moving forward without sound science—as in the case of the recent Chloroform lawsuit. However, this avenue of accountability is prohibitively costly for small communities who generally rely on the Congress to monitor EPA actions.

Second,-stakeholder input, we have been disappointed by the consistency in which the Agency dismisses or sets aside input from stakeholders, the scientific community and the public. Numerous local officials have participated, at great length, on panels and stakeholders groups, only to see EPA unilaterally make all policy decisions. Ultimately, stakeholders are having very little impact on the final rule. Work groups to provide background information to stakeholder committees and panels frequently are pressured to put on the table information that is incomplete, not peer reviewed and submitted at the last possible moment. Concerns about the compounding effect of the new rules on small communities and state primacy agencies ability to implement is largely ignored. Individually, here are some examples:

Arsenic and D/DBP Stakeholders and small communities petitioned the Agency without success to delay rulemaking for 2 to 5 years until the new research gives meaningful answers to the question of health effects. In both cases, new epidemiology studies once evaluated will clearly characterize the dose-response relationship for non cancer end points. Currently, work groups and scientific panelists are pressured into creating conclusions that are weak and not supported by the data or health effects at the lower levels suggested by EPA.

Third, flexibility as a remedy to bureaucracy. The question has to be asked, is it possible for EPA to ever choose to be flexible in its approach. We can conclude based on empirical and theoretical observation that it is not possible for EPA to utilize flexibility. They can not be faulted for this however, because EPA is first and foremost a regulatory Agency. They are only liable, politically and legally, when they don't fully enforce any and every regulatory measure to its fullest extent. Success for a regulatory Agency is not measured in the vagaries of public health progress, but in application of finite regulations. Due to its mission, incentives, and culture EPA at every opportunity has chosen to use any discretion in the SDWA to increase the bureaucracy of its regulations.

The following are a few examples of our concerns:

Capacity Development: the Act provides for states to develop a program for assuring that there is sufficient technical, managerial and financial capacity for all new water systems and for water systems applying for State Revolving Fund assistance. This is the scope of the law with a very limited Federal role. Rural water recommended that states (not EPA) to develop a state capacity development strategy for meeting four specific areas written into the statute. This would provide states the full flexibility to address small system capacity development. Contrary to this input, EPA has written formal guidelines for these capacity development strategies despite the fact that there is no statutory authority for EPA to write such a guidance. Our contention is that states have ultimate flexibility in this process and that every state is presently operating a form of capacity development strategy simply in its regulatory compliance and technical assistance programs. EPA says that the guidelines were supported by a majority of the stakeholders in the stakeholder meeting. However, this was not a stakeholder idea—it was a proposal initiated by EPA and pushed vigorously in the meeting.

Ground Water Rule: We felt that the rule should clearly demonstrate ground water contamination (physical, chemical, biological, or radiological substance or matter in the water) before requiring systems to disinfect or take any other steps. This common sense, "innocent until proven guilty" idea is the direction that the small communities feel EPA should adopt. However, EPA chose to develop a rule that regulates what a community must do to prevent contamination—a major change in the Federal regulatory model. All EPA instruction on how to run a community (water

system) to prevent contamination should be NON-regulatory (i.e., information, grants, training, education etc. to encourage towns to adopt the latest practices). EPA's ambiguous and opened ended rule functions more like a permit and leaves small communities without any discernable idea of when compliance is achieved. It can be interpreted differently from state to state and case to case.

Consumer Confidence Reports: We encouraged EPA to support a grassroots outreach program to assist communities with the first generation of CCRs because the enormous complexity of publishing the reports we thought, at least for the first report, EPA should use educational programs and flexibility to get systems to comply. Unfortunately this was not what Agency chose. After making the rule as complex and detailed as possible EPA has initiated an enforcement policy that resulted in EPA letters saying: "you are in violation of the CCR rule . . . your system could be subject to Federal formal enforcement actions . . . [which] carry potential penalties of up to $257,000 per day." Keep in mind, that many of these towns don't have computers. have never heard of the Consumer Confidence Report.

Operator Certification Money: under section 123, EPA was to provide for the "reimbursement for the costs of training, including an appropriate per diem for unsalaried operators, and certification for persons operating systems serving 3,300 persons or fewer that are required to undergo training pursuant to this section. . . through grants to States." EPA was authorized to use up to $30,000,000 from the SRF to accomplish this objective. To date, these funds have not been allocated to state even through EPA is evaluating state certification programs.

Radon: EPA has proposed a radon maximum contaminant level 300 psi/l. Under the Act, a community can comply with the outdoor air equivalent if its state initiates a multimedia mitigation program. However, EPA appears to be requiring overly prescriptive mitigation program rather than an education/technical assistance approach. If states do not adopt workable multi-media programs than small communities will be required to do so, or comply with the 300 psi/l standard—an unreasonably stringent standard. Small systems should not be penalized by state inaction or EPA's overly complex MMP demands.

In closing Mr. Chairman, we must acknowledge and thank EPA for willingness to invite small systems in the stakeholder process, and the efforts on the part of the staff to include small communities in their rulemaking process. However, let me close by highlighting what is working in rural areas to help communities provide safe drinking water and comply with EPA's implementation of the rules.

Ask yourself, which communities in my state can't be trusted to take every et fort to provide safe drinking water. We continually ask for the list of the small communities that need to improve their drinking water and are not willing to take the steps to do it. No such list exists. Under the SDWA EPA was required to make such a list for recalcitrant systems. This has never been accomplished to our knowledge.

What is axiomatic in rural Amencan and overlooked in Washington is that small towns will take the necessary measures to protect their water. However they need common-sense assistance in a form they can understand (reasonable, practical and affordable). It takes someone siting down with them evening after evening, and working with them through the ENTIRE process. Giving them a copy of the Federal register and phone number to call is no help at all.

This is why much of the SDWA is misdirected—improving drinking water in small communities is more of a RESOURCE problem than a REGULATORY problem. Every community wants to provide safe water and meet all drinking water standards. After all, local water systems are operated by people whose families drink the water every day, who are locally elected by their community, and who know, ilrsthand, how much their community can afford.

An anecdote from rural New York captures what is happening across the country: the Village of Cato is a typical rural community, consisting of 230 homes, a parttime Mayor, a village budget of three hundred thousand dollars and two full-time employees.

Last year, the EPA mandated that Cato publish a Consumer Confidence Report. This lengthy, confusing report is detailed in 26 pages of the Federal Register prose.

Over 50 thousand small communities across the country, just like Cato, had to comply with the rule. On behalf of those communities, we feel that there are two ways to implement this rule and one is better than the other.

First, is the rural water, grassroots way. Using funds provided by Congress, New York Rural Water Association helped over 500 communities publish their Consumer Confidence Report. For about half of the 500, they held regional 1-day training sessions. The towns could bring their required data to our sessions and using our staff, our computers, a simplified template of EPA's requirements. and a little magic—the towns could leave at the end of the day with their Report and the knowledge to do it on their own next year. The second half of the 500 communities needed more indi-

vidual attention because their staff was not able to leave their j obs for a day, or they were too small to have staff. Keep in mind, that many of these towns don't have computers, have never heard of the Consumer Confidence Report, and have priorities of their own. This was the case in Cato, a circuit rider technician traveled to Cato and using his expertise and laptop, walked the village clerk and the water operator through the process, so that they could publish the report and comply with the rule. Across the country, rural water circuit riders assisted tens of thousands of small communities in a similar fashion. The result was a compliance rate for the rule higher than anyone had anticipated.

The second way to implement this rule is simply to send a letter to all the systems informing them of the rule and giving them an arbitrary compliance date. And following up that letter with another one from EPA saying: "you are in violation of the CCR rule . . . your system could be subject to Federal formal enforcement actions . . . [which] carry potential penalties of up to $25,000 per day."

This so-called Consumer Confidence Rule, is just one of many that EPA has promulgated—some are over 100 Federal register pages. Small towns depend on rural water assistance for help with EPA's complicated rules. What is working in small towns is providing common-sense assistance in a form they can understand and afford.

Last year, rural water technicians and Circuit Riders made over 50,000 ON-SITE contacts with small and rural water/wastewater systems. This is the only useful assistance many of these communities ever receive. Often the contacts result in important public health protection, substantial money savings to the community, avoidance of EPA fines, and enhanced long-term viability of the system.

I would like to again thank the committee for this hearing, ask for your continued support for additional technical resources to the grassroots level, your assistance to clarify the intent and meaning of key provision in the 96 Amendments, and your resistance to calls from special interest groups for more and more, ever stringent Federal unfunded mandates on communities. Unfortunately things aren't that simple. The key to long-term improvement is local support, local education and available resources.

STATEMENT OF THE CITY OF ALBUQUERQUE, NM

The City is committed to protecting the health and welfare of our citizens and appreciates the opportunity to testify regarding the proposed revision to the drinking water standard for arsenic. Our water system serves more than 450,000 residents through a distributed network of 92 wells and 45 reservoirs. The majority of these facilities are located in existing neighborhoods adjacent to residences, businesses and schools. Although the City has successfully implemented water conservation measures and is working toward direct use of our San Juan-Chama water, we pumped more than 3 8 billion gallons of water from the underlying aquifer in 1999.

Arsenic is a naturally occurring element in our ground water with concentrations ranging from 2 to 50 parts per billion (ppb). The EPA proposal to lower the maximum contaminant level (MCL) from 50 ppb to 5 ppb will impact about 70 percent of the wells at an estimated cost of compliance between $190 and $380 million ($20/month/customer). At a standard of 20 ppb, the City's cost is estimated to ranges from $40 to $70 million ($5/month/customer). Our cost of compliance estimates, which are based on 3 years of research in Albuquerque by the University of Houston, thousands of water quality samples, and cost estimates developed by local and national experts, attempted to address some of the issues that EPA has refused to estimate. For example, EPA has refused to develop and include the cost for acquisition of new land for construction of the facilities, increase in arsenic concentrations with depth in the aquifer and acquisition of new water supplies to offset water lost during treatment. One serious question that is still unresolved is the disposal of the residuals. Is the residual arsenic in the waste stream going to be considered a hazardous waste? If the answer is yes, the City's cost of compliance figures do not reflect the need to transport hazardous waste out of New Mexico because there are currently no permitted hazardous waste facilities that can safely dispose of the residuals in New Mexico.

According to EPA, the high national costs for water treatment are justified because they prevent arsenic-related bladder and lung cancer cases and deaths. EPA estimated arsenic-related risks by extrapolating bladder cancer study results from populations in southern Taiwan consuming high water borne arsenic levels as compared to U.S. populations consuming low waterborne arsenic. A linear statistical model was used to extrapolate from high to low dose arsenic exposures. Although there is considerable evidence suggesting that the arsenic dose-response relationship

for cancer is sub-linear, EPA acknowledges this problem and states "because current data on potential modes of action are supportive of sub-linear extrapolation, the linear approach could overestimate risk at low doses". They also note that the overestimate "makes an increasing difference as dose decreases". Given the uncertainty in the model, EPA concludes that "decisions about safe levels are public health policy judgments".

While EPA has concluded that they have overestimated the risks by using the linear approach, there are other uncertainties with the health science. The Taiwan study was a ecological epidemiological study where the actual waterborne arsenic levels for each person were not known, but were estimated. Based on the findings from a study completed in Millard County, Utah, one could argue that the results from a study of arsenic health effects in Taiwan cannot be extrapolated to the U.S. More specifically, no evidence of increased cancer risk has been seen in studies of U.S. populations exposed to low levels of drinking water arsenic.

When the Nation invests in public health programs, such as the revised arsenic MCL, it is critical that the projected benefits be certain. The best science should be applied before a standard is adopted. In fact, the costs of achieving a 5 ppb MCL for arsenic range from 93 to 374 times the $50,000 per year cost criteria used to evaluate other public health and medical intervention programs. Only for an MCL of 20 ppb can we estimate that the most optimistic assumptions of benefits, with no discounting for the delay in observing the benefits, meets EPA's own cost-effectiveness criteria.

Given the fact that EPA acknowledges that they have overestimated the risks in the U.S., the City feels strongly that Congress should investigate how EPA is meeting the science requirements as directed by the Amendments to the 1996 Safe Drinking Water Act. In addition, we recommend that the MCL be set at 20 ppb in the interim until the necessary research is completed for reevaluation of the standard in 6 years.

AMERICAN DENTAL ASSOCIATION,
July 13, 2000.

The Honorable MICHAEL CRAPO, *Chairman,*
Subcommittee on Fisheries, Wildlife, and Drinking Water,
Environment and Public Works Committee,
U.S. Senate,
Washington, DC 20510

RE: "Safe Drinking Water Act", June 29, 2000

DEAR MR. CHAIRMAN: The American Dental Association (ADA) has endorsed fluoridation oaf community water systems for 50 years as a safe and effective way to prevent tooth decay. Fluoride is nature's cavity fighter, occurring naturally in the earth's crust, in combination with other minerals in rocks and soil. Small amounts of fluoride occur naturally in all foods and beverages. Water fluoridation is the process of adjusting the natural level of fluoride to a concentration sufficient to protect against tooth decay, a range of from 0.7 parts per million (ppm) to 12 ppm.

Thanks in large part to community water fluoridation, half of all children ages 5 to 17 have never had a cavity in their permanent teeth. According to the April 2000 Journal of Dental Research, She use of fluorides in the past 40 years has been the primary factor in saving some $40 billion in oral health case costs in the 1 United States.

Just last month, Surgeon General David Satcher wrote in his report, *Oral Health Care in America*, "Community water fluoridation is safe and effective in preventing dental caries in both children and adults. Water fluoridation benefits all residents served by community water supplies regardless of their social or economic status."

Revised national health objectives in *Healthy People 2010* again include objectives to improve the nation's oral health. *Oral Health Objective 9* states that at least 75 percent of the population should be receiving the benefits of optimally fluoridated water by the year 2010. According to the most recent Centers for Disease Control and Prevention (CDC) Fluoridation Census, only 62 percent of the population served by public water systems has access to fluoridated water.

After 50 years of research and practical experience, the preponderance of scientific evidence indicates that fluoridation of community water supplies is both safe and effective. Methods and populations differ, but studies show that water fluoridation can reduce decay in baby teeth by as much as 60 percent and can reduce tooth decay in permanent teeth by nearly 35 percent.

Even before the first community fluoridation program began in 1945, epidemiological data from the 1930's and 1940's revealed lower decay rates in children con-

suming naturally occurring fluoridated water compared to children consuming fluoride-deficient water.

Since that time, innumerable studies have been conducted to demonstrate the safety and/or effectiveness of water fluoridation. Three outstanding reviews of community water fluoridation are:

- Newbrun E. Effectiveness of water fluoridation. J Public Health Dent 1989; 49(5):279–89. (Results of 113 studies in 23 countries were analyzed.)
- Ripa LW. A half-century of community water fluoridation in the United States: review and commentary. J Public Health Dent 1993; 53(1): 17–44. (Analysis of 50-year history of community water fluoridation.)
- Murray JJ. Efficacy of preventive agents for dental caries. Caries Res 1993; 27(Suppl 1):2–8. (Review of studies conducted from 1976 through 1987.)

Numerous large-scale epidemiological studies of water fluoridation have been conducted, making fluoridation one of the most widely studied public health measures. Because these large investigations have been consistently validated, water fluoridation is not as frequently studied as in past decades. Water fluoridation is a perfect example of how well designed studies stand the test of time and scientific scrutiny. Studies included in the review articles listed continue to be referenced today and have become "classics" in the public health field.

Many well-documented studies have compared the decay rates of children before and after fluoridation in the same community, as well as with children in naturally fluoridated and/or nonfluoridated communities. Because of the high geographic mobility of our populations and the widespread use of fluoride toothpastes, supplements and other topical agents, such comparisons are becoming more difficult to conduct.

Although other forms of fluoride are available, persons in nonfluoridated communities continue to demonstrate higher dental decay rates than their counterparts in communities with water fluoridation as determined in the following studies:

- Brunelle JA, Carlos JP. Recent trends in dental caries in U.S. children and the effect of water fluoridation. J Dent Res 1990; 69(Spec Iss):723–7. (Review of 1987 survey of 40,000 school children compared to survey in 1979–80.)
- Horowitz HS. The effectiveness of community water fluoridation in the United States. J Public Health Dent 1996 Spec Iss; 56(5):253–8. (Review of 50 years of water fluoridation.)
- Selwitz RH, Nowjack-Raymer RE, Kingman A, Driscoll WS. Dental caries and dental fluorosis among schoolchildren who were lifelong residents of communities having either low or optimal levels of fluoride in drinking water. J Public Health Dent 1998; 58(1):28–35. (Review of tooth decay experience between children who were lifelong residents of optimally fluoridated communities versus those who were lifelong residents of communities having low fluoride levels in drinking water.)

The safety and/or effectiveness of community water fluoridation have been examined not only in communities within the US, but also in other communities worldwide. Below are several international studies of community water fluoridation:

- Fluoride, teeth and health. Royal College of Physicians. Pitman Medical, London; 1976. (There is no evidence of a relationship between water fluoridation and congenital malformations, thyroid disorders, cancers or allergies.)
- Knox KG. Fluoridation of water and cancer: a review of the epidemiological evidence. Report of the Working Party. London: Her Majesty's Stationary Office; 1985. (Neither fluoride occurring naturally in water, nor fluoride added to water supplies, is capable of inducing cancer, or of increasing the mortality from cancer.)
- Spencer AJ, Slade GD, Davies M. Water fluoridation in Australia. Comm Dent Health 1996; 13(Suppl 2):27–37. (Water fluoridation is the most effective and socially equitable means of achieving community wide reductions in dental decay.)
- World Health Organization. Fluorides and oral health. Report of a WHO Expert Committee on Oral Health Status and Fluoride Use. WHO Technical Report Series 846. Geneva; 1994. (Water fluoridation is the most effective method of reaching an entire population so that all social classes benefit without the need for active participation on the part of individuals. It is essential that water fluoridation have the support of the leading health authorities and of the government.)

Mr. Chairman, community water fluoridation plays an important role in the health of infants and toddlers. Early childhood caries (ECC) is a serious socio-behavioral and dental problem that afflicts infants and toddlers in many communities and populations in the United States and other countries. The condition reaches epidemic proportions in low-income and Native American communities in the United States. Known also as baby bottle tooth decay or nursing bottle mouth, the condition is characterized by severe decay, especially in the upper front teeth, which can re-

sult in tooth loss in infants and toddlers. Water fluoridation has been identified as the most highly recommended preventive strategy for early childhood caries.

• Ismail AI. Prevention of early childhood caries. Community Dent Oral Epidemiol 1998; 26(Suppl 1):49–61. (Water fluoridation provides the only means of ECC prevention that does not require a dental visit or parental motivation.)

From time to time, the safety and effectiveness of water fluoridation has been questioned. None of these charges has ever been substantiated by generally accepted science. It is important to review information about fluoridation with a critical eye.

Recently, extensive investigative reports found no scientific evidence that exposure to fluoride at the levels found in optimally fluoridated water presents any risk for the development of any disease process.

There have been claims that exposure to fluoride presents a neurotoxic (harmful or damaging to nerve tissue) risk or lowered intelligence. Such claims are based on a 1995 study (Mullenix PJ, Denbesten PK, Schunior A, Kernan WJ. Neurotoxicity of sodium fluoride in rats. Neurotoxicol Teratol 1995; 17(2): 169–77) in which rats were fed fluoride at levels up to 125 times greater than that found in optimally fluoridated water. The study attempted to demonstrate that rats fed extremely high levels of fluoride (75 ppm to 125 ppm in drinking water) showed behavior-specific changes related to cognitive deficits. These amounts are far in excess of the U.S. Public Health Service recommended fluoride levels of 0.7 to 1.2 ppm in water systems.

In addition, the experiment also studied the offspring of rats who were injected two to three times a day with fluoride during their pregnancies in an effort to show that prenatal exposure resulted in hyperactivity in male offspring. Independent scientific review of this finding did not support the conclusions made by the authors and discounts the potential of sodium fluoride as a potential neurotoxicant. (Ross JF, Daston GP. Neurotoxicology and Teratology 1995; 17(6): 685–6.) (Whitford GM. The metabolism and toxicity of fluoride, 2nd rev. ed. Monographs in oral science, Vol. 16. Basel, Switzerland: Karger; 1996.)

Other studies attempted to link fluoride exposure to direct effects of the brain. One such 1998 study raised concerns about potential relationships between aluminum-fluoride and sodium-fluoride and Alzheimer's disease. (Warner JA, Jensen KF, Horvath W. Isaacson RL. Chronic administration of aluminum-fluoride or sodium-fluoride to rats in drinking water: alterations in neuronal and cerebrovascular integrity. Brain Res 1998; 784: 284–98.) Upon further review by other scientists, the study was found to contain major flaws in the experimental design, making it impossible for any definitive conclusions to be drawn. (American Dental Association, Health Media Watch: Study linking fluoride and Alzheimer's under scrutiny. J Am Dent Assoc 1998; 129: 1216–8). The study also conflicts with the position of the Alzheimer's Disease Foundation, which states that there is little evidence to suggest that aluminum has a causative role in the disease.

Another study related to the comparison of fluoridated versus non-fluoridated communities in upstate New York (Schlesinger ER, Overton DE, Chase HC, Cantwell KT. Newburgh-Kingston caries-fluorine study XIII: pediatric findings after 10 years. J Am Dent Assoc 1956; 52:296–306). The original study noted a 5-month difference in the average age of menarche between girls from the two cities, which the authors indicated as "not statistically significant."

One risk that has been attributed to water fluoridation is the possible formation of very mild dental fluorosis on permanent teeth in about 13 percent of children. Dental fluorosis is not a health effect; it is a cosmetic effect usually unnoticeable by untrained examiners. Mild dental fluorosis is characterized by nearly imperceptible white flecks in the enamel of permanent teeth. The risk of dental fluorosis can be greatly reduced by simple steps and without denying children the benefits of water fluoridation.

In 1997, the Food and Nutrition Board of the Institute of Medicine developed a comprehensive set of reference values for dietary nutrient intakes. These new reference values, the Dietary Reference Intakes (DRI), replace the Recommended Dietary Allowances (RDA) that had been set by the National Academy of Sciences since 1941. The new values present nutrient requirements to optimize health and, for the first time, set maximum-level guidelines to reduce the risk of adverse effects from excessive consumption of a nutrient. Along with calcium, phosphorous, magnesium and vitamin D, DRIs for fluoride were established because of its proven effect on tooth decay.

Mr. Chairman, the ADA's policies regarding community water fluoridation are based on generally accepted scientific knowledge. This body of knowledge is based on the efforts of nationally recognized scientists who have conducted research using the scientific method, have drawn appropriate balanced conclusions based on their

research findings and have published their results in peer-reviewed professional journals that are widely held or circulated. Confirmation of scientific findings also reinforces the validity of existing studies.

With the advent of the Information Age, a new type of "pseudo-scientific literature" has developed. The public often sees scientific and technical information quoted in the press, printed in a letter to the editor or distributed via an Internet Web page. Often the public accepts such information as true simply because it is in print. Yet the information is not always based on research conducted according to the scientific method, and the conclusions drawn from research are not always scientifically justifiable. In the case of water fluoridation, an abundance of misinformation has been circulated. Therefore, scientific information from all print and electronic sources must be critically reviewed before conclusions can be drawn.

We have attached a copy of the ADA's recent publication Fluoridation Facts to provide additional information concerning the safety and effectiveness of community water fluoridation. Nearly 100 national and international organizations recognize the public health benefits of fluoridation for preventing dental decay. We would appreciate your including this along with our letter in the hearing record.

Sincerely,

RICHARD F. MASCOLA, D.D.S. *President.*
JOHN S. ZAPP, D.D.S. *Executive Director.*

[From the American Dental Association, Council on Access, Prevention and Interprofessional Relations]

FLUORIDATION FACTS

INTRODUCTION

Background

Since 1956, the American Dental Association (ADA) has published *Fluoridation Facts*. Revised periodically, *Fluoridation Facts* answers frequently asked questions about community water fluoridation. In this 1999 edition, the ADA Council on Access, Prevention and Interprofessional Relations provides updated information for individuals and groups interested in the facts about fluoridation. The United States now has over 50 years of practical experience with community water fluoridation. Its remarkable longevity is testimony to fluoridation's significance as a public health measure.

Important points to remember about fluoride and community water fluoridation are:

- Fluoridation is considered beneficial by the over-whelming majority of the health and scientific communities as well as the general public.
- Fluoride helps prevent tooth decay. All ground and surface water in the U.S. contains some naturally occurring fluoride. If a community's water supply is fluoride-deficient (less than 0.7 parts fluoride per million parts water) fluoridation simply adjusts the fluoride's natural level, bringing it to the level recommended for decay prevention (0.7–1.2 parts per million).
- Fluoridation is a community health measure that benefits children and adults. Simply by drinking optimally fluoridated water, members of a community benefit, regardless of income, education or ethnicity—not just those with access to dental care.
- Fluoridation protects over 360 million people in approximately 60 countries worldwide, with over 10,000 communities and 145 million people in the United States alone.[1]
- As with other nutrients, fluoride is safe and effective when used and consumed properly. From time to time, opponents of fluoridation have questioned its safety and effectiveness. None of these charges has ever been substantiated by generally accepted science. After 50 years of research and practical experience, the overwhelming weight of scientific evidence indicates that fluoridation of community water supplies is both safe and effective.
- Just 50 cents per person per year covers the cost of fluoridation in an average community. Over a lifetime, that is the approximate price of one dental filling, making fluoridation very cost effective.
- Time and time again, public opinion polls show an overwhelming majority of Americans support water fluoridation.[2]

Support for Water Fluoridation

Since 1950, the American Dental Association (ADA), along with the United States Public Health Service (USPHS), has continuously and unreservedly endorsed the optimal fluoridation of community water supplies as a safe and effective public health measure for the prevention of dental decay. The ADA's policy on fluoridation is based on its continuing evaluation of the scientific research on the safety and effectiveness of fluoride. Over the years, and as recently as 1997, the ADA has continued to reaffirm its position of support for water fluoridation and has strongly urged that its benefits be extended to communities served by public water systems.[3] Today, fluoridation is the single most effective public health measure to prevent tooth decay and to improve oral health over a lifetime.

The American Dental Association, the U.S. Public Health Service, the American Medical Association and the World Health Organization all support community water fluoridation. Other national and international health, service and professional organizations that recognize the public health benefits of community water fluoridation for preventing dental decay are listed on the inside back cover of this publication.

Scientific Information on Fluoridation

The ADA's policies regarding community water fluoridation are based on generally accepted scientific knowledge. This body of knowledge is based on the efforts of nationally recognized scientists who have conducted research using the scientific method, have drawn appropriate balanced conclusions based on their research findings and have published their results in refereed (peer-reviewed) professional journals that are widely held or circulated. Confirmation of scientific findings also reinforces the validity of existing studies.

From time to time, opponents of fluoridation have questioned its safety and effectiveness. None of these charges has ever been substantiated by generally accepted science. It is important to review information about fluoridation with a critical eye. Listed below are several key elements to consider when reviewing information about fluoride research.

1. The author's background and credentials should reflect expertise in the area of research undertaken.
2. The year of the publication should be apparent. The information should be relatively current, although well-designed studies can stand the test of time and scientific scrutiny (e.g. overwhelming evidence already exists to prove the effectiveness of water fluoridation). A review of existing literature can provide insight into whether the results of older studies have been superceded by subsequent studies.
3. If the information is a review of other studies, it should be representative of the original research. Information quoted directly from other sources should be quoted in its entirety.
4. The research should be applicable to community water fluoridation and use an appropriate type and amount of fluoride. Many research projects investigate the use of fluoride at much higher levels than recommended for community water fluoridation. For example, the results of a study using a concentration of 125 parts per million (ppm) doses of fluoride are not comparable to water fluoridated at 0.7 to 1.2 ppm.
5. How the research is conducted is relevant. Research conducted in vitro (outside the living body and in a laboratory environment) may not lead to the same results as research conducted in viva (in a living human or other animal).
6. Animal studies should be carefully reviewed. In animal studies (e.g., rodent), excessively high doses of fluoride are sometimes used. In addition, the fluoride used in these experiments is often administered by means other than in drinking water (e.g. by injection). Information obtained in animal studies may be highly questionable as a predictor of the effects of human exposure to low concentrations of fluoride, such as those used to fluoridate water.
7. Publications presenting scientific information should have an editorial review board to help ensure that scientifically sound articles are published.
8. The publication should be easily obtainable through a medical/dental library.

With the advent of the Information Age, a new type of "pseudo-scientific literature" has developed. The public often sees scientific and technical information quoted in the press, printed in a letter to the editor or distributed via an Internet Web page. Often the public accepts such information as true simply because it is in print. Yet the information is not always based on research conducted according to the scientific method, and the conclusions drawn from research are not always scientifically justifiable. In the case of water fluoridation, an abundance of misinformation has been circulated. Therefore, scientific information from all print and electronic sources must be critically reviewed before conclusions can be drawn. Pseu-

do-scientific literature may peak a reader's interest but when read as science, it can be misleading. The scientific validity and relevance of claims made by opponents of fluoridation might be best viewed when measured against criteria set forth by the U.S. Supreme Court. (Additional discussion on this topic may be found in Question 36.)

Fluoridation Facts is designed to answer frequently asked questions about fluoridation by summarizing relevant published articles as indicated by numbered references within the document. A corresponding list of references appears in the back of the booklet.

Fluoridation Facts is not intended to include and review the extensive literature on community water fluoridation and fluorides.

History of Water Fluoridation

Research into the beneficial effects of fluoride began in the early 1900's. Frederick McKay, a young dentist, opened a dental practice in Colorado Springs, Colorado, and was surprised to discover that many local residents exhibited strange brown stains on their permanent teeth. McKay could find no documentation of the condition in the dental literature and eventually convinced Dr. G.V. Black, an expert on dental enamel, to study the condition. Through their research, Black and McKay determined that mottled enamel, as Black termed the condition, resulted from developmental imperfections in teeth. (Mottled enamel is a historical term. Today, this condition is called severe dental fluorosis.) Black and McKay also noted that these stained teeth were surprisingly resistant to decay.

Following years of observation and study, McKay determined that it was high levels of naturally occurring fluoride in the drinking water that was causing the mottled enamel. McKay's deductions were researched by Dr. H. Trendley Dean, a dental officer of the U.S. Public Health Service. Dean designed the first fluoride studies in the United States. These early studies were aimed at evaluating how high the fluoride levels in water could be before visible, severe dental fluorosis occurred. By 1936, Dean and his staff had made the critical discovery that fluoride levels of up to 1.0 part per million (ppm) in the drinking water did not cause mottling, or severe dental fluorosis. Dean additionally noted a correlation between fluoride levels in the water and reduced incidence of dental decay.[4] [5] Following Dean's initial findings, community-wide studies were carried out to evaluate the addition of sodium fluoride to fluoride-deficient water supplies. The first community water fluoridation program began in Grand Rapids, Michigan, in 1945.[6] [7]

Water Fluoridation as a Public Health Measure

Throughout decades of research and more than 50 years of practical experience, fluoridation of public water supplies has been responsible for dramatically improving the public's oral health status. In 1998, recognizing the ongoing need to improve health and well being, the U.S. Public Health Service revised national health objectives to be achieved by the year 2010. Included under oral health was an objective to significantly expand the fluoridation of public water supplied In 1994, the U.S. Department of Health and Human Services issued a report which reviewed public health achievements. Along with other successful public health measures such as the virtual eradication of polio and reductions in childhood blood lead levels, fluoridation was lauded as one of the most economical preventive values in the nations Finally, a policy statement on water fluoridation reaffirmed in 1995 by the USPHS stated that water fluoridation is the most cost-effective, practical and safe means for reducing the occurrence of tooth decay in a community.[10]

Simply by drinking optimally fluoridated water, the entire community benefits regardless of age, socioeconomic status, educational attainment or other social variables.[11] Community water fluoridation does not discriminate against anyone based on income, education or ethnicity. Fluoridation's benefits are realized without behavior change on the part of an individual. The benefits of water fluoridation are not limited to those with access to dental care.

Water Fluoridation's Role in Reducing Dental Decay

Water fluoridation and the use of topical fluoride have played a significant role in improving oral health. Studies show that water fluoridation can reduce the amount of cavities children get in their baby teeth by as much as 60 percent; and can reduce tooth decay in permanent adult teeth by nearly 35 percent. Increasing numbers of adults are retaining their teeth throughout their lifetimes due in part to the benefits they receive from water fluoridation. Dental expenditures for these individuals are likely to have been reduced and innumerable hours of needless pain and suffering due to untreated dental decay have been avoided.

It is important to note that dental decay is caused by dental plaque, a thin, sticky, colorless deposit of bacteria that constantly forms on teeth. When sugar and carbo-

hydrates are eaten, the bacteria in plaque produce acids that attack the tooth enamel. After repeated attacks, the enamel breaks down, and a cavity (hole) is formed. There are several factors that increase an individual's risk for decay: [12]

- Recent history of dental decay
- Elevated oral bacteria count
- Inadequate exposure to fluorides
- Exposed roots
- Frequent sugar and carbohydrate intake
- Fair to poor oral hygiene
- Inadequate saliva flow
- Deep pits and fissures in the chewing surfaces of teeth

Exposure to fluoride is not the only measure available to decrease the risk of decay. In formulating a decay prevention program, a number of intervention strategies may be recommended.

Ongoing Need for Water Fluoridation

Because of the decay risk factors noted previously, many individuals and communities skill experience high levels of dental decay. Although water fluoridation demonstrates an impressive record of effectiveness and safety, only 62.2 percent of the United States population on public water supplies receives fluoridated water containing protective levels of fluoride.[13] Unfortunately, some people continue to be confused about this effective public health measure. If the number of individuals drinking fluoridated water is to increase, the public must be accurately informed about its benefits.

Question 1. What is fluoride and how does it reduce tooth decay?

Answer. Fluoride is a naturally occurring element that prevents tooth decay systemically when ingested during tooth development and topically when applied to erupted teeth.

Fact

The fluoride ion comes from the element fluorine. Fluorine, the 17th most abundant element in the earth's crust, is a gas and never occurs in its free state in nature. Fluorine exists only in combination with other elements as a fluoride compound. Fluoride compounds are constituents of minerals in rocks and soil. Water passes over rock formations and dissolves the fluoride compounds that are present, creating fluoride ions. The result is that small amounts of soluble fluoride ions are present in all water sources, including the oceans. Fluoride is present to some extent in all foods and beverages, but the concentrations vary widely. [14] [15] [16]

Simply put, fluoride is obtained in two forms: topical and systemic. Topical fluorides strengthen teeth already present in the mouth. In this method of delivery, fluoride is incorporated into the surface of teeth making them more decay-resistant. Topically applied fluoride provides local protection on the tooth surface. Topical fluorides include toothpastes, mouthrinses and professionally applied fluoride gels and rinses.

Systemic fluorides are those that are ingested into the body and become incorporated into forming tooth structures. In contrast to topical fluorides, systemic fluorides ingested regularly during the time when teeth are developing are deposited throughout the entire surface and provide longer-lasting protection than those applied topically.[17] Systemic fluorides can also give topical protection because ingested fluoride is present in saliva, which continually bathes the teeth providing a reservoir of fluoride that can be incorporated into the tooth surface to prevent decay. Fluoride also becomes incorporated into dental plaque and facilitates further remineralization.[18] Sources of systemic fluorides include water, dietary fluoride supplements in the forms of tablets, drops or lozenges, and fluoride present in food and beverages.

Researchers have observed fluoride's decay preventive effects through three specific mechanisms:[19] [20]

1. it reduces the solubility of enamel in acid by converting hydroxyapatite into less soluble fluorapatite;

2. it exerts an influence directly on dental plaque by reducing the ability of plaque organisms to produce acid; and

3. it promotes the remineralization or repair of tooth enamel in areas that have been demineralized by acids.

The remineralization effect of fluoride is of prime importance. Fluoride ions in and at the enamel surface result in fortified enamel that is not only more resistant to decay, but enamel that can repair or remineralize early dental decay caused by acids from decay-causing bacteria.[17] [21] [25] Fluoride ions necessary for remineraliza-

tion are provided by fluoridated water as well as various fluoride products such as toothpaste.

Maximum decay reduction is produced when fluoride is available for incorporation during all stages of tooth formation (systemically) and by topical effect after eruption.[26]

Question 2. What is water fluoridation?

Answer. Water fluoridation is the adjustment of the natural fluoride concentration of fluoridedeficient water to the level recommended for optimal dental health.

Fact

Based on extensive research, the United States Public Health Service (USPHS) established the optimum concentration for fluoride in the water in the United States in the range of 0.7 to 1.2 parts per million.* This range effectively reduces tooth decay while minimizing the occurrence of dental fluorosis. The optimum level is dependent on the annual average of the maximum daily air temperature in the geographic area.[27]

* One milligram per liter (mg/L) is identical to one part per million (ppm). At 1 ppm, one part of fluoride is diluted in a million parts of water. Large numbers such as a million can be difficult to visualize. While not exact, the following comparisons can be of assistance in comprehending one part per million:

- 1 inch in 16 miles
- 1 minute in 2 years
- 1 cent in $10,000

For clarity, the following terms and definitions are used in this booklet:

Community water fluoridation is the adjustment of the natural fluoride concentration in water up to the level recommended for optimal dental health (a range of 0.7 to 1.2 ppm).Other terms used interchangeably in this booklet are water fluoridation, fluoridation and optimally fluoridated water. Optimal levels of fluoride (a range of 0.7 to 1.2 ppm) may be present in the water naturally or by adjusted means. (Additional discussion on this topic may be found in Question 3.)

Sub-optimally fluoridated water is water that contains less than the optimal level (below 0.7 ppm) of fluoride. Other terms used interchangeably in this booklet are nonfluoridated water and fluoridedeficient water supplies.

(Additional discussion on this topic may be found hi Question 32.)

Question 3. Is there a difference in the effectiveness between naturally occurring fluoridated water (at optimal fluoride levels) and water that has fluoride added to reach the optimal level?

Answer. No. The dental benefits of optimally fluoridated water occur regardless of the fluoride's source.

Fact

Fluoride is present in water as "ions" or electrically charged atoms.[27] These ions are the same whether acquired by water as it seeps through rocks and sand or added to the water supply under carefully controlled conditions. When fluoride is added under controlled conditions to fluoride-deficient water, the dental benefits are the same as those obtained from naturally fluoridated water. Fluoridation is merely a supplementation of the naturally occurring fluoride present in all drinking water sources.

Some individuals mistakenly use the term "artificial fluoridation" to imply that the process of water fluoridation is unnatural and that it delivers a foreign substance into a water supply when, in fact, all water sources contain some fluoride. Community water fluoridation is a natural way to improve oral health.[28] (Additional discussion on this topic may be found in Question 32.)

Prior to the initiation of "adjusted" water fluoridation, several classic epidemiological studies were conducted that compared naturally occurring fluoridated water to fluoride-deficient water. Strikingly low decay rates were found to be associated with the continuous use of water with fluoride content of 1 part per million.[5]

A fluoridation study conducted in the Ontario, Canada, communities of Brantford (optimally fluoridated by adjustment), Stratford (optimally fluoridated naturally) and Sarnia (fluoridedeficient) revealed much lower decay rates in both Brantford and Stratford as compared to nonfluoridated Sarnia. There was no observable difference in decay-reducing effect between the naturally occurring fluoride and adjusted fluoride concentration water supplies, proving that dental benefits were similar regardless of the source of fluoride.[29]

Question 4. Is further proof of the effectiveness of water fluoridation needed?

Answer. Overwhelming evidence already exists to prove the effectiveness of water fluoridation.

Fact

The effectiveness of water fluoridation has been documented in scientific literature for well over 50 years. Even before the first community fluoridation program began in 1945, epidemiologic data from the 1930's and 1940's revealed lower decay rates in children consuming naturally occurring fluoridated water compared to children consuming fluoride deficient water.[4] [5] Since that time, numerous studies have been done which continue to prove fluoride's effectiveness in decay reduction. Three selected reviews of this work follow.

In 1993, the results of 113 studies in 23 countries were compiled and analyzed.[30] (Fifty-nine out of the 113 studies analyzed were conducted in the United States.) This review provided effectiveness data for 66 studies in primary teeth and for 86 studies in permanent teeth. Taken together, the most frequently reported decay reductions observed were:

40–49 percent for primary teeth or baby teeth; and
50–59 percent for permanent teeth or adult teeth.

In a second review of studies conducted from 1976 through 1987,[3] for different age groups were isolated, the decay reduction rates in fluoridated communities were:

30–60 percent in the primary dentition or baby teeth;
20–40 percent in the mixed dentition* (aged 8 to 12);
15–35 percent in the permanent dentition or adult teeth (aged 14 to 17); and
15–35 percent in the permanent dentition (adults and seniors).
(*A mixed dentition is composed of both baby teeth and adult teeth.)

Lastly, a comprehensive analysis of the fifty-year history of community water fluoridation in the United States further demonstrated that the inverse relationship between higher fluoride concentration in drinking water and lower levels of dental decay discovered a half-century ago continues to be true today.[32]

(Additional discussion on this topic may be found in Question 6.)

Many well-documented studies have compared the decay rates of children before and after fluoridation in the same community, as well as with children in naturally fluoridated and/or nonfluoridated communities. The earlier studies were conducted at a time when sources of topical fluoride, such as toothpastes, mouthrinses and professionally applied fluoride gels were not available. The results from these early studies were dramatic. Over the years, as sources of topical fluoride became more readily available, the decay reductions observed in these comparative evaluations, although still significant, tapered off. Because of the high geographic mobility of our populations and the widespread use of fluoride toothpastes, supplements and other topical agents, such comparisons are becoming more difficult to conduct.[31]

Nevertheless, recent data continue to demonstrate that decay rates are higher for individuals who reside in nonfluoridated communities than that of individuals living in fluoridated communities.[30] [33] [36] The following paragraphs provide a sample of studies conducted in the subsequent decades on the effectiveness of water fluoridation.

In Grand Rapids, Michigan, the first city in the world to fluoridate its water supply, a 15-year landmark study showed that children who consumed fluoridated water from birth had 50–63 percent less tooth decay than children who had been examined during the original baseline survey.[37]

Ten years after fluoridation in Newburgh, New York, 6- to 9-year-olds had 58 percent less tooth decay than their counterparts in Kingston, New York, which was fluoride-deficient. After 15 years, 13- to 14-year-olds in Newburgh had 70 percent less decay than the children in Kingston.[33]

After 14 years of fluoridation in Evanston, Illinois, 14-year-olds had 57 percent fewer decayed, missing or filled teeth than control groups drinking water low in fluoride.[39]

In 1983, a study was undertaken in North Wales (Great Britain) to determine if the decay rate of fluoridated Anglesey continued to be lower than that of nonfluoridated Arfon, as had been indicated in a previous survey conducted in 1974. Decay rates of life-long residents in Anglesey aged 5, 12 and 15 were compared with decay rates of similar aged residents in nonfluoridated Arfon. Study results demonstrated that a decline in decay had occurred in both communities since the previous survey in 1974. However, the mean decay rate of the children in fluoridated Anglesey was still 45 percent lower than that of those living in nonfluoridated Arfon.[40] These findings indicated a continuing need for fluoridation although decay levels had declined.[41]

A controlled study conducted in 1990 demonstrated that average tooth decay experience among schoolchildren who were lifelong residents of communities having low fluoride levels in drinking water was 61–100 percent higher as compared with tooth

decay experience among schoolchildren who were lifelong residents of a community with an optimal level of fluoride in the drinking water.[36] In addition, the findings of this study suggest that community water fluoridation still provides significant public health benefits and that dental sealants can play a significant role in preventing tooth decay.

Using data from the dental surveys in 1991–2 and 1993–4, a British study predicted that on average, water fluoridation produces a 44 percent reduction in tooth decay in 5-year-old children. The study further demonstrated that children in lower socioeconomic groups derive an even greater benefit from water fluoridation with an average 54 percent reduction in tooth decay. Therefore, children with the greatest dental need benefit the most from water fluoridation.[42]

In 1993–4, an oral health needs assessment of children in California found that children living in nonfluoridated areas had more tooth decay than those in fluoridated areas.[43] Of most concern was the high decay rate affecting young children from low income families. Specifically, children in grades K–3, whose families were lifetime residents of nonfluoridated communities and whose income was below 200 percent of the Federal Poverty Level, had 39 percent more decay in their baby teeth when compared to counterparts who were lifetime residents of optimally fluoridated areas.[35]

Question 5. What happens if water fluoridation is discontinued?

Answer. Dental decay can be expected to increase if water fluoridation in a community is discontinued for 1 year or more, even if topical products such as fluoride toothpaste and fluoride rinses are widely used.

Fact

The following paragraphs provide a summary of some of the historical studies that have been conducted on the discontinuation of water fluoridation. Antigo, Wisconsin began water fluoridation in June 1949, and ceased adding fluoride to its water in November 1960. After 5½ years without optimal levels of fluoride, second grade children had over 200 percent more decay, fourth graders 70 percent more, and sixth graders 91 percent more than those of the same ages in 1960. Residents of Antigo reinstituted water fluoridation in October 1965 on the basis of the severe deterioration of their children's oral health.[44]

Because of a government decision in 1979, fluoridation in the northern Scotland town of Wick was discontinued after 8 years. The water was returned to its suboptimal, naturally occurring fluoride level of 0.02 ppm. Data collected to monitor the oral health of Wick children clearly demonstrated a negative health effect from the discontinuation of water fluoridation. Five years after the cessation of water fluoridation, decay in permanent (adult) teeth had increased 27 percent and decay in primary (baby) teeth increased 40 percent. This increase in decay occurred during a period when there had been a reported overall reduction in decay nationally and when fluoride toothpaste had been widely adopted.[45] These data suggest that decay levels in children can be expected to rise where water fluoridation is interrupted or terminated, even when topical fluoride products are widely used.

In a similar evaluation, the prevalence of decay in 10-year-old children in Stranraer, Scotland, increased after the discontinuation of water fluoridation, resulting in a 115 percent increase in the mean cost of restorative dental treatment for decay and a 21 percent increase in the mean cost of all dental treatment. These data support the important role water fluoridation plays in the reduction of dental decay.[46]

A U.S. study of 6- and 7-year-old children who had resided in optimally fluoridated areas and then moved to the nonfluoridated community of Coldwater, Michigan, revealed an 11 percent increase in decayed, missing or filled tooth surfaces (DMFS) over a 3-year period from the time the children moved. These data reaffirm that relying only on topical forms of fluoride is not an effective or prudent public health practice.[47] Decay reductions are greatest where water fluoridation is available in addition to topical fluorides, fluoride toothpaste and fluoride rinses.

Finally, a study that reported the relationship between fluoridated water and decay prevalence focused on the city of Galesburg, Illinois, a community whose public water supply contained naturally occurring fluoride at 2.2 ppm.In 1959, Galesburg switched its community water source to the Mississippi River. This alternative water source provided the citizens of Galesburg a suboptimal level of fluoride at approximately 0.1 ppm. During the time when the fluoride content was below optimal levels, data revealed a 10 percent decrease in the number of decay-free 14-year-olds (oldest group observed), and a 38 percent increase in dental decay. Two years later, in 1961, the water was fluoridated at the recommended level of 1.0 ppm. [48]

Question 6. Is water fluoridation still an effective method for preventing dental decay?

Answer. Water fluoridation continues to be a very effective method for preventing tooth decay for children, adolescents and adults. Continued assessment, however, is important as the patterns and extent of dental decay change in populations. Although other forms of fluoride are available, persons in nonfluoridated communities continue to demonstrate higher dental decay rates than their counterparts in communities with water fluoridation.

Fact

Numerous recent studies indicate a trend toward decreased decay prevalence in children living in the United States. This trend also has been reported for children in other developed countries. One of several factors that explains these findings is the increased use of fluorides, including water fluoridation and fluoride toothpaste. In studies conducted from 1976 through 1987,[31] the level of decay reduction achieved through water fluoridation in industrialized countries was:

30–60 percent in the primary dentition or baby teeth;
20–40 percent in the mixed dentition* (aged 8 to 12);
15–35 percent in the permanent dentition or adult teeth (aged 14 to 17); and
15–35 percent in the permanent dentition (adults and seniors). (*A mixed dentition is composed of both baby teeth and adult teeth)
(Additional discussion on this topic may be found in Question 4.)

Community water fluoridation remains the safest, most cost-effective and most equitable method of reducing tooth decay in a community in the United States and in other countries. [32] [34] [49] [50] [51] [52] A controlled study conducted in 1990 demonstrated that average tooth decay experience among schoolchildren who were lifelong residents of communities having low fluoride levels in drinking water was 61–100 percent higher as compared with tooth decay experience among schoolchildren who were lifelong residents of a community with an optimal level of fluoride in the drinking water.[36] In addition, the findings of this study suggest that community water fluoridation still provides significant public health benefits and that dental sealants can play a significant role in preventing tooth decay.

Baby bottle tooth decay is a severe type of early childhood decay that seriously affects babies and toddlers in some populations. Water fluoridation is highly effective in preventing decay in baby teeth, especially in children from low socioeconomic groups.[33] For very young children, water fluoridation is the only means of prevention that does not require a dental visit or motivation of parents and caregivers.[53]

In the 1940's, children in communities with optimally fluoridated drinking water had reductions in decay rates of approximately 60 percent as compared to those living in non-fluoridated communities. At that time, drinking water was the only source of fluoride other than fluoride that occurs naturally in foods. Recent studies reveal that decay rates are lower in naturally or adjusted fluoridated areas and nonfluoridated areas as well because of the universal availability of fluoride from other sources including food, beverages, dental products and dietary supplements.[54] Foods and beverages processed in optimally fluoridated cities can contain optimal levels of fluoride. These foods and beverages are consumed not only in the city where processed, but may be distributed to and consumed in non-fluoridated areas. "halo" or "diffusion" effect results in increased fluoride intake by people in nonfluoridated communities, providing them increased protection against dental decay.[32] [52] As a result of the widespread availability of these various sources of fluoride, the difference between decay rates in fluoridated areas and nonfluoridated areas is somewhat less than several decades ago but still significant.[55]

A British study conducted in 1987 compared the decay scores for 14-year-old children living in South Birmingham, fluoridated since 1964, with those of children the same age living in nonfluoridated Bolton. The two cities had similar social class profiles and similar proportions of unemployed residents and minority groups. The average decayed, missing, and filled tooth score for the children of South Birmingham was 2.26, compared to an average score of 3.79 for children in non-fluoridated Bolton. These scores indicate a statistically significant difference of 40 percent between the decay rates in the two cities. Because of the similarity in social and demographic factors, the investigators attributed difference in decay experience found in this study to differences in water fluoride level.[56]

In the United States, an epidemiological survey of nearly 40,000 schoolchildren was completed in 1987.[50] Nearly 50 percent of the children in the study aged 5 to 17 years were decay-free in their permanent teeth, which was a major change from a similar survey in 1980 in which approximately 37 percent were decayfree. This dramatic decline in decay rates was attributed primarily to the widespread use of fluoride in community water supplies, toothpastes, supplements and mouthrinses. Although decay rates had declined overall, data also revealed that the decay rate was 25 percent lower in children with continuous residence in fluoridated commu-

nities when the data was adjusted to control for fluoride exposure from supplements and topical treatments.

More recently, data from the Third National Health and Nutrition Examination Survey (NHANES III), conducted from 1988 to 1991, yielded weighted estimates for over 58 million U.S. children. Nearly 55 percent of the children aged 5 to 17 years had no decay in their permanent teeth.[57]

(Additional discussion on this topic may be found in Question 8.)

Question 7. Is tooth decay still a serious problem?

Answer. Yes. Tooth decay or dental decay is an infectious disease that continues to be a significant oral health problem.

Fact

Tooth decay is, by far, the most common and costly oral health problem in all age groups.[58] It is one of the principal causes of tooth loss from early childhood through middle age. A dramatic increase in tooth loss occurs among people 35 through 44 years of age. The two leading causes of tooth loss in this age group are dental decay and periodontal diseases.[8] Decay continues to be problematic for middle-aged and older adults, particularly root decay because of receding gums. In addition to its effects in the mouth, dental decay can affect general well-being by interfering with an individual's ability to eat certain foods and by impacting an individual's emotional and social well-being by causing pain and discomfort. Tooth decay, particularly in the front teeth, can detract from appearance, thus affecting self-esteem.

Despite a decrease in the overall decay experience of U.S. schoolchildren over the past two decades, tooth decay is still a significant oral health problem, especially in certain segments of the population. The 1986–1987 National Institute of Dental Research (NIDR) survey of approximately 40,000 U.S. school children found that 25 percent of students ages 5 to 17 accounted for 75 percent of the decay experienced in permanent teeth.[58] Some of the risk factors that increase an individual's risk for decay are irregular dental visits, deep pits and fissures in the chewing surfaces of teeth, inadequate saliva flow, frequent sugar intake and very high oral bacteria counts.

(Additional discussion on this topic may be found in the Introduction-Water Fluoridation's Role in Reducing Dental Decay.)

Because dental decay is so common, it mistakenly tends to be regarded as an inevitable part of life. Data from NHANES III collected on adults aged 18 and older revealed that 94 percent showed evidence of past or present decay in the crowns of teeth, and 22.5 percent had evidence of root surface decay.[59]

In addition to impacting emotional and social wellbeing, the consequences of dental disease are reflected in the cost of its treatment. The nation's dental health bill in 1997 was $50.6 billions the goal must be prevention rather than repair. Fluoridation is presently the most cost-effective method for the prevention of tooth decay for residents of a community in the United States.[61] [62]

Question 8. Do adults benefit from fluoridation?

Answer. Fluoridation plays a protective role against dental decay throughout life, benefiting both children and adults. In fact, inadequate exposure to fluoride places children and adults in the high risk category for dental decay.

Fact

Fluoride has both a systemic and topical effect and is beneficial to adults in two ways. The first is through the remineralization process in enamel, in which early decay does not enlarge, and can even reverse, because of frequent exposure to small amounts of fluoride. Studies have clearly shown that the availability of topical fluoride in an adult's mouth during the initial formation of decay can not only stop the decay process, but also make the enamel surface more resistant to future acid attacks. Additionally, the presence of systemic fluoride in saliva provides a reservoir of fluoride ions that can be incorporated into the tooth surface to prevent decay.[63]
(Additional discussion on this topic may be found in Question 1.)

Another protective benefit for adults is the prevention of root decay. Adults with gumline recession are at risk for root decay because the root surface becomes exposed to decay-causing bacteria in the mouth. Studies have demonstrated that fluoride is incorporated into the structure of the root surface, making it more resistant to decay.[19] [63] [64] [65] [66] In Ontario, Canada, lifelong residents of the naturally fluoridated (1.6 ppm) community of Stratford had significantly lower root decay experience than those living in the matched, but nonfluoridated, community of Woodstock.[65]

People in the United States are living longer and retaining more of their natural teeth than ever before. Because older adults experience more problems with gumline recession, the prevalence of root decay increases with age. A large number of ex-

posed roots or a history of past root decay places an individual in the high risk category for decay.[12] Data from the 1988–1991 National Health and Nutrition Examination Survey (NHANES III) showed that 22.5 percent of all adults with natural teeth experienced root decay. This percentage increased markedly with age:

1. in the 18- to 24-year-old age group, only 6.9 percent experienced root decay;
2. in the 35- to 44-year-old age group, 20.8 percent experienced root decay;
3. in the 55- to 64-year-old age group, 38.2 percent showed evidence of root decay; and
4. in the over–75 age group, nearly 56 percent had root decay.[59]

In addition to gumline recession, older adults tend to experience decreased salivary flow, or xerostomia, due to the use of medications or medical conditions.[67 68] Inadequate saliva flow places an individual in the high risk category for decay. This decrease in salivary flow can increase the likelihood of dental decay because saliva contains many elements necessary for early decay repair—including fluoride.

There are data to indicate that individuals who have consumed fluoridated water continuously from birth receive the maximum protection against dental decay. However, teeth present in the mouth when exposure to water fluoridation begins also benefit from the topical effects of exposure to fluoride. In 1989, a small study in the state of Washington suggested adults exposed to fluoridated water only during childhood had similar decay rates as adults exposed to fluoridated water only after age 14. This study lends credence to the topical and systemic benefits of water fluoridation. The topical effects are reflected in the decay rates of adults exposed to water fluoridation only after age 14. The study also demonstrates that the pre-eruptive, systemic effects of fluoridation have lifetime benefits as reflected in the decay rates of adults exposed to fluoridation only during childhood. The same study also noted a 31 percent reduction of dental disease (based on the average number of decayed or filled tooth surfaces) in adults with a continuous lifetime exposure to fluoridated water as compared to adults with no exposure to water fluoridation.[64]

A Swedish study investigating decay activity among adults in optimal and low fluoride areas revealed that not only was decay experience significantly lower in the optimal fluoride area, but the difference could not be explained by differences in oral bacteria, buffer capacity of saliva or salivary flow. The fluoride concentration in the drinking water was solely responsible for decreased decay rates.[69]

Water fluoridation contributes much more to overall health than simply reducing tooth decay: it prevents needless infection, pain, suffering and loss of teeth; improves the quality of life; and saves vast sums of money in dental treatment costs." Additionally, fluoridation conserves natural tooth structure by preventing the need for initial fillings and subsequent replacement fillings.[70]

Question 9. Are dietary fluoride supplements effective?

Answer. For children who do not live in fluoridated communities, dietary fluoride supplements are an effective alternative to water fluoridation for the prevention of tooth decay.[51 71 72 73]

Fact

Dietary fluoride supplements are available only by prescription and are intended for use by children living in nonfluoridated areas to increase their fluoride exposure so that it is similar to that by children who live in optimally fluoridated areas.[74] Dietary fluoride supplements are available in two forms: drops for infants aged 6 months and up, and chewable tablets for children and adolescents.[12] In order to decrease the risk of dental fluorosis in permanent teeth, fluoride supplements should only be prescribed for children living in nonfluoridated areas. The correct amount of a fluoride supplement is based on the child's age and the existing fluoride level in the drinking water. [16 54 75] Consideration should also be given to the child's risk for decay and to all sources of fluoride exposure for children. (An excellent source of information regarding decay risk assessment and prevention is the American Dental Association's "Caries Diagnosis and Risk Assessment: A Review of Preventive Strategies and Management." [12])

Because fluoride is so widely available, it is recommended that dietary fluoride supplements be used only according to the recommended dosage schedule and after consideration of all sources of fluoride exposure. For optimum benefits, use of supplements should begin at 6 months of age and be continued daily until the child is at least 16 years old.[12] The current dietary fluoride supplement schedule is shown in Table 1.

The need for compliance over an extended period of time is a major procedural and economic disadvantage of community-based fluoride supplement programs, one that makes them impractical as an alternative to water fluoridation as a public health measure. In a controlled situation, as shown in a study involving children of health professionals, fluoride supplements achieve effectiveness comparable to

that of water fluoridation. However, even with this highly educated and motivated group of parents, only half continued to give their children fluoride tablets for the necessary number of years.[76] Independent reports from several countries, including the United States, have demonstrated that community-wide trials of fluoride supplements in which tablets were distributed for use at home were largely unsuccessful because of poor compliance.[77]

While total costs for the purchase of supplements and administration of a program are small (compared with the initial cost of the installation of water fluoridation equipment), the overall cost of supplements per child is much greater than the per capita cost of community fluoridation.[62] In addition, community water fluoridation provides decay prevention benefits for the entire population regardless of age, socioeconomic status, educational attainment or other social variables.[11] This is particularly important for families who do not have access to regular dental services.

Table 1

Dietary Fluoride Supplement Schedule 1994[12]

Approved by the American Dental Association American Academy of Pediatrics American Academy of Pediatric Dentistry

Age	Fluoride ion level in drinking wafer (ppm)*		
	<0.3 ppm	0.3–0.6 ppm	>0.6 ppm
Birth–6 months	None	None	None
6 months–3 years	0.25 mg/day**	None	None
3–6 years	0.50 mg/day	0.25 mg/day	None
6–6 –16 years	1.0 mg/day	0.50 mg/day	None

* 1.0 part per million (ppm) = 1 milligram/liter (mg/L)
** 2.2 mg sodium fluoride contains 1 mg fluoride ion.

Question 10. In areas where water fluoridation is not feasible because of engineering constraints, are alternatives to water fluoridation available?

Answer. Yes. Some countries outside the United States that do not have piped water supplies that can accommodate community water fluoridation have chosen to use salt fluoridation.

Fact

Studies evaluating the effectiveness of salt fluoridation outside the U.S. have concluded that fluoride delivered via salt produces decay reductions similar to that of optimally fluoridated water.[78] Salt fluoridation is used in over 30 countries, including Switzerland, Columbia, Jamaica, Costa Pica, Mexico, France, Spain and Germany.[79] [80] Published results of studies in many of these countries show that, for 12-year-old children, the initial level of decay reduction due to salt fluoridation is between 35 percent and 80 percent.[81] An advantage of salt fluoridation is that it does not require a centralized piped water system. This is of particular use in many developing countries that do not have such water systems. When both domestic salt and bulk salt (used by commercial bakeries, restaurants, institutions, and industrial food production) is fluoridated, the decay-reducing effect may be comparable to that of water fluoridation over an extended period of time.[81] On the other hand, when only domestic salt is fluoridated, the decay-reducing effect may be diminished.[78]

Salt fluoridation has several disadvantages that do not exist with water fluoridation. Challenges occur with implementation of salt fluoridation when there are multiple sources of drinking water in an area. The natural fluoride level of each source must be determined and, if the level is optimal or excessive, fluoridated salt should not be distributed in that area. Also, salt fluoridation requires refined salt produced with modern technology and technical expertise.[82] Finally, there is general agreement that a high consumption of sodium is a risk factor for hypertension (high blood pressure).[83] [34] People who have hypertension or must restrict their salt intake may find salt fluoridation an unacceptable method of receiving fluoride.

Fluoridated milk has been suggested as another alternative to community water fluoridation in countries outside the United States. Studies among small groups of children have demonstrated a decrease in dental decay rates due to consumption of fluoridated milk; however, these studies were not based on large-scale surveys. More research is needed before milk fluoridation can be recommended as an alternative to water or salt fluoridation.[85] The rationale for adding fluoride to milk is that this method "targets" fluoride directly to children. Concerns have been raised about decreased widespread benefits due to the slower absorption of fluoride from milk than from water and the considerable number of persons, especially adults, who do not drink milk for various reasons.[86] The monitoring of fluoride content in milk is tech-

nically more difficult than for drinking water because there are many more dairies than communal water supplies. In addition, because fluoridated milk should not be sold in areas having natural or adjusted fluoridation, regulation would be difficult, and established marketing patterns would be disrupted.[17]

(Additional discussion on this topic may be found in Question 40.)

Question 11. Can the consistent use of bottled water result in individuals missing the benefits of optimally fluoridated water?

Answer. Yes. The majority of bottled waters on the market do not contain optimal levels (0.7–1.2 ppm) of fluoride.

Fact

Individuals who drink bottled water as their primary source of water could be missing the decay preventive effects of optimally fluoridated water available from their community water supply. Therefore, consumers should seek advice from their dentist about specific fluoride needs.

The fluoride content of bottled water can vary greatly. A 1989 study of pediatric dental patients and their use of bottled water found the fluoride content of bottled water from nine different sources varied from 0.04 ppm to 1.4 ppm.[87] In a 1991 study of 39 bottled water samples, 34 had fluoride levels below 0.3 ppm. Over the 2 years the study was conducted, six products showed a two- to four-fold drop in fluoride contents In evaluating how bottled water consumption affects fluoride exposure, there are several factors to consider. First is the amount of bottled water consumed during the day. Second is whether bottled water is used for drinking, in meal preparation and for reconstituting soups, juices and other drinks. Third is whether another source of drinking water is accessed during the day such as an optimally fluoridated community water supply at daycare, school or work. A final important issue is determining the fluoride content of the bottled water. If the fluoride level is not shown on the label of the bottled water, the company can be contacted, or the water can be tested to obtain this information. The fluoride level should be tested periodically if the source of the bottled water changes and, at a minimum, on a yearly basis.[87]

Information regarding the existing level of fluoride in a community's public water supply can be obtained by asking a local dentist, contacting the local or state health department, or contacting the local water supplier.

Question 12. Can home water treatment systems (e.g. water filters) affect optimally fluoridated water supplies?

Answer. Yes. Some types of home water treatment systems can reduce the fluoride levels in water supplies potentially decreasing the decay-preventive effects of optimally fluoridated water.

Fact

There are many kinds of home water treatment systems including carafe filters, faucet filters, reverse osmosis systems, distillation units and water softeners. There has not been a large body of research regarding the extent to which these treatment systems affect fluoridated water. Available research is often conflicting and unclear. However, it has been consistently documented that reverse osmosis systems and distillation units remove significant amounts of fluoride from the water supply.[16] [89] On the other hand, a recent study regarding water softeners confirmed earlier research indicating the water softening process caused no significant change in fluoride levels.[90] [91] With water filters, the fluoride concentration remaining in the water depends on the type and quality of the filter being used, the status of the filter and the filter's age.

Individuals who drink water processed by home water treatment systems as their primary source water could be losing the decay preventive effects of optimally fluoridated water available from their community water supply. Therefore, consumers should seek advice from their dentist about specific fluoride needs.

Consumers using home water treatment systems should have their water tested at least annually to establish the fluoride level of the treated water. More frequent testing may be needed. Testing is available through local and state public health departments. Private laboratories may also offer testing for fluoride levels in water.

Information regarding the existing level of fluoride in a community's public water system can be obtained by asking a local dentist, contacting your local or state health department, or contacting the local water supplier.

Consumers should seek advice from their dentist about specific fluoride needs.

SAFETY

Question 13. Does fluoride in the water supply, at the levels recommended for the prevention of tooth decay, adversely affect human health?

Answer. The overwhelming weight of scientific evidence indicates that fluoridation of community water supplies is both safe and effective.

Fact

For generations, millions of people have lived in areas where fluoride is found naturally in drinking water in concentrations as high or higher than those recommended to prevent tooth decay. Research conducted among these persons confirms the safety of fluoride in the water supply.[54] [92] [93] [94] [95] In fact, in August 1993, the National Research Council, a branch of the National Academy of Sciences, released a report prepared for the Environmental Protection Agency (EPA) that confirmed that the currently allowed fluoride levels in drinking water do not pose a risk for health problems such as cancer, kidney failure or bone disease.[96] Based on a review of available data on fluoride toxicity, the expert subcommittee that wrote the report concluded that the EPA's ceiling of 4 ppm for naturally occurring fluoride in drinking water was "appropriate as an interim standard."[96] Subsequently, the EPA announced that the ceiling of 4 ppm would protect against adverse health effects with an adequate margin of safety and published a notice of intent not to revise the fluoride drinking water standard in the Federal Register.[97]

As with other nutrients, fluoride is safe and effective when used and consumed properly. No charge against the benefits and safety of fluoridation has ever been substantiated by generally accepted scientific knowledge. After 50 years of research and practical experience, the preponderance of scientific evidence indicates that fluoridation of community water supplies is both safe and effective.[98] (Additional discussion on this topic may be found in Question 19 and Question 32.)

Many organizations in the U.S. and around the world involved with health issues have recognized the benefits of community water fluoridation. The American Dental Association adopted its original resolution in support of fluoridation in 1950, and has repeatedly reaffirmed its position publicly and in its House of Delegates based on its continuing evaluation of the safety and effectiveness of fluoridation.[3] The American Medical Association's (AMA) House of Delegates first endorsed fluoridation in 1951. In 1986, and again in 1996, the AMA reaffirmed its support for fluoridation as an effective means of reducing dental decay.[99] The World Health Organization, which initially recommended the practice of water fluoridation in 1969,[100] reaffirmed its support for fluoridation in 1994 stating that: "Providing that a community has a piped water supply, water fluoridation is the most effective method of reaching the whole population, so that all social classes benefit without the need for active participation on the part of individuals."": Following a comprehensive 1991 review and evaluation of the public health benefits and risks of fluoride, the U.S. Public Health Service reaffirmed its support for fluoridation and continues to recommend the use of fluoride to prevent dental decay.[54]

National and international health, service and professional organizations that recognize the public health benefits of community water fluoridation for preventing dental decay are listed on the inside back cover of this publication.

Question 14. Are additional studies being conducted to determine the effects of fluorides in humans?

Answer. Yes. Since its inception, fluoridation has undergone a nearly continuous process of reevaluation. As with other areas of science, additional studies on the effects of fluorides in humans can provide insight as to how to make more effective choices for the use of fluoride. The American Dental Association and the U.S. Public Health Service support this on-going research.

Fact

For the past 50 years, detailed reports have been published on all aspects of fluoridation.[54] [96] The accumulated dental, medical and public health evidence concerning fluoridation has been reviewed and evaluated numerous times by academicians, committees of experts, special councils of government and most of the world's major national and international health organizations. The verdict of the scientific community is that water fluoridation, at the recommended levels, provides major oral health benefits. The question of possible secondary health effects caused by fluorides consumed in optimal concentrations throughout life has been the object of thorough medical investigations which have failed to show any impairment of general health.[82] 92–95

In scientific research, there is no such thing as "final knowledge." New information is continuously emerging and being disseminated. While research continues, the

weight of scientific evidence indicates water fluoridation is safe and effective in preventing dental decay in humans.[54]

(Additional discussion on this topic may be found in Question 36.)

Question 15. Does the total intake of fluoride from air, water and food pose significant health risks?

Answer. The total intake of fluoride from air, water and food in an optimally fluoridated community in the United States does not pose significant health risks.

Fact

Fluoride from the Air

The atmosphere normally contains negligible concentrations of airborne fluorides. Studies reporting the levels of fluoride in air in the United States suggest that ambient fluoride contributes little to an individual's overall fluoride intake.[101] [102]

Fluoride from Water

Fresh or ground water in the United States has naturally occurring fluoride levels that can vary widely from less than 0.1 to over 13 parts per million. Few private well water sources exceed 7 ppm.[102] Public water systems in the U.S. are monitored by the Environmental Protection Agency (EPA), which requires that public water systems not exceed fluoride levels of 4 ppm.[97] The optimal concentration for fluoride in water in the United States has been established in the range of 0.7 to 1.2 ppm. This range will effectively reduce tooth decay while minimizing the occurrence of mild dental fluorosis. The optimal fluoride level is dependent on the annual average of the maximum daily air temperature in the geographic area.27 (Additional discussion on this topic may be found in Question 32.)

Children living in a community with water fluoridation get a portion of their daily fluoride intake from fluoridated water and a portion from dietary sources which would include food and other beverages. When considering water fluoridation, an individual must consume one liter of water fluoridated at 1 part per million (1 ppm) to receive 1 milligram (1 ma) of fluoride.[17] [103] Children under 6 years of age, on average, consume less than one-half liter of drinking water a day.[103] Therefore, children under 6 years of age would consume, on average, less than 0.5 mg of fluoride a day from drinking optimally fluoridated water (at 1 ppm).

A 10-year comparison study of long-time residents of Bartlett and Cameron, Texas, where the water supplies contained 8.0 and 0.4 parts per million of fluoride respectively, included examinations of organs, bones and tissues. Other than a higher prevalence of dental fluorosis in the Bartlett residents, the study indicated that long-term consumption of dietary fluoride (resident average length of fluoride exposure was 36.7 years), even at levels considerably higher than recommended for decay prevention, resulted in no clinically significant physiological or functional effects.[95]

Fluoride in Food

The fluoride content of fresh solid foods in the United States generally ranges from 0.01 to 1.0 part per million.[104] Fish, such as sardines, may contribute to higher dietary fluoride intake if the bones are ingested. Brewed teas may also contain fluoride concentrations of 1 ppm to 6 ppm depending on the amount of dry tea used, the water fluoride concentration and the brewing time.[104]

The average daily dietary intake of fluoride (expressed on a body weight basis) by children residing in optimally fluoridated (1 ppm) communities is 0.05 mg/kg/day; in communities without optimally fluoridated water, average intakes for children are about 50 percent lower.[74] Dietary fluoride intake by adults in optimally fluoridated (1 ppm) areas averages 1.4 to 3.4 mg/day, and in nonfluoridated areas averages 0.3 to 1.0 mg/day.[74]

A 1990 review of literature identified no significant increases in concentrations of fluoride in food associated with water fluoridation.[105]

Questions concerning the possible concentration of fluoride through the biologic food chain have been addressed by the National Academy of Sciences, which concluded:[106]

Indeed, domestic animals can serve as a protective barrier for humans. Approximately 99 percent of the fluoride retained in the body is stored in bone, and only slight increases in the concentration of soft tissue fluoride occur even at high levels of dietary fluoride intake. There is, therefore, little danger to humans from the consumption of meat or milk from domestic animals even if the animals have ingested excessive fluoride. A few meat and fish products prepared for human consumption contain portions of comminuted (crushed) bone that may contribute to a higher fluoride content. The proportion of the total diet represented by these products, however, would generally be very small indeed.

The U.S. Food and Drug Administration has established "market baskets" which reflect the actual 14-day consumption of various food items by an average individual in different age groups from 6-month-old children to adults. In a nationwide study of market baskets from areas with varying levels of fluoride in water supplies, it was determined that little or no change in food fluoride content has occurred as a result of the fluoridation of U.S. water supplies.[107] [108]

Question 16. How much fluoride should an individual consume each day to reduce the occurrence of dental decay?

Answer. The appropriate amount of daily fluoride intake varies with age and body weight. As with other nutrients, [Fluoride is safe and effective when used and consumed properly.

Fact

In 1997, the Food and Nutrition Board of the Institute of Medicine developed a comprehensive set of reference values for dietary nutrient intakes.[74] These new reference values, the Dietary Reference Intakes (DRI), replace the Recommended Dietary Allowances (RDA) which had been set by the National Academy of Sciences since 1941. The new values present nutrient requirements to optimize health and, for the first time, set maximum-level guidelines to reduce the risk of adverse effects from excessive consumption of a nutrient. Along with calcium, phosphorous, magnesium and vitamin D, DRIs for fluoride were established because of its proven effect on tooth decay.

As demonstrated in Table 2, fluoride intake in the United States has a large range of safety.

The first DRI reference value is the Adequate Intake (AI) which establishes a goal for intake to sustain a desired indicator of health without causing side effects. In the case of fluoride, the AI is the daily intake level required to reduce tooth decay without causing moderate dental fluorosis. The AI for fluoride from all sources (fluoridated water, food, beverages, fluoride dental products and dietary fluoride supplements) is set at 0.05 mg/kg/day (milligram per kilogram of body weight per day).

Using the established AI of 0.05 mg/kg, the amount of fluoride for optimal health to be consumed each day has been calculated by gender and age group (expressed as average weight). See Table 2 in this Question.

The DRIs also established a second reference value for maximum-level guidelines called tolerable upper intake levels (UL). The UL is higher than the AI and is not the recommended level of intake. The UL is the estimated maximum intake level that should not produce unwanted effects on health. The UL for fluoride from all sources (fluoridated water, food, beverages, fluoride dental products and dietary fluoride supplements) is set at 0.10 mg/kg/day (milligram per kilogram of body weight per day) for infants, toddlers, and children through 8 years of age. For older children and adults, who are no longer at risk for dental fluorosis, the UL for fluoride is set at 10 mg/day regardless of weight.

Table 2

DIETARY REFERENCE INTAKES FLUORIDE

Food and Nutrition Board of the Institute of Medicine 199774

Age Group	Reference Weights kg (lbs) *	Adequate Intake (mg/day)	Tolerable Upper Intake (mg/day)
Infants 0–6 months	7 (16)	0.01	0.7
Infants 6–12 months	9 (20)	0.5	0.9
Children 1–3 years	13 (29)	0.7	1.3
Children 4–8 years	22 (48)	1.0	2.0
Children 9–13 years	40 (88)	2.0	10
Boys 14–18 years	64 (142)	3.0	3.0
Girls 14–18 years	57 (125)	10	10
Males 19 years and over	76 (166)	4.0	10
Females 19 years and over	61 (133)	3.0	10

*Value base on data collected during 1988–94 as part of the Third National Health and Nutrition Examination Survey (NHANES III) in the United States[74]

Using the established ULs for fluoride, the amount of fluoride that may be consumed each day to reduce the risk of moderate dental fluorosis for children under eight, has been calculated by gender and age group (expressed as average weight). See Table 2.

As a practical example, daily intake of 2 mg of fluoride is adequate for a nine to 13-year-old child weighing 88 pounds (40 kg). This was calculated by multiplying 0.05 mg/kg/day (AI) times 40 kg (weight) to equal 2 ma. At the same time, that 88

pound (40 kg) child could consume 10 mg of fluoride a day as a tolerable upper intake level.

Children living in a community with water fluoridation get a portion of their daily fluoride intake from fluoridated water and a portion from dietary sources which would include food and other beverages. When considering water fluoridation, an individual must consume one liter of water fluoridated at 1 part per million (1 ppm) to receive 1 milligram (1 ma) of fluoride.[17] [103] Children under 6 years of age, on average, consume less than one-half liter of drinking water a day.[103] Therefore, children under 6 years of age would consume, on average, less than 0.5 mg of fluoride a day from drinking optimally fluoridated water (at 1 ppm).

If a child lives in a nonfluoridated area, the dentist or physician may prescribe dietary fluoride supplements. As shown in Table 1 "Dietary Fluoride Supplement Schedule 1994" (See Question 9), the current dosage schedule recommends supplemental fluoride amounts that are below the AI for each age group. The dosage schedule was designed to offer the benefit of decay reduction with margin of safety to prevent mild to moderate dental fluorosis. For example, the AI for a child 3 years of age is 0.7 mg/day.The recommended dietary fluoride supplement dosage for a child 3 years of age in a nonfluoridated community is 0.5 mg/day. This provides leeway for some fluoride intake from processed food and beverages, and other sources.

Decay rates are declining in many population groups because children today are being exposed to fluoride from a wider variety of sources than decades ago. Many of these sources are intended for topical use only; however, some fluoride is inadvertently ingested by children.[109] Inappropriate ingestion of fluoride can be prevented, thus reducing the risk for dental fluorosis without jeopardizing the benefits to oral health.

For example, it has been reported in a number of studies that young children inappropriately swallow an average of 0.30 mg of fluoride from fluoride toothpaste at each brushing.[110] [111] [112] [113] If a child brushes twice a day, 0.60 mg may be inappropriately ingested. This may slightly exceed the Adequate Intake (AI) values from Table 2. The 0.60 mg consumption is 0.10 mg over the AI value for children 6 to 12 months and is 0.10 mg under the AI for children from 1–3 years of age.[74] Although toothpaste is not meant to be swallowed, children may consume the daily recommended Adequate Intake amount of fluoride from toothpaste alone. In order to decrease the risk of dental fluorosis, the American Dental Association has since 1992 recommended that parents and caregivers put only one pea-sized amount of fluoride toothpaste on a young child's toothbrush at each brushing. Also, young children should be supervised while brushing and taught to spit out, rather than swallow, the toothpaste.

It should be noted that the amounts of fluoride discussed here are intake, or ingested, amounts. When fluoride is ingested, a portion is retained in the body and a portion is excreted. This issue will be discussed further in Question 17.

Question 17. When fluoride is ingested, where does it go?

Answer. Much is excreted; almost all of the fluoride retained in the body is found in calcified (hard) tissues, such as bones and teeth.

Fluoride helps to prevent dental decay when incorporated into the teeth.

Fact

After ingestion of fluoride, such as drinking a glass of optimally fluoridated water, the majority of the fluoride is absorbed from the stomach and small intestine into the blood stream.[114] This causes a short-term increase in the fluoride levels in the blood. The fluoride levels increase quickly and reach a peak concentration within 20–60 minutes.[115] The concentration declines rapidly, usually within 3 to 6 hours following the peak levels, due to the uptake of fluoride by hard tissue and efficient removal of fluoride by the kidneys.[104] Approximately 50 percent of the fluoride absorbed each day by young or middle-aged adults becomes associated with hard tissues within 24 hours while virtually all of the remainder is excreted in the urine. Approximately 99 percent of the fluoride present in the body is associated with hard tissues.[114]

Ingested or systemic fluoride becomes incorporated into forming tooth structures. Fluoride ingested regularly during the time when teeth are developing is deposited throughout the entire surface of the tooth and contributes to long lasting protection against dental decay.[17] (Additional discussion on this topic may be found in Question 1.)

An individual's age and stage of skeletal development will affect the rate of fluoride retention. The amount of fluoride taken up by bone and retained in the body is inversely related to age. More fluoride is retained in young bones than in the bones of older adults.[104] [114] [115]

According to generally accepted scientific knowledge, the ingestion of optimally fluoridated water does not have an adverse effect on bone health." Evidence of advanced skeletal fluorosis, or crippling skeletal fluorosis, "was not seen in communities in the United States where water supplies contained up to 20 ppm (natural levels of fluoride)."[74] [121] In these communities, daily fluoride intake of 20 mg/day would not be uncommon.[74] Crippling skeletal fluorosis is extremely rare in the United States and is not associated with optimally fluoridated water; only 5 cases have been confirmed during the last 35 years.[74] (Additional discussion on this topic may be found in Question 18.)

The kidneys play the major role in the removal of fluoride from the body. Normally kidneys are very efficient and excrete fluoride very rapidly. However, decreased fluoride removal may occur among persons with severely impaired kidney function who may not be on kidney dialysis.[96] No cases of dental fluorosis or symptomatic skeletal fluorosis have been reported among persons with impaired kidney function; however, the overall health significance of reduced fluoride removal is uncertain and continued followup is recommended especially for children with impaired kidney function.[54] (Additional discussion on this topic may be found in Question 31.)

Question 18. Will the ingestion of optimally fluoridated water over a lifetime adversely affect bone health?

Answer. According to generally accepted scientific knowledge, the ingestion of optimally fluoridated water does not have an adverse effect on bone health.[116] [117] [118] [119] [120] [122]

Fact

The weight of scientific evidence does not supply an adequate basis for altering public health policy regarding fluoridation because of bone health concerns. A number of investigations have studied the effects on bone structure of individuals residing in communities with optimal and higher than optimal concentrations of fluoride in the drinking water. These studies have focused on whether there exists a possible link between fluoride and bone fractures. In addition, the role of fluoride in strengthening bone and preventing fractures has been investigated. Last, the possible association between fluoride and bone cancer has been studied.

Water Fluoridation Has No Significant Impact on Bone Mineral Density

In 1991, a workshop, co-sponsored by the National Institute of Arthritis and Musculoskeletal and Skin Diseases and the National Institute of Dental Research, addressed the potential relationship of hip fracture and bone health in humans to fluoride exposure from drinking water. Meeting at the National Institutes of Health, researchers examined historic and contemporary research on fluoride exposure and bone health. At that time, participants concluded there was no basis for altering current public health policy regarding current guidelines for levels of fluoride in drinking water. Recommendations were made regarding additional research in several areas.[116]

In 1993, two studies were published demonstrating that exposure to fluoridated water does not contribute to an increased risk for hip fractures. One study looked at the risk of hip fractures in residents of two similar communities in Alberta, Canada.[117] In this study, researchers compared a city with fluoridated drinking water optimally adjusted to 1 ppm to a city whose residents drank water containing naturally occurring fluoride at a concentration of only 0.3 ppm. No significant difference was observed in the overall hip fracture hospitalization rates for residents of both cities. "These findings suggest that fluoridation of drinking water has no impact, neither beneficial nor deleterious, on the risk of hip fracture."[117]

The second study examined the incidence of hip fracture rates before and after water fluoridation in Rochester, Minnesota.[118] Researchers compared the hip fracture rates of men and women aged 50 and older from 1950 to 1959 (before the city's water supply was fluoridated in 1960) with the 10-year period after fluoridation. Their findings showed that hip fracture rates had decreased, and that the decrease began before fluoridation was introduced, and then continued. These data demonstrate no increase in the risk of hip fracture associated with fluoridation of the public water supply in Rochester, Minnesota.

Prior to 1993, the lead author of the 1993 Minnesota study had authored two earlier fluoridation-hip fracture studies showing a very slight increase in fracture risk in fluoridated communities.[123] [124] The 1990 study examined the regional variation within the United States in the incidence of hip fracture in women aged 65 and over. The analysis of hip fracture incidence data at the county level demonstrated a strong pattern of regional variation among women, with a band of increased risk in the southern United States. The results of the analysis suggested that soft and

fluoridated water, poverty, reduced sunlight exposure and rural location all increased the risk of hip fracture. In the summary, the author stated that no presently recognized factor or factors adequately explained the geographic variation.[123] The second study, published in 1992, was a national ecologic study of the association between water fluoridation and hip fractures in women and men aged 65 and over. (In ecological studies, groups of people are studied instead of individuals.) The study reported a small positive ecologic association between fluoridation of public water supplies and the incidence of hip fracture among the aged. The authors stated that this observation did not yet provide a firm platform for health policy, but stated further research was warranted.[124]

In 1997, the lead author of the 1993 Minnesota study and the two studies noted in the preceding paragraph, issued a statement which concluded: "To my knowledge, no study has demonstrated that the introduction of fluoride to the public water supplies has increased the risk of (hip) fracture, let alone a doubling of the risk."[125]

An ecological study conducted in eastern Germany compared the incidence of hip fractures for adults living in Chemnitz (optimally fluoridated) and Halle(fluoride-deficient). The results suggested the consumption of optimally fluoridated water reduced the incidence of hip fractures in elderly individuals, especially women over 84 years of age.[122]

According to generally accepted scientific knowledge, the ingestion of optimally fluoridated water does not have an adverse effect on bone health.[116 120 122] Exposure to fluoride at levels considered optimal for the prevention of dental decay appears to have no significant impact on bone mineral density.[126]

Fluoride's Role in Strengthening Bone

The second major area of study regarding fluoride and bone health is the role of fluoride in strengthening bone and preventing fractures. For nearly 30 years, fluoride, primarily in the form of slowrelease sodium fluoride, has been used as an experimental therapy to treat osteoporosis, a condition characterized by a reduction in the amount of bone mass. Individuals with osteoporosis may suffer bone fractures as a result of what would be considered minimal trauma. Sodium fluoride therapy has been used in individuals in an effort to reduce further bone loss, or add to existing bone mass and prevent further fractures." The results of the clinical trials have been mixed as noted in the two following studies. The need for further research is indicated.

In 1995, the final report of a 4-year study was published demonstrating the ability of fluoride to aid in an increase in bone mass.[127] The study examined females with post-menopausal osteoporosis who took slow-release sodium fluoride (25 mg twice a day) and calcium citrate (400 mg twice a day) for 4 years in repeated 14 month cycles (12 months receiving treatment and 2 months not receiving treatment). The study concluded this treatment was safe and effective in reducing the number of new spinal fractures and adding new bone mass to the spine.[127]

In a 6-year clinical trial in 50 postmenopausal women, treatment with sodium fluoride and supplemental calcium was not effective in the treatment of osteoporosis.[128]

No Association Between Fluoride and Bone Cancer

Lastly, the possible association between fluoride and bone cancer has been studied. In the early 1990's, two studies were conducted to evaluate the carcinogenicity of sodium fluoride in laboratory animals. The first study was conducted by the National Toxicology Program (NTP) of the National Institute of Environmental Health Sciences.[129] The second study was sponsored by the Proctor and Gamble Company.[130] In both studies, higher than optimal concentrations of sodium fluoride were consumed by rats and mice. When the NTP and the Proctor and Gamble studies were combined, a total of eight individual sex/species groups became available for analysis. Seven of these groups showed no significant evidence of malignant tumor formation. One group, male rats from the NTP study, showed "equivocal" evidence of carcinogenicity, which is defined by NTP as a marginal increase in neoplasms—i.e., osteosarcomas (malignant tumors of the bone)—that may be chemically related. The Ad Hoc Subcommittee on Fluoride of the U.S. Public Health Service combined the results of the two studies and stated: "Taken together, the two animal studies available at this time fail to establish an association between fluoride and cancer.[54] (Additional discussion on this topic may be found in Question 22.)

Question 19. What is dental fluorosis?

Answer. Dental fluorosis is a change in the appearance of teeth and is caused when higher than optimal amounts of fluoride are ingested in early childhood while tooth enamel is forming. The risk of dental fluorosis can be greatly reduced by closely monitoring the proper use of fluoride products by young children.

Fact

Dental fluorosis is caused by a disruption in enamel formation which occurs during tooth development in early childhood.[104] Enamel formation of permanent teeth, other than third molars (wisdom teeth), occurs from about the time of birth until approximately 5 years of age. After tooth enamel is completely formed, dental fluorosis cannot develop even if excessive fluoride is ingested.[131] Older children and adults are not at risk for dental fluorosis. Dental fluorosis only becomes apparent when the teeth erupt. Because dental fluorosis occurs while teeth are forming under the gums, teeth that have erupted are not at risk for dental fluorosis.

Dental fluorosis has been classified in a number of ways. One the most universally accepted classifications was developed by H.T. Dean in 1942; its descriptions can be easily visualized by the public (See Table 3).[132]

In using Dean's Fluorosis Index, each tooth present in an individual's mouth is rated according to the fluorosis index in Table 3. The individual's fluorosis score is based upon the severest form of fluorosis recorded for two or more teeth.

Very mild to mild fluorosis has no effect on tooth function and may make the tooth enamel more resistant to decay. This type of fluorosis is not readily apparent to the affected individual or casual observer and often requires a trained specialist to detect. In contrast, the moderate and severe forms of dental fluorosis are generally characterized by esthetically (cosmetically) objectionable changes in tooth color and surface irregularities. Most investigators regard even the more advanced forms of dental fluorosis as a cosmetic effect rather than a functional adverse effect.[74] The EPA, in a decision supported by the U.S. Surgeon General, has determined that objectionable dental fluorosis is a cosmetic effect with no known health effects.[97] Little research on the psychological effects of dental fluorosis on children and adults has been conducted, perhaps because the majority of those who have the milder forms of dental fluorosis are unaware of this condition.[54]

Table 3

DENTAL FLUOROSIS CLASSIFICATION BY H.T. DEAN–1942[132]

Classification	Criteria—Description of Enamel
Normal	Smooth, glossy, pale creamy-white translucent surface
Questionable	A few white flecks or white spots
Very Mild	Small opaque, paper-white areas covering less than 25 percent of the tooth surface
Mild	Opaque white areas covering less than 25 percent of the tooth surface
Moderate	All tooth surfaces affected; marked wear on biting, surfaces; brown stain may be present
Severe	All tooth surfaces affected; discrete or confluent pitting; brown stain present

In a 1986–7 national survey of U.S. school children conducted by the National Institute of Dental Research, dental fluorosis was present in 22.3 percent of the children examined using Dean's Index.s4 These children were exposed to all sources of fluoride (fluoridated water, food, beverages, fluoride dental products and dietary supplements). The prevalence of the types of fluorosis were:

Very mild fluorosis 17.0 percent
Mild fluorosis 4.0 percent
Moderate fluorosis 1.0 percent
Severe fluorosis 0.3 percent
Total cases of fluorosis 22.3 percent

The incidence of moderate or severe fluorosis comprised a very small portion (6 percent) of the total amount of fluorosis. In other words, 94 percent of all dental fluorosis is the very mild to mild form of dental fluorosis.

As with other nutrients, fluoride is safe and effective when used and consumed properly. The recommended optimum water fluoride concentration of 0.7 to 1.2 ppm was established to maximize the decay preventive benefits of fluoride, and the same time minimize the likelihood of mild dental fluorosis.[54]

As with all public health measures, the benefits and risks of community water fluoridation have been examined. The benefits of water fluoridation are discussed extensively in the Benefits Section of this document and the safety of water fluoridation is discussed in great detail in the remainder of this (Safety) Section. In assessing the risks in regards to dental fluorosis, scientific evidence shows it is probable that approximately 10 percent of children consuming optimally fluoridated water, in the absence of fluoride from all other sources, will develop very mild dental fluorosis.?33 As defined in Table 3, very mild fluorosis is characterized by small opaque, paper-white areas covering less than 25 percent of the tooth surface. The risk of teeth forming with the very mildest form of fluorosis must be weighed

against the benefit that the individual's teeth will also have a lower rate of dental decay thus saving dental treatment costs.[45] In addition, the risk of fluorosis may be viewed as an alternative to having dental decay, which is a disease that may cause cosmetic problems much greater than fluorosis.[134]

In 1994, a review of five recent studies indicated that the amount of dental fluorosis attributable to water fluoridation was approximately 13 percent. This represents the amount of fluorosis that might be eliminated if community water fluoridation was discontinued. In other words, the majority of dental fluorosis can be associated with other risk factors such as the inappropriate ingestion of fluoride products. (Additional discussion on this topic may be found in Question 20.)

The type of fluorosis seen today remains largely limited to the very mild and mild categories, although the prevalence of enamel fluorosis in both fluoridated and nonfluoridated communities in the United States is higher than it was when original epidemiological studies were done approximately 60 years ago. Because fluoride intake from water and the diet appears not to have increased since that time, the additional intake by children at risk for dental fluorosis is believed to be caused by consumer's inappropriate use of fluoride-containing dental products. As the ADA has recommended, the risk of fluorosis can be greatly reduced by following label directions for the use of these fluoride products.[74] [96]

Question 20. Can fluorosis in children's teeth be prevented?

Answer. Because risk factors have been identified and verified by generally accepted scientific knowledge, the occurrence of dental fluorosis in the United States can be reduced! without denying young children the decay prevention benefits of community water fluoridation.

Fact

During the period of enamel formation in young children (before teeth appear in the mouth), inappropriate ingestion of high levels of fluoride is the risk factor for dental fluorosis.[52] [135] Studies of fluoride intake from the diet including foods, beverages and water indicate that fluoride ingestion from these sources has remained relatively constant for over half a century and, therefore, is not likely to be associated with an observed increase in dental fluorosis.[104] [107]

Dental decay has decreased because children today are being exposed to fluoride from a wider variety of sources than decades ago. Many of these sources are intended for topical use only; however, some fluoride is inadvertently ingested by children.[109] Inappropriate ingestion of topical fluoride can be prevented, thus reducing the risk for dental fluorosis without reducing decay prevention benefits.

Since 1992, the American Dental Association has required manufacturers of toothpaste to include the phrase "Use only a pea-sized amount (of toothpaste) for children under six" on fluoride toothpaste labels with the ADA Seal of Acceptance. The rationale for choosing 6 years of age for the toothpaste label is based on the fact that the swallowing reflex is not fully developed in children of preschool age and they may inadvertently swallow toothpaste during brushing. In addition, the enamel formation of permanent teeth is basically complete at six and so there is a decreased risk of fluorosis. Because dental fluorosis occurs while teeth are forming under the gums, individuals whose teeth have erupted are not at risk for dental fluorosis.

(Additional discussion on this topic may be found in Question 16 and Question 19.)

Numerous studies have established a direct relationship between young children brushing with more than the recommended pea-sized amount of fluoride toothpaste and the risk of very mild or mild dental fluorosis.[136] [137] [138] One study of 916 children residing in a fluoridated community revealed that an estimated 71 percent of identified fluorosis cases could be explained by a history of having brushed more than once a day with more than the recommended amount (only one pea-sized dab at each brushing) of fluoride toothpaste throughout the first 8 years of life.[139] Parents and caregivers should put only one pea-sized amount of fluoride toothpaste on a young child's toothbrush at each brushing. Young children should be supervised while brushing and taught to spit out, rather than swallow, the toothpaste.

Additionally, it has been shown that 25 percent of the fluorosis cases could be explained by a history of taking dietary fluoride supplements inappropriately (i.e., while also consuming fluoridated water) during the first 8 years of life.[139] Dietary fluoride supplements should be prescribed as recommended in the Dietary Fluoride Supplement Schedule approved by the American Dental Association, the American Academy of Pediatrics and the American Academy of Pediatric Dentistry in 1994 (See Table 1 in Question 9).[12] Fluoride supplements should only be prescribed for children living in nonfluoridated areas. Because of many sources of fluoride in the diet, proper prescribing of fluoride supplements can be complex. It is suggested that all sources of fluoride be evaluated with a thorough fluoride history before supple-

ments are prescribed for a child.[73] Included in that evaluation is the testing of the home water supply if the fluoride concentration is unknown.

Parents, caregivers and health care professionals should judiciously monitor use of all fluoride-containing dental products by children under age six. As is the case with any therapeutic product, more is not always better. Care should be taken to adhere to label directions on fluoride prescriptions and over-the-counter products (e.g. fluoride toothpastes and rinses). The American Dental Association recommends the use of fluoride mouthrinses, but not for children under 6 years of age because they may swallow the rinse. In addition, these products should be stored out of the reach of children.

Finally, in areas where naturally occurring fluoride levels in ground water are higher than 2 ppm, consumers should consider action to lower the risk of dental fluorosis for young children. (Adults are not affected because dental fluorosis occurs only when developing teeth are exposed to elevated fluoride levels.) Families on community water systems should contact their water supplier to ask about the fluoride level. Consumers with private home wells should have the source tested to accurately determine the fluoride content. Consumers should consult with their dentist regarding water testing and discuss appropriate dental health care measures. In homes where young children are consuming water with a fluoride level greater than 2 ppm, families should use an alternative primary water source, such as bottled water, for drinking and cooking. Private wells should be tested at least yearly due to possible fluctuations in water tables. It is important to remember that the American Dental Association recommends dietary fluoride supplements only for children living in areas with less than optimally fluoridated water.

(Additional discussion on this topic may be found in Question 9 and Question 32.)

Question 21. Is fluoride, as provided by community water fluoridation, a toxic substance?

Answer. Fluoride, at the concentrations found optimally fluoridated water, is not toxic according to generally accepted scientific knowledge.

Fact

Like many common substances essential to life and good health—salt, iron, vitamins A and D, chlorine, oxygen and even water itself—fluoride can be toxic in excessive quantities. Fluoride in the much lower concentrations (0.7 to 1.2 ppm) used in water fluoridation is not harmful or toxic.

Acute fluoride toxicity occurring from the ingestion of optimally fluoridated water is impossible."[104] The amount of fluoride necessary to cause death for a human adult (155 pound man) has been estimated to be 5–10 grams of sodium fluoride, ingested at one time.[140] This is more than 10,000–20,000 times as much fluoride as is consumed at one time in a single 8 ounce glass of optimally fluoridated water.

Chronic fluoride toxicity may develop after 10 or more years of exposure to very high levels of fluoride, levels not associated with fluoride intake in drinking optimally fluoridated water. The primary functional adverse effect associated with long-term excess fluoride intake is skeletal fluorosis. The development of skeletal fluorosis and its severity is directly related to the level and duration of fluoride exposure. For example, the ingestion of water naturally fluoridated at approximately 5 ppm for 10 years or more is needed to produce clinical signs of osteosclerosis, a mild form of skeletal fluorosis, in the general population. In areas naturally fluoridated at 5 ppm, daily fluoride intake of 10 mg/day would not be uncommon.[74] A survey of X-rays from 170,000 people in Texas and Oklahoma whose drinking water had naturally occurring fluoride levels of 4 to 8 ppm revealed only 23 cases of osteosclerosis and no cases of skeletal fluorosis.[141] Evidence of advanced skeletal fluorosis, or crippling skeletal fluorosis, "was not seen in communities in the United States where water supplies contained up to 20 ppm (natural levels of fluoride)."[74 121] In these communities, daily fluoride intake of 20 mg/day would not be uncommon.[74] Crippling skeletal fluorosis is extremely rare in the United States and is not associated with optimally fluoridated water; only 5 cases have been confirmed during the last 35 years.[74]

(Additional discussion of this topic may be found in Question 16 and Question 32.)

The possibility of adverse health effects from continuous low level consumption of fluoride over long periods has been extensively studied. As with other nutrients, fluoride is safe and effective when used and consumed properly. No charge against the benefits and safety of fluoridation has ever been substantiated by generally accepted scientific knowledge. After 50 years of research and practical experience, the preponderance of scientific evidence indicates that fluoridation of community water supplies is both safe and effective.[98]

At one time, high concentrations of fluoride compounds were used in insecticides and rodenticides.[27] Today fluoride compounds are rarely used in pesticides because

more effective compounds have been developed.[104] While large doses of fluoride may be toxic, it is important to recognize the difference in the effect of a massive dose of an extremely high level of fluoride versus the recommended amount of fluoride found in optimally fluoridated water. The implication that fluorides in large doses and in trace amounts have the same effect is completely unfounded. Many substances in widespread use are very beneficial in small amounts, but may be harmful in large doses-such as salt, chlorine and even water itself.

Question 22. Does drinking optimally fluoridated water cause or accelerate the growth of cancer?

Answer. According to generally accepted scientific knowledge, there is no connection between cancer rates in humans and adding fluoride to drinking water.[142]

Fact

Since community water fluoridation was introduced in 1945, more than 50 epidemiologic studies in different populations and at different times have failed to demonstrate an association between fluoridation and the risk of cancer.s4 Studies have been conducted in the United States,[143] [144] [145] [146] [147] [147] [148] Japan,[149] the United Kingdom,[150] [151] [152] Canada [153] and Australia.[154] In addition, several independent bodies have conducted extensive reviews of the scientific literature and concluded that there is no relationship between fluoridation and cancer. [54] [94] [96] [155]

The United States Environmental Protection Agency (EPA) further commented on the safety of appropriate fluoride exposure in the December 5, 1997, Federal Register.[156] In a notice of a final rule relating to fluoride compounds the EPA stated, ". . . the weight of evidence from more than 50 epidemiological studies does not support the hypothesis of an association between fluoride exposure and increased cancer risk in humans. The EPA is in agreement with the conclusions reached by the National Academy of Sciences (NAS)."

Despite the abundance of scientific evidence, claims of a link between fluoridation and increased cancer rates continue. This assertion is based on one study comparing cancer death rates in ten large fluoridated cities versus ten large nonfluoridated cities in the United States. The results of this study have been refuted by a number of organizations and researchers.[157] The National Cancer Institute analyzed the same data and found that the original investigators failed to adjust their findings for variables, such as age and gender differences, that affect cancer rates. A review by other researchers pointed to further shortcomings in the study. The level of industrialization in the fluoridated cities was much higher than the nonfluoridated cities. Researchers noted that a higher level of industrialization is usually accompanied by a higher incidence of cancer. While the researchers noted that the fluoridated cities did have higher cancer rates over the 20-year study, the rate of increase in the nonfluoridated cities was exactly the same (15 percent) as the fluoridated cities. Following further reviews of the study, the consensus of the scientific community continues to support the conclusion that the incidence of cancer is unrelated to the introduction and duration of water fluoridation.[54]

In the early 1990's, two studies using higher than optimal levels of fluoride were conducted to evaluate the carcinogenicity of sodium fluoride in laboratory animals. The first study was conducted by the National Toxicology Program (NTP) of the National Institute of Environmental Health Sciences.[129] The second study was sponsored by the Proctor and Gamble Company.[130] In both studies, higher than optimal concentrations of sodium fluoride were consumed by rats and mice. When the NTP and the Proctor and Gamble studies were combined, a total of eight individual sex/species groups became available for analysis. Seven of these groups showed no significant evidence of malignant tumor formation. One group, male rats from the NTP study, showed "equivocal" evidence of carcinogenicity, which is defined by NTP as a marginal increase in neoplasms-i.e., osteosarcomas (malignant tumors of the bone)that may be chemically related. The Ad Hoc Subcommittee on Fluoride of the U.S. Public Health Service combined the results of the two studies and stated: "Taken together, the two animal studies available at this time fail to establish an association between fluoride and cancer."[54]

In a 1990 study, scientists at the National Cancer Institute evaluated the relationship between fluoridation of drinking water and cancer deaths in the United States during a 36-year period, and the relationship between fluoridation and the cancer rate during a 15-year period. After examining more than 2.3 million cancer death records and 125,000 cancer case records in counties using fluoridated water, the researchers saw no indication of a cancer risk associated with fluoridated drinking water.[54]

In a document entitled "Fluoride and Drinking Water Fluoridation," the American Cancer Society states, "Scientific studies show no connection between cancer rates in humans and adding fluoride to drinking water."[142]

Question 23. Does fluoride, as provided by community water fluoridation, inhibit the activity of enzymes in humans?

Answer. Fluoride, in the amount provided through optimally fluoridated water, has no effect on human enzyme activity according to generally accepted scientific knowledge.

Fact

Enzymes are organic compounds that promote chemical change in the body. Generally accepted scientific knowledge has not indicated that optimally fluoridated water has any influence on human enzyme activity. There are no available data to indicate that, in humans drinking optimally fluoridated water, the fluoride affects enzyme activities with toxic consequences.[105] The World Health Organization report, Fluorides and Human Health states, "No evidence has yet been provided that fluoride ingested at 1 ppm in the drinking water affects intermediary metabolism of food stuffs, vitamin utilization or either hormonal or enzymatic activity."[158]

The concentrations of fluoride used in laboratory studies to produce significant inhibition of enzymes are hundreds of times greater than the concentration present in body fluids or tissues.[140] While fluoride may affect enzymes in an artificial environment outside of a living organism in the laboratory, it is unlikely that adequate cellular levels of fluoride to alter enzyme activities would be attainable in a living organism.[105] The two primary physiological mechanisms that maintain a low concentration of fluoride ion in body fluids are the rapid excretion of fluoride by the kidneys and the uptake of fluoride by calcified tissues.

Question 24. Can fluoride, as found in optimally fluoridated drinking water, alter immune function or produce allergic reaction (hypersensitivity)?

Answer. According to generally accepted scientific knowledge, there is no evidence of any adverse effect on specific immunity from fluoridation, nor have there been any confirmed reports of allergic reaction.[159]

Fact

There are no confirmed cases of allergy to fluoride, or of any positive skin testing in human or animal models.[159] The American Academy of Allergy reviewed clinical reports of possible allergic responses to fluoride and concluded, "There is no evidence of allergy or intolerance to fluorides as used in the fluoridation of community water supplies."[160] A committee of the National Academy of Sciences evaluated the same clinical data and reported, "The reservation in accepting (claims of allergic reaction) at face value is the lack of similar reports in much larger numbers of people who have been exposed to considerably more fluoride than was involved in the original observations."[14] The World Health Organization also judged these cases to represent "a variety of unrelated conditions" and found no evidence of allergic reactions to fluoride.[161 162]

A 1996 review of the literature on fluoride and white cell function examined numerous studies and concluded that there is no evidence of any harmful effect on specific immunity following fluoridation nor any confirmed reports of allergic reactions.[159]

Question 25. Does drinking optimally fluoridated water cause AIDS?

Answer. There is no generally accepted scientific evidence linking the consumption of optimally fluoridated water and AIDS (acquired immune deficiency syndrome).

Fact

AIDS is caused by a retrovirus known as the human immunodeficiency virus (HIV). The routes of transmission of HIV include unprotected sexual activity, exposure to contaminated blood or blood products and as a result of an infected woman passing the virus to the fetus during pregnancy or to the newborn at birth.[163]

There is no scientific evidence linking HIV or AIDS with community water fluoridation.[164]

Question 26. Is fluoride, as provided by community water fluoridation, a genetic hazard?

Answer. Following a review of generally accepted scientific knowledge, the National Research Council of the National Academy of Sciences supports the conclusion that drinking optimally fluoridated water is not a genetic hazard.[96]

Fact

Chromosomes are the DNA-containing bodies of cells that are responsible for the determination and transmission of hereditary characteristics. Genes are the functional hereditary unit that occupy a fixed location on a chromosome. Many studies have examined the possible effects of fluoride on chromosome damage. While there

are no published studies on the genotoxic (damage to DNA) effect of fluoride in humans, numerous studies have been done on mice.[96] These studies have shown no evidence that fluoride damages chromosomes in bone marrow or sperm cells even at fluoride levels 100 times higher than that in fluoridated water.[165] [166] [167] [168] [169] [170] [171] Another independent group of researchers reported a similar lack of fluoride-induced chromosomal damage to human white blood cells, which are especially sensitive to agents which cause genetic mutations. Not only did fluoride fail to damage chromosomes, it protected them against the effect of a known mutagen (an agent that causes changes in DNA).[172] [173] The genotoxic effects of fluoride were also studied in hamster bone marrow cells and cultured hamster ovarian cells. Again, the results supported the conclusion that fluoride does not cause chromosomal damage, and therefore, was not a genetic hazard.[174] In further tests, fluoride has not caused genetic mutations in the most widely used bacterial mutagenesis assay (the Ames test) over a wide range of fluoride levels.[174] [175] [176] [177]

Occasional questions arise regarding fluoride's effects on human reproduction, fertility and birth rates. Very high levels of fluoride intake have been associated with adverse effects on reproductive outcomes in many animal species. Based on these findings, it appears that fluoride concentrations associated with adverse reproductive effects in animals are far higher (100–200 ppm) than those to which human populations are exposed. Consequently, there is insufficient scientific basis on which to conclude that ingestion of fluoride at levels found in community water fluoridation (0.7–1.2 ppm) would have adverse effects on human reproduction.[96]

One human study compared county birth data with county fluoride levels greater than 3 ppm and attempted to show an association between high fluoride levels in drinking water and lower birth rates.[178] However, because of serious limitations in design analysis, the investigation failed to demonstrate a positive correlation.[179]

The National Research Council (NRC) of the National Academy of Sciences (NAS) supports the conclusion that drinking optimally fluoridated water is not a genetic hazard. In a statement summarizing its research, the NRC states, "in vitro data indicate that:

1. the genotoxicity of fluoride is limited primarily to doses much higher than those to which humans are exposed,
2. even at high doses, genotoxiceffects are not always observed, and
3. the preponderance of the genotoxic effects that have been reported are of the types that probably are of no or negligible genetic significance.[96]

The lowest dose of fluoride reported to cause chromosomal changes in mammalian cells was approximately 170 times that found normally found in human cells in areas where drinking water is fluoridated, which indicates a very large margin of safety.[96]

Question 27. Does drinking optimally fluoridated water cause an increase in the rate of children born with Down Syndrome?

Answer. There is no generally accepted scientific knowledge establishing a relationship between Down Syndrome and the consumption of optimally fluoridated drinking water.

Fact

This question originally arose because of two studies published in 1956 and 1963. Data collected in several Midwest states in 1956 formed the basis for two articles published in French journals, purporting to prove a relationship between fluoride in the water and Down Syndrome.[180] [181]

Experienced epidemiologists and dental researchers from the National Institute of Dental Research and staff members of the National Institute of Mental Health have found serious shortcomings in the statistical procedures and designs of these two studies. Among the most serious inadequacies is the fact that conclusions were based on the fluoridation status of the communities where the mothers gave birth, rather than the status of the rural areas where many of the women lived during their pregnancies.[140] In addition, the number of Down Syndrome cases found in both fluoridated and nonfluoridated communities were much lower than the rates found in many other parts of the United States and the world, thus casting doubt on the validity of findings.

The following paragraphs provide a summary of numerous studies that have been conducted which refute the conclusions of the 1956 studies.

A British physician reviewed vital statistics and records from institutions and school health officers, and talked with public health nurses and others caring for children with Down Syndrome. The findings noted no indication of any relationship between Down Syndrome and the level of fluoride in water consumed by the mothers.[182]

These findings were confirmed by a detailed study of approximately 2,500 Down Syndrome births in Massachusetts. A rate of 1.5 cases per 1,000 births was found in both fluoridated and nonfluoridated communities, providing strong evidence that fluoridation does not increase the risk of Down Syndrome.[183]

Another large population-based study with data relating to nearly 1.4 million births showed no association between water fluoridation and the incidence of congenital malformations including Down Syndrome.[184]

In 1980, a 25-year review of the prevalence of congenital malformations was conducted in Birmingham, England. Although Birmingham initiated fluoridation in 1964, no changes in the prevalence of children born with Down Syndrome occurred since that time.[185]

A comprehensive study of Down Syndrome births was conducted in 44 U.S. cities over a 2-year period. Rates of Down Syndrome were comparable in both fluoridated and nonfluoridated cities.[186]

Question 28. Does ingestion of optimally fluoridated water have any neurological impact?

Answer. There is no generally accepted scientific knowledge establishing a causal relationship between consumption of optimally fluoridated water and central nervous system disorders, including effects on intelligence.

Fact

There have been claims that exposure to fluoride presents a neurotoxic (harmful or damaging to nerve tissue) risk or lowered intelligence. Such claims are based on a 1995 study in which rats were fed fluoride at levels up to 125 times greater than that found in optimally fluoridated water.[187] The study attempted to demonstrate that rats fed extremely high levels of fluoride (75 ppm to 125 ppm in drinking water) showed behavior-specific changes related to cognitive deficits.

In addition, the experiment also studied the offspring of rats who were injected two to three times a day with fluoride during their pregnancies in an effort to show that prenatal exposure resulted in hyperactivity in male offspring.

However, two scientists who reviewed the 1995 study[188] have suggested that the observations made can be readily explained by mechanisms that do not involve neurotoxicity. The scientists found inadequacies in experimental design that may have led to invalid conclusions. For example, the results of the experiment were not confirmed by the use of control groups which are an essential feature of test validation and experimental design. In summary the scientists stated, "We do not believe the study by Mullenix et al. can be interpreted in any way as indicating the potential for NaF (sodium fluoride) to be a neurotoxicant." Another reviewer[104] noted, ". . . it seems more likely that the unusually high brain fluoride concentrations reported in Mullenix et al. were the result of some analytical error."

A 7-year study compared the health and behavior of children from birth through 6 years of age in communities with optimally fluoridated water with those of children the same age without exposure to optimally fluoridated water. Medical records were reviewed yearly during the study. At age six and seven, child behavior was measured using both maternal and teacher ratings. The results suggested that there was no evidence to indicate that exposure to optimally fluoridated water had any detectable adverse effect on children's health or behavior. These results did not differ even when data was controlled for family social background.[189]

Question 29. Does drinking optimally fluoridated water cause Alzheimer's disease?

Answer. Generally accepted science has not demonstrated an association between drinking optimally fluoridated water and Alzheimer's disease.

Fact

The exact cause of Alzheimer's disease (AD) has yet to be identified. Scientists have identified the major risk factors for AD as age and family history. Other possible risk factors include a serious head injury and lower levels of education. Scientists are also studying additional factors to see if they may be associated with the disease. These include genetic (inherited) factors, viruses and environmental factors such as aluminum, zinc and other metals. Researchers have found these metals in the brain tissue of people with AD, but it is not known if these metals cause AD or buildup in the brain as a result of the disease.[190]

Because aluminum has been found in the brain tissue of people with AD, claims have been made that fluoridated water "leaches" out the aluminum in cookware when used for boiling water, thereby implicating fluoride as a co-factor in the development of AD. One experiment attempted to test this claim by measuring the release of aluminum from aluminum cookware under the most adverse conditions, with and without the presence of fluoride. Throughout these trials, scientists were

unable to leach out significant amounts of aluminum from any of the cookware, including those that were exposed to extreme acidic or alkaline conditions.[191]

A study published in 1998[192] raised concerns about the potential relationship between fluoride and Alzheimer's disease. However, several flaws in the experimental design preclude any definitive conclusions from being drawn.[193]

Interestingly, there is evidence that aluminum and fluoride are mutually antagonistic in competing for absorption in the human body.[17 194] While a conclusion cannot be made that consumption of fluoridated water has a preventive effect on AD, there is no generally accepted scientific knowledge to show consumption of optimally fluoridated water is a risk factor for AD.

Question 30. Does drinking optimally fluoridated water cause or contribute to heart disease?

Answer. Broad national experience and generally accepted scientific knowledge demonstrate that drinking optimally fluoridated water is not a risk factor for cardiovascular disease.

Fact

This conclusion is supported by results of a study conducted by the National Heart and Lung Institute of the National Institutes of Health. Researchers examined a wide range of data from communities that have optimally fluoridated water and from areas with insufficient fluoride. The final report concluded that:

Thus, the evidence from comparison of the health of fluoridating and nonfluoridating cities, from medical and pathological examination of persons exposed to a lifetime of naturally occurring fluorides or persons with high industrial exposures, and from broad national experience with fluoridation all consistently indicate no adverse effect on cardiovascular health.[195]

The American Heart Association has reaffirmed its historical position that heart disease is not related to the amount of fluoride present in drinking water.[196] The American Heart Association identifies cigarette and tobacco smoke, high blood cholesterol levels, high blood pressure, physical inactivity and obesity as major risk factors for cardiovascular disease.[197]

A number of studies have considered trends in urban mortality in relation to fluoridation status. In one study, the mortality trends from 1950–70 were studied for 473 cities in the United States with populations of 25,000 or more. Findings showed no relationship between fluoridation and heart disease death rates over the 20-year period.[145] In another study, the mortality rates for approximately 30 million people in 24 fluoridated cities were compared with those of 22 nonfluoridated cities for 2 years. No evidence was found of any harmful health effects, including heart disease, attributable to fluoridation. As in other studies, crude differences in the mortality experience of the cities with fluoridated and nonfluoridated water supplies were explainable by differences in age, gender and race composition.[144]

Question 31. Is the consumption of optimally fluoridated water harmful to kidneys?

Answer. Generally accepted scientific knowledge suggests that the consumption of optimally fluoridated water does not cause or worsen human kidney disease.

Fact

Approximately 50 percent of the fluoride ingested daily is removed from the body by the kidneys.[104 114 115] Because the kidneys are constantly exposed to various fluoride concentrations, any health effects caused by fluoride would likely manifest themselves in kidney cells. However, several large community-based studies of people with long-term exposure to drinking water with fluoride concentrations up to 8 ppm have failed to show an increase in kidney disease.[95 198 199]

In a report issued in 1993 by the National Research Council, the Subcommittee on Health Effects of Ingested Fluoride stated that the threshold dose of fluoride in drinking water which causes kidney effects in animals is approximately 50 ppm-more than 12 times the maximum level allowed in drinking water by the Environmental Protection Agency. Therefore, they concluded that "ingestion of fluoride at currently recommended concentrations is not likely to produce kidney toxicity in humans."[96]

Many people with kidney failure depend on hemodialysis (treatment with an artificial kidney machine) for their existence. During hemodialysis, the patient's blood is exposed to large amounts of water each week (280–560 quarts). Therefore, procedures have been designed to ensure that the water utilized in the process contain a minimum of dissolved substances that could diffuse indiscriminately into the patient's bloodstream.[200]

Since the composition of water varies in different geographic locations in the United States, the U.S. Public Health Service recommends dialysis units use tech-

niques such as reverse osmosis and deionization to remove excess iron, magnesium, aluminum, calcium, and other minerals, as well as fluoride, from tap water before the water is used for dialysis.[200] [201]

Question 32. Will the addition of fluoride affect the quality of drinking water?

Answer. There is no scientific evidence that optimal levels of fluoride affect the quality of water. All ground and surface water in the United States contains some naturally occurring flouride.

Fact

Nearly all water supplies must undergo various water treatment processes to be safe and suitable for human consumption. The substances used for this purpose include aluminum sulfate, ferric chloride, ferric sulfate, activated carbon, lime, soda ash and, of course, chlorine. Fluoride is added only to water that has naturally occurring lower than optimal levels of this mineral.[27]

Fluoridation is the adjustment of the fluoride concentration of fluoride-deficient water supplies to the recommended range of 0.7 to 1.2 parts per million of fluoride for optimal dental health. The EPA has stated that fluoride in children's drinking water at levels of approximately 1.0 ppm reduces the number of dental cavities.[202] The optimal level is dependent on the annual average of the maximum daily air temperature in the geographic area.[27]

Under the Safe Drinking Water Act, the EPA has established drinking water standards for a number of substances, including fluoride, in order to protect the public's health. There are several areas in the United States where the ground water contains higher than optimal levels of naturally occurring fluoride. Therefore, Federal regulations were established to require that naturally occurring fluoride levels in a community water supply not exceed a concentration of 4.0 mg/L.[202] Under the Safe Drinking Water Act, this upper limit is the Maximum Contaminant Level (MCL) for fluoride. Under the MCL standard, if the naturally occurring level of fluoride in a public water supply exceeds the MCL (4.0 mg/L for fluoride), the water supplier is required to lower the level of fluoride below the MCL. This process is called defluoridation.

The EPA has also set a Secondary Maximum Contaminant Level (SMCL) of 2.0 mg/L, and requires consumer notification by the water supplier if the fluoride level exceeds 2.0 mg/L. The SMCL is intended to alert families that regular consumption of water with natural levels of fluoride greater than 2.0 mg/L by young children may cause dental fluorosis in the developing permanent teeth, a cosmetic condition with no known health effect.[202] The notice to be used by water systems that exceed the SMCL must contain the following points:

1. The notice is intended to alert families that children under 9 years of age who are exposed to levels of fluoride greater than 2.0 mg/liter may develop dental fluorosis.

2. Adults are not affected because dental fluorosis occurs only when developing teeth are exposed to elevated fluoride levels.

3. The water supplier can be contacted for information on alternative water source or treatments that will insure the drinking water would meet all standards (including the SMCL).

The 1993 National Research Council report, "Health Effects of Ingested Fluoride," reviewed fluoride toxicity and exposure data for the EPA and concluded that the current standard for fluoride at 4.0 mg/L (set in 1986) was appropriate as an interim standard to protect the public healthy In the EPA's judgment, the combined weight of human and animal data support the current fluoride drinking water standard and, in December 1993, the EPA published a notice in the Federal Register stating the ceiling of 4 mg/L would protect against adverse health effects with an adequate margin of safety and published a notice of intent not to revise the fluoride drinking water standards in the Federal Register.[97]

The EPA further commented on the safety of fluoride in the December 5, 1997, Federal Register.[156] In a notice of a final rule relating to fluoride compounds the EPA stated, "There exists no directly applicable scientific documentation of adverse medical effects at levels of fluoride below 8 mg/L (0.23 mg/kg/day)." The EPA's Maximum Concentration Limit (MCL) of 4.0 mg/L (0.114 mg/kg/day) is one half that amount, providing an adequate margin of safety.

The EPA indirectly regulates the intentional fluoridation of drinking water by having an enforceable Federal standard for fluoride at 4.0 mg/L. As long as the 4.0 mg/L standard is not exceeded, State or local authorities determine whether or not to fluoridate.[237]

(Additional discussion on this topic may be found in Question 2.)

Question 33. Does fluoridation present difficult engineering problems?

Answer. No. Properly maintained and monitored water fluoridation systems do not present difficult engineering problems.

Fact

With proper planning and maintenance of the system, fluoride adjustment is compatible with other water treatment processes. Today's equipment allows water treatment personnel to easily monitor and maintain the desired fluoride concentration. Automatic monitoring technology is available that can help to assure that the fluoride concentration of the water remains within the recommended range. Depending on the climate, the range for optimally fluoridated water is 0.7–1.2 ppm for an individual water plant.[27]

There are only three basic compounds used to fluoridate community drinking water: 1) sodium fluoride, a white, odorless crystalline material; 2) sodium fluorosilicate, a white or yellow-white, odorless crystalline powder; and 3) fluorosilicic acid, a white to straw-colored liquid. The three fluoride compounds are derived from the mineral apatite which is a mixture of calcium compounds. Apatite contains 3 percent to 7 percent fluoride and is the main source of fluorides used in water fluoridation at the present time. Apatite is also the raw material used for production of phosphate fertilizers;[27] [203] however, standards and minimum requirements have been established for all three compounds used in water fluoridation.[204]

From time to time, opponents of water fluoridation allege that the three compounds used in water fluoridation are impure or contain impurities at a level that may be potentially harmful. To help ensure the public's safety, compounds used for water fluoridation conform to standards established by the American Water Works Association.[204] The American Water Works Association (AWWA) is an international nonprofit scientific and educational society dedicated to the improvement of drinking water quality and supply. Regarding impurities, the AWWA Standards state, "The [fluoride compound] supplied under this standard shall contain no soluble materials or organic substances in quantities capable of producing deleterious or injurious effects on the health of those consuming water that has been properly treated with the [fluoride compound]." Certified analyses of the compounds must be furnished by the manufacturer or supplier.[204]

When added to community water supplies fluoride compounds become diluted to the recommended range of 0.7 to 1.2 parts per million. At 1 ppm, one part of fluoride is diluted in a million parts of water. Large numbers such as a million can be difficult to visualize. While not exact, the following comparisons can be of assistance in comprehending one part per million:

- 1 inch in 16 miles
- 1 minute in 2 years
- 1 cent in $10,000

(Additional discussion on this topic may be found in Question 21.)

Fluoride compounds are added to the water supply as liquids, but are measured by two basic types of devices, dry feeders or solution feeders (metering pumps). By design, and with proper maintenance and testing, water systems limit the amount of fluoride that can be added to the system (i.e., the use of a day tank that only holds 1 day's supply of fluoride) so prolonged over-fluoridation becomes a mechanical impossibility.[27] It is very important that the water treatment operators responsible for monitoring the addition of fluoride to the water supply be appropriately trained, and that the equipment used for this process is adequately maintained.[203] As with any mechanical equipment, water fluoridation equipment should be tested, maintained and replaced as needed. State health departments can procure Federal grant moneys for these purposes.

While the optimal fluoride concentration found in drinking water has been proven safe, water plant operators and engineers may be exposed to much higher fluoride levels when handling fluoride compounds at the water treatment facility.[27] In order to prevent overexposure to fluoride compounds by water plant operators, and ensure that fluoridated water systems provide optimal fluoride levels, the Centers for Disease Control and Prevention and the Occupational Safety and Health Administration provide guidelines/ recommendations for managers of fluoridated public water systems.[203] [204] Adherence to these guidelines should assure continuous levels of optimally fluoridated drinking water while maintaining safe operation of all fluoridated water systems.

Allegations that fluoridation causes corrosion of water delivery systems are not supportable.[27] Corrosion by drinking water is related primarily to dissolved oxygen concentration, pH, water temperature, alkalinity, hardness, salt concentration, hydrogen sulfide content and the presence of certain bacteria. Under some water quality conditions, a small increase in the corrosivity of drinking water that is already corrosive may be observed after treatment with alum, chlorine, fluorosilicic acid or

sodium florosilicate. In such cases, further water treatment is indicated to adjust the pH upward. This is part of routine water plant operations.

PUBLIC POLICY

Question 34. Is water fluoridation a valuable public health measure?

Answer. Yes. Fluoridation is a public health program that benefits people of all ages, is safe and is cost effective because it saves money.

Fact

A former Surgeon General of the United States, Dr. Luther Terry, called fluoridation as vital a public health measure as immunization again disease, pasteurization of milk and purification of water.[205] Another former U.S. Surgeon General, Dr. C. Everett Koop, has stated, "Fluoridation is the single most important commitment that a community can make to the oral health of its citizens." In 1998, the U.S. Public Health Service revised national health objectives to be achieved by the year 2010. Included under oral health was an objective to significantly expand the fluoridation of public water supplies.[8] Water fluoridation has been lauded as one the most economical preventive values in the nation,[9] and today still has the greatest dental public health impact.[36]

Question 35. Has the legality of water fluoridation been upheld by the courts?

Answer. Yes. Fluoridation has been thoroughly tested in the United States' court system, and found to be a proper means of furthering public health and welfare. No court of last resort has ever determined fluoridation to be unlawful. Moreover, fluoridation has been clearly held not to be an unconstitutional invasion of religious freedom or other individual rights guaranteed by the First, Fifth or Fourteenth Amendments to the U.S. Constitution.

Fact

During the last 50 years, the legality of fluoridation in the United States has been thoroughly tested in our court systems. Fluoridation is viewed by the courts as a proper means of furthering public health and welfare.[206] No court of last resort has ever rendered an opinion against fluoridation. The highest courts of more than a dozen states have confirmed the constitutionality of fluoridation.[207] In 1984, the Illinois Supreme Court upheld the constitutionality of the state's mandatory fluoridation law, culminating 16 years of court action at a variety of judicial levels.[203] Moreover, the U.S. Supreme Court has denied review of fluoridation cases 13 times, citing that no substantial Federal or constitutional questions were involved.[207]

It has been the position of the American courts that a significant government interest in health and welfare of the public generally overrides individual objections to public health regulation.[207] Consequently, the courts have rejected the contention that fluoridation ordinances are a deprivation of religious or individual freedoms guaranteed under the Constitution.[207 209] In reviewing the legal aspects of fluoridation, the courts have dealt with this concern by ruling that: (1) fluoride is a nutrient, not a medication, and is present naturally in the environment; (2) no one is forced to drink fluoridated water as alternative sources are available; and (3) in cases where a person believes that fluoridation interferes with religious beliefs, there is a difference between the freedom to believe, which is absolute, and the freedom to practice beliefs, which may be restricted in the public's interest.[210 211]

Fluoridation is the adjustment of a naturally occurring element found in water in order to prevent dental decay. Courts have consistently ruled that water fluoridation is not a form of compulsory mass medication or socialized medicine.[207 210 212] A medication implies a substance used to treat disease. Fluoridation simply provides an individual with an increased level of protection against developing dental disease. Water that has been fortified with fluoride is similar to fortifying salt with iodine, milk with vitamin D and orange juice with vitamin C.

Question 36. Why does opposition to community water fluoridation continue?

Answer. Fluoridation is considered beneficial by the overwhelming majority of the health and scientific communities as well as the general public. However, a vocal minority continues to speak out against fluoridation of municipal water supplies. Some individuals may view fluoridation of public water as limiting their freedom of choice; other opposition can stem from misinterpretations or inappropriate extrapolations of the science behind the fluoridation issue.

Fact

A vast body of scientific literature endorses water fluoridation as a safe means of reducing the incidence of tooth decay. Support for fluoridation among scientists and health professionals, including physicians and dentists, is nearly universal. Rec-

ognition of the benefits of fluoridation by the American Dental Association, the American Medical Association, governmental agencies and other national health and civic organizations (see inside of back cover) continues as a result of published, peer-reviewed research.

The majority of Americans also approves of water fluoridation. In June 1998, the Gallup Organization conducted a national survey of just over 1,000 adults on their attitudes toward community water fluoridation. When asked, "Do you believe community water should be fluoridated?", 70 percent answered yes, 18 percent answered no and 12 percent responded don't know. Results characterized by U.S. Census Region showed the level of support for community water fluoridation to be relatively constant throughout the United States, with 73 percent in the Northeast, 72 percent in the Midwest, 68 percent in the South and 70 percent in the West favoring community water fluoridation.[2] These results are consistent with a December 1991 Gallup survey that asked 1,200 parents, "Whether or not you presently have fluoridated water, do you approve or disapprove of fluoridating drinking water?" More than three-quarters (78 percent) of the responding parents approved, 10 percent disapproved and 12 percent answered don't know or refused to answer the question. Disapproval ranged from 4 percent in communities where water was fluoridated to 16 percent in communities where it was not.[213] [214]

Opposition to fluoridation has existed since the initiation of the first community programs in 1945. An article that appeared in the local newspaper shortly after the first fluoridation program was implemented in Grand Rapids, Michigan, noted that the fluoridation program was slated to commence January 1 but did not actually begin until January 15. Interestingly, health officials in Grand Rapids began receiving complaints of physical ailments attributed to fluoridation from citizens weeks before fluoride was actually added to the water.[7]

Of the small faction that opposes water fluoridation for philosophical reasons, freedom of choice probably stands out as the most important single issue.[213] Some individuals are opposed to community action on any health issue, others because of environmental or economic arguments and some because they are misinformed. Some opponents may knowingly or unknowingly use half-truths and innuendoes to support their opinions, either misquoting or applying statements out of context. The sometimes alarming statements used by some antifluoridationists, however, are not substantiated by general accepted scientific knowledge.[213] [215] [216]

"Junk science," a term coined by the press and used over the past decade to characterize data derived from atypical or questionable scientific techniques, also can play a role in provoking opposition to water fluoridation. In fact, decisionmakers have been persuaded to postpone action on several cost-effective public health measures after hypothetical risks have made their way into the public media.[217] Junk science impacts public policy and costs society in immeasurable ways. More people, especially those involved in policy decisions, need to be able to distinguish junk science from legitimate scientific research. Reputable science is based on the scientific method of testing hypotheses in ways that can be reproduced and verified by others; junk science, which often provides too-simple answers to complex questions, often cannot be substantiated.

In 1993 the U.S. Supreme Court issued a landmark decision that many view as likely to restrict the use of junk science in the courts. The Court determined that while "general acceptance" is not needed for scientific evidence to be admissible, Federal trial judges have the task of ensuring that an expert's testimony rests on a reasonable foundation and is relevant to the issue in question.

According to the Supreme Court, many considerations will bear on whether the expert's underlying reasoning or methodology is scientifically valid and applicable in a given case. The Court set out four criteria judges could use when evaluating scientific testimony: (1) whether the expert's theory or technique can be (and has been) tested, using the scientific method, (2) whether it has been subject to peer review and publication (although failing this criteria alone is not necessarily grounds for disallowing the testimony), (3) its known or potential error rate and the existence and maintenance of standards in controlling its operation, and (4) whether it has attracted widespread acceptance within a relevant scientific community, since a known technique that has been able to attract only minimal support may properly be viewed with skepticism. The scientific validity and relevance of claims made by opponents of fluoridation might be best viewed when measured against these criteria.[218]

Opinions are seldom unanimous on any scientific subject. In fact, there may be no such thing as "final knowledge," since new information is continuously emerging and being disseminated. As such, the benefit evidence must be continually weighed against risk evidence. Health professionals, decisionmakers and the public should be cooperating partners in the quest for that accountability.[219]

(Additional discussion on this topic may be found in the Introduction—Scientific Information on Fluoridation.)

Question 37. Where can reliable information about water fluoridation be found on the Internet and World Wide Web?

Answer. The American Dental Association, as well as other reputable health and science organizations, and government agencies have sites on the Internet/Web that provide information on fluorides and fluoridation. These sites provide information that is consistent with generally accepted scientific knowledge.

Fact

The Internet and World Wide Web are evolving as accessible sources of information. However, not all "science" posted on the Internet and Web is based on scientific fact. Searching the Internet for "fluoride" or "water fluoridation" directs individuals to a number of Web sites. Some of the content found in the sites is scientifically sound. Other less scientific sites may look highly technical, but contain information based on science that is unconfirmed or has not gained widespread acceptance. Commercial interests, such as the sale of water filters, may also be promoted.

One of the most widely respected sources for information regarding fluoridation and fluorides is the American Dental Association's (ADA) home page at <http://www.ada.org>. From the ADA Web site individuals can make contact with other Web sites for more information about fluoride.

Question 38. Why does community water fluoridation sometimes lose when it is put to a public vote?

Answer. Voter apathy, blurring of scientific issues, lack of leadership by elected officials and a lack of political campaign skills among health professionals are some of the reasons fluoridation votes are sometimes unsuccessful.

Fact

Despite the continuing growth of fluoridation in this country during the past decades, millions of Americans do not yet receive the protective benefits of fluoride in their drinking water. At the present time, only 62.2 percent of the population served by public water systems have access to fluoridated watery In 1992, approximately 70 percent of all U.S. cities with populations of more than 100,000 fluoridated their water, including 42 of the 50 largest cities.[220] In 1998, the U.S. Public Health Service revised national health objectives to be achieved by the year 2010. Oral Health Objective 10 deals specifically with community water fluoridation and states that at least 85 percent of the population served by community water systems should be receiving the benefits of optimally fluoridated water by the year 2010.[8] At the time the objectives were revised, less than half of the states met the 85 percent goal.

The adoption of fluoridation by communities has slowed during the past several decades. Social scientists have conducted numerous studies to determine why this phenomenon has occurred. Among the factors noted are lack of funding, public and professional apathy, the failure of many legislators and community leaders to take a stand because of perceived controversy, low voter turnout and the difficulty faced by an electorate in evaluating scientific information in the midst of emotional charges by opponents. Unfortunately, citizens may mistakenly believe their water contains optimal levels of fluoride when, in fact, it does not.

Clever use of emotionally charged "scare" propaganda by fluoride opponents creates fear, confusion and doubt within a community when voters consider the use of fluoridation.[221] [222] Defeats of referenda or the discontinuance of fluoridation have occurred most often when a small, vocal and well organized group has used a barrage of fear-inspiring allegations designed to confuse the electorate. In addition to attempts to influence voters, opponents have also threatened community leaders with personal litigation.[215] While no court of last resort has ever ruled against fluoridation, community leaders may be swayed by the threat of litigation due to the cost and time involved in defending even a groundless suit. In no instance has fluoridation been discontinued because it was proven harmful in any way as [215] [216] [223]

Adoption of fluoridation is ultimately a decision of state or local decisionmakers, whether determined by elected officials, health officers or the voting public. Fluoridation can be enacted through state legislation, administrative regulation or a public referendum. Fluoridation is not legislated at the Federal level and is perceived in most states as a local issue. From 1989–94, 318 communities authorized fluoridation by administrative governmental action. In the same hme period, 32 referenda were held with fluoridation authorization approved in 19 and defeated in 13.[224] As noted above, referenda can be unsuccessful for a variety of reasons. Nonetheless, a community's decision to protect the oral health and welfare of its citizens must, in some cases, override individual objections to implement appropriate public health measures.

Question 39. Is community water fluoridation accepted by other countries?

Answer. Yes. Water fluoridation is practiced in approximately 60 countries benefiting over 360,000,000 (three hundred 60 million) people.!

Fact

The value of water fluoridation is recognized internationally. Countries and geographic regions with extensive fluoridation include the U.S., Australia, Brazil, Canada, Hong Kong, Malaysia, United Kingdom, Singapore, Chile, New Zealand, Israel, Columbia, Costa Rica and Ireland.[79] The most recent county-wide decision for fluoridated drinking water occurred in South Africa.[225] Following the recommendations of the World Health Organization (WHO), the initial phase of the project is expected to reach 40 percent of the country's population. By the year 2000, the goal is to reach 60 percent of the population which is widely spread in rural areas. Some of the most thorough investigations of fluoridation have been conducted in Britain and Australia. These investigations have resulted in a significant amount of published documentation which supports the safety and effectiveness of water fluoridation.[92 94 226] Considering the extent to which fluoridation has already been implemented throughout the world, the lack of documentation of adverse health effects is remarkable testimony to its safety.[54 92 93 94 95 96]

The World Health Organization (WHO) and the Pan American Health Organization have endorsed the practice of water fluoridation since 1964. In 1994, an expert committee of WHO published a report which reaffirmed its support of fluoridation as being safe and effective in the prevention of tooth decay, and stated that "provided a community has a piped water supply, water fluoridation is the most effective method of reaching the whole population, so that all social classes benefit without the need for active participation on the part of individuals."[82] In many parts of the world, fluoridation is not feasible or a high priority, usually due to the lack of a central water supply, the existence of more life threatening health needs and the lack of sufficient funds for startup and maintenance costs.

Political actions contrary to the recommendations of health authorities should not be interpreted as a negative response to water fluoridation. For example, although fluoridation is not carried out in Sweden and the Netherlands, both countries support WHO's recommendations regarding fluoridation as a preventive health measure, in addition to the use of fluoride toothpastes, mouthrinses and dietary fluoride supplements.[82 227]

Question 40. Is community water fluoridation banned in Europe?

Answer. No country in Europe has banned community water fluoridation.

Fact

The claim that fluoridation is banned in Europe is frequently used by fluoridation opponents. In truth, European countries construct their own water quality regulations within the framework of the 1980 European Water Quality Directive. The Directive provides maximum admissible concentrations for many substances, one of which is fluoride. The Directive does not require or prohibit fluoridation, it merely requires that the fluoride concentration in water does not exceed the maximum permissible concentration.

Many fluoridation systems that used to operate in Eastern and Central Europe did not function properly and, when the Iron Curtain fell in 1989–90, shut down because of obsolete technical equipment and lack of knowledge as to the benefits of fluoridated water.[229] Water fluoridation is not practical in many European countries because of complex water systems with numerous water sources. As an alternative to water fluoridation, many European countries have opted for salt fluoridation, in addition to the use of fluoride toothpaste for topical benefits, as a means of bringing the protective benefits of fluoride to the public.

(Additional discussion on this topic may be found in Question 10.)

Again, no European country has specifically imposed a "ban" on fluoridation, it has simply not been implemented for a variety of technical or political reasons.

COST EFFECTIVENESS

Question 41. Is water fluoridation a cost-effective means of preventing tooth decay?

Answer. Yes. Data from generally accepted scientific studies continue to confirm that fluoridLation has substantial lifelong decay preventive effects and is a highly cost-effective means of preventing tooth decay in the United States, regardless of socioeconomic status.[58 61 62 230 231 232]

Fact

It has been calculated that the annual cost of community water fluoridation in the U.S. is approximately $0.50 per person.[233] The annual cost ranges between $0.12 and $5.41 per person, depending mostly on the size of a community, labor costs, and type of fluoride compounds and equipment utilized.[27 62 231 232 234] It can be calculated from these data that the lifetime cost per person to fluoridate a water system is less than the cost of one dental filling. With the escalating cost of health care, fluoridation remains a preventive measure that benefits members of the community at minimal cost.

Historically, the cost to purchase fluoride compounds has remained fairly constant over the years in contrast to the continued rising cost of dental care.[27] School-based dental disease prevention activities (such as fluoride mouthrinse or tablet programs), professionally applied topical fluorides and dental health education are beneficial but have not been found to be as cost-effective in preventing tooth decay as community water fluoridation.[230] Fluoridation remains the most cost-effective and practical form of preventing decay in the United States and other countries with established municipal water systems.[9 58 62 230 234]

Due to the decay-reducing effects of fluoride, the need for restorative dental care is typically lower in fluoridated communities. Therefore, an individual residing in a fluoridated community will generally have fewer restorative dental expenditures during a lifetime. Health economists at a 1989 workshop concluded that fluoridation costs approximately $3.35 per tooth surface when decay is prevented, making fluoridation "one of the very few public health procedures that actually saves more money than it costs."[234] Considering the fact that the national average fee for a two surface amalgam (silver) restoration in a permanent tooth placed by a general dentist is $75.84*, fluoridation clearly demonstrates significant cost savings.[235]

The economic importance of fluoridation is underscored by the fact that frequently the cost of treating dental disease is paid not only by the affected individual, but also by the general public through services provided by health departments, welfare clinics, health insurance premiums, the military and other publicly supported medical programs.[61]

Indirect benefits from the prevention of dental decay may include:

- freedom from dental pain
- a more positive self image
- fewer missing teeth
- fewer cases of malocclusion aggravated by tooth loss
- fewer teeth requiring root canal treatment
- reduced need for dentures and bridges
- less time lost from school or work due to dental pain or visits to the dentist

These intangible benefits are difficult to measure economically, but are extremely importantly [58 231]

The survey data should not be interpreted as conshtuhng a fee schedule in any way, and should not be used for that purpose. Dentists must establish their own fees based on their individual practice and market considerations.

Question 42. Is it practical to fluoridate an entire water system?

Answer. It is more practical to fluoridate an entire water supply than to attempt to treat individual water sources.

Fact

It is technically difficult, perhaps impossible, and certainly more costly to fluoridate only the water used for drinking. Community water that is chlorinated, softened, or in other ways treated is also used for watering lawns, washing cars and for most industrial purposes. The cost of compounds for fluoridating a community's water supply is inexpensive on a per capita basis; therefore, it is practical to fluoridate the entire water supply. Fluoride is but one of more than 40 different chemicals that may be used to treat water in the United States.[27] The American Water Works Association, an international nonprofit scientific and educational society dedicated to the improvement of drinking water quality and supply, supports the practice of fluoridation of public water supplies.[236]

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AMERICAN LEAGUE OF ANGLERS AND BOATERS,
July 18, 2000.

The Honorable MICHAEL CRAPO, *Chairman,*
Subcommittee on Fisheries, Wildlife and Drinking Water,
Committee on Environment and Public Works,
U.S. Senate,
Washington, DC 20510

DEAR MR. CHAIRMAN: The American League of Anglers and Boaters (ALAB) was created in 1984 to continue the partnership between national conservation and recreation organizations which successfully campaigned for the enactment of amendments to the Sport Fish Restoration Act of 1950, better known as the Wallop-Breaux Act. We ask that our views be considered as your subcommittee conducts oversight hearings on the Fish and Wildlife Service's administration of the Federal Aid Program.

The Sport Fish Restoration Program and the Pittman-Robertson Wildlife Restoration Program (upon which the initial sport fish program was modeled) are two of the most significant and successful programs in the history of fish and wildlife management in our country. The majority of funds are apportioned to the states to deliver on-the-ground programs for the conservation of fish and wildlife resources. They are vitally important to state fish and wildlife management programs and, together with revenues from the sale of state hunting and fishing licenses, form the single most important funding source for state fish and wildlife agencies.

There is no doubt that the U.S. Fish and Wildlife Service (F&WS) can and should do a better and more effective job of administering these national programs. H.R. 3671, recently passed by the House, clearly redefines the responsibilities of the F&WS in this regard and increases their accountability to Congress and the states. This legislative approach is needed and has the support of ALAB and our member organizations.

The members of ALAB have a primary interest in the Sport Fish Restoration Program. However, since the Sport Fish and the Wildlife Restoration Programs are implemented by a single state Agency and are administered by a single unit of the F&WS, both programs are closely interrelated. Legislative changes to one of the programs can have indirect impacts on the other. Our interest, therefore, is directed toward the administration of both programs as reflected in H.R. 3671.

ALAB would like to share its concerns about four areas of H.R. 3671:

1. H.R. 3671 would provide $5 million annually for a Multi-State Conservation Grants Program ($2.5 million from each fund). At least four existing programs (National Survey of Fishing, Hunting, and Wildlife-Associated Recreation, Management Assistance Team, Administrative Grants Program, and Library Reference Service), at the recommendation and concurrence of the states, have been funded for several years and would fall under this proposed program. The $5 million provided by H.R. 3671 is not sufficient to fund these four programs or to include other projects of multi-state or national benefit that might need to be carried out collectively at much less expense than if each state conducted them individually. It is ALAB's recommendation that 2 percent of each fund (approximately $4.5 million each) be available annually for the Multi-State Conservation Grants Program.

2. The Sport Fishing and Boating Partnership Council (SEBPC) was created to provide a mechanism to give advice to the Secretary of the Interior on sport fish restoration and other fishing and boating issues. The SFBPC has been widely recognized for its collaborative efforts and has undertaken mayor assignments by the Congress such as that called for in TEA–21. Those that contribute to the sport fish

restoration fund, including a number of members of ALAB, deem the SFBPC an invaluable tool for ensuring that those that pay the tax are heard when critical decisions are made within the F&WS. The activities of the SFBPC have been funded by Sport Fish Restoration administrative funds at approximately $400,000 per year. It is ALAB's recommendation that language be included in H.R. 3671 specifying that funding be set aside for the work of the SFBPC.

3. Under existing law, the F&WS can currently utilize up to 6 percent of Sport Fish Restoration and 8 percent of Wildlife Restoration Funds to administer the two programs. H.R. 3671 would reduce this to a straight dollar amount of $14,180,000 the first year, with gradual reductions over the next 2 years to $12.6 million. This is a significant reduction In administrative funding and we are concerned it would have a negative impact on these two very successful programs. ALAB recommends that 3 percent of Wallop-Breaux and 4 percent of Pittman-Robertson funds, or $16 million, be available annually to the F&WS for administration of the program and delivery of apportioned funds to the states.

4. Over the years, several grant programs have been added to the Sport Fish Restoration Program. These include the Clean Vessel Act Pumpout Program ($10 million/year), the Boating Infrastructure Grant Program ($8 million/year), and the National Outreach and Communications Program ($5–10 million/ year). Although funds for these programs are withdrawn from the Sport Fish Restoration Account before the calculation of administrative funds is made, no specific provision is made in H.R. 3671 for funds to administer these small grant programs. The F&WS is now considering using Sport Fish Restoration administrative funds to administer these programs. This would further weaken the administration of the Sport Fish Restoration Program. It is ALAB's recommendation that language be included in H.R. 3671 specifying that administrative costs for each small grant program be made available from the fund specified for each program and not from Sport Fish Restoration administrative funds.

Implementation of the provisions of H.R. 3671 would improve the administration of the Sport Fish and Wildlife Restoration Programs. The four recommendations that we have made will bring improvements to the bill that will significantly enhance and ensure the continued success of these vital programs. Your consideration of our recommendations is sincerely appreciated.

Sincerely,

DERRICK CRANDALL, *Co-Chair.*
VERONICA FLOYD, *Co-Chair.*

ALAB MEMBER ORGANIZATIONS

American Fisheries Society (AFS)
American Recreation Coalition (ARC)
American Sportfishing Association (ASA)
Atlantic States Marine Fisheries Commission (ASMFC)
Bass Anglers Sportsman Society (B.A.S.S., INC)
Boat Owners Association of the United States (BOAT/US)
Boating Trades Association of Texas (BTAT)
Brunswick Corporation
Congressional Sportsmen's Foundation (CSF)
International Association of Fish & Wildlife Agencies (IAFWA)
International Game Fish Association
International Jet Sports Boating Association
Izaak Walton League of America (IWLA)
Marina Operators Association of America (MOM)
Marine Retailers Association of America (MRM)
National Association of State Boating Law Administrators (NASBLA)
National Boating Federation (NBF)
National Marine Manufacturers Association
National Recreation and Park Association
National Safe Boating Council
Personal Watercraft Industry Association
Sail America States Organization for Boating Access (SOBA)
Trout Unlimited
U.S. Sailing Association

STATEMENT OF THE CALIFORNIA WATER ASSOCIATION ON THE PROPOSED NATIONAL PRIMARY DRINKING WATER REGULATION FOR RADON

The California Water Association (CWA) appreciates the opportunity to provide written comment to the Senate Environment and Public Works Committee, Subcommittee on Fisheries, Wildlife, and Water on the National Primary Drinking Water Regulation for Radon at the Safe Drinking Water Act Oversight Hearing,

June 29, 2000. CWA is a professional organization representing a consortium of investor-owned water utilities providing high-caliber water utility services to more than 6,000,000 customers throughout California. With more than 52 active member companies, CWA provides a forum for sharing best practices; a means of promoting sound, reasonable and science-based policymaking by regulatory agencies and legislators; support to small water systems; and opportunities for educating the public on efficient water use and protection of water resources.

California water utilities are very concerned about the way in which EPA has proposed the NPDWR for Radon. CWA's comments (see attachments A and B) to EPA identify many of the deficiencies in EPA's proposed regulation and indicates the potential impact on CWA member utilities.

CWA conducted a survey of its member and affiliated utilities regarding radon which revealed the following:

- 173 groundwater systems responded
  - responses addressed 1,555 water wells
  - these wells pumped to 1,319 entry points
- Only 600 of these wells had been sampled for radon (39 percent)
- Of these, 399 wells exceed the proposed radon MCL of 300 pCi/L (67 percent)
- 70 of 75 water systems that have sampled for radon had at least one source exceed the proposed radon MCL of 300 pCi/L (93 percent) Of those entry points exceeding 300 pCi/L, 295 (74 percent) will require additional land purchases to build radon treatment plants.
- The range of land cost was from $50,000 to $500,000 with an average of $150,000.
- The range of radon analyses were non-detect (<100 pCi/L) to 44,475 pCi/L
  - The arithmetic mean of radon = 743 pCi/L
  - The geometric mean of radon = 373 pCi/L
- EPA radon proposal assumed a mean radon level in California ground water to be 150 pCI/L to 300 pCi/L.

It should be noted that the Association of California Water Agencies conducted an identical survey of their publicly owned water utility members, obtaining virtually identical results, thus validating the CWA survey. CWA will let the attached comments and study speak for themselves. It is clear from these studies that EPA's cost estimates for the proposed radon regulation do not accurately reflect the potential impact on California utilities.

CWA believes that Congress did not intend for water utilities to be performing Multi-media mitigation (MMM) programs. While the water industry in general feels they do an outstanding job delivering high quality and affordable drinking water, we are not qualified to do indoor air radon mitigation. CWA believes that the correct path to implementation of MMM is to enhance the existing state voluntary indoor air programs to effectively deal with an air radon problem. CWA also believes that this was the intent of Congress when they directed EPA, as part of the 1996 SDWA amendments, to address indoor air problems with MMM if the MCL could not be set at the level equivalent to ambient outdoor air.

CWA continues to believe that EPA has inappropriately treated smokers as a sensitive sub-population in the radon regulation as 85 percent of the benefits of the regulation go to them. Smoking is a personal preference and should not qualify someone for sensitive sub-population status. EPA uses an argument that smokers are members of the general population and therefore are not being treated as sensitive sub-population. However, the typical sensitive sub-population class of infants, the elderly, immuno-compromised, etc. are also members of the general population. The difference is that they have not chosen their situation as smokers have. EPA's position on smokers as a sensitive sub-population is not persuasive or defensible. CWA believes the MCL for radon should be determined without the inclusion of smokers as a sensitive sub-population in the risk assessment. The MCL should also reflect the minimal contribution (1 to 2 percent) that water makes to indoor air levels.

CWA encourages the Committee to review the attached comments and radon study to obtain a sense of real numbers and their potential impact on California water utilities.

ATTACHMENT

CALIFORNIA WATER ASSOCIATION,
January 20, 2000.

Comment Clerk, Radon–222
Docket Number W–99–08
Water Docket (MC–4101)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

DEAR SIR OR MADAM: The California Water Association (CWA) appreciates the opportunity to comment on 40CFR, Parts 141 and 142, National Primary Drinking Water Regulations; Radon–222; proposed rule, published in the Federal Register, Volume 64, No. 211, November 2, 1999. CWA is a professional organization representing a consortium of investor-owned water utilities providing high-caliber water utility services to more than six million customers throughout California. With more than 52 active member companies, CWA provides a forum for sharing best practices; a means of promoting sound, reasonable and science-based policy-making by regulatory agencies and legislators; support to small water systems; and opportunities for educating the public on efficient water use and protection of water resources.

CWA first became aware of certain issues pertaining to the cost of the proposed radon regulation when the Radon in Drinking Water Health Risk Reduction and Cost Analysis was first noticed in the February 26, 1999 Federal Register, Volume 64, No. 38. Because of concern over many of the cost issues, CWA performed a survey of it's members and affiliated utilities to ascertain certain facts about California investor-owned water utilities and radon. The study is enclosed (Attachment A) and contains the following conclusions:

- 173 groundwater systems responded includes 1,555 wells
  - includes 1,319 entry points 600 wells have been sampled for radon (39 percent)
  - 399 wells exceed the proposed radon MCL of 300 pCi/L (67 percent)
- 70 of 75 water systems that have sampled for radon had at least one source exceed the proposed radon MCL of 300 pCi/L (93 percent)
- Of those entry points exceeding 300 pCi/L, 295 (74 percent) will require additional land purchases to build radon treatment plants
  - Range of land cost: $50,000—$500,000. Avg. land cost = $150,000
- The range of radon analyses were non-detect (<100 pCi/L) to 44,475 pCi/L
  - Arithmetic mean of radon = 743 pCi/L
  - Geometric mean of radon = 373 pCi/L

Except for the number of responding systems, these numbers reflect only utilities that provide at least 20 percent of their water as groundwater.

Of great concern to CWA was the display in Table 5–4 of the February 1999 HRRCA, indicating EPA's estimates on average number of sites (wells) per ground water system by system size. This clearly did not fit the typical California ground water system and led to the CWA survey. CWA was pleased to find that EPA had significantly modified this estimate in Table XIII.3 of the proposed regulation. A comparison is shown below.

CWA Radon Survey

System Size (population)	Feb. 1999 HRRCA No. of wells	CWA Survey No. of wells	CWA Survey No. of Entry Points	Table XIII.3 EPA Rn Prop. No. of wells
25–100	1.1	1.4	1.4	1.5
101–500	1.2	2	1.8	2
501–1,000	1.4	2.5	2.3	2.3
1,001–3,300	1.7	3.4	3	3.1
3,301–10,000	2.3	5.4	5	4.6
10,001–50,000	3.9	12.8	11.2	9.8
50,001–100,000	8.7	25.1	23.5	16.1
>1 00,000	8.8	57.5	40.3	49.9

Below, you will find calculations of the total number of wells impacted by this regulation based on the number of ground water systems per system size (Table XIII.2 in the proposed regulation) and the estimated number of wells indicated in the EPA

HRRCA estimates (Table 5–4) versus the proposed regulation estimates (Table XIII.3).

System Size	Rn. Prop. Reg. Table XIII.2 No. of CWSs	Feb. 1999 HRRCA No. of wells	Total wells based on HRRCA	Rn Prop. Reg. Table XIII.3 No. of wells	Total wells based on Rn proposal
25–100	14,232	1.1	15,655	1 .5	21,348
101–500	15,070	1.2	18,084	2	30,140
501–1,000	4,739	1.4	6,635	2.3	10,900
1,001–3,300	5,726	1.7	9,734	3.1	17,751
3,301–10,000	2,489	2.3	5,725	4.6	11,449
10,001–50,000	1,282	3.9	5,000	9.8	12,564
50,001–100,000	139	8.7	1,209	16.1	2,238
>100,000	72	8.8	634	49.9	3,593
Totals			62,676		109,983

Section 7.6.1 of the Regulatory Impact Analysis and Revised Health Risk Reduction and Cost Analysis for Radon in Drinking Water (RIA & Revised HRRCA) indicates that "The number of sources per system that were used in the analysis (for capital and O&M costs) are summarized in Table 5–2". These are the same numbers in Table XIII.3 in the proposed regulation. The calculations above indicate a 75 percent increase in the number of wells impacted from the February 1999 HRRCA to the proposed regulation. The Docket

support document titled "Methods, Occurrence, and Monitoring Document For Radon in Drinking Water—Addendum: Statistical Analysis of Radon Monitoring Requirements", dated August 6, 1999 prepared by ICE Consulting, provides a determination of the numbers of wells in the proposed regulation package. The number in this document is 70,464 wells and is used to calculate monitoring costs for the regulation. Clearly this number does not accurately reflect Table XIII.3 of the proposed regulation (which calculates to 109,983 wells). It is clear that EPA calculated the $14.1 million monitoring costs based on 70,464 wells. This is clearly an error. Likewise, there is clearly an error in the way EPA calculated capital and O&M costs for this regulation, failing to reflect the 75 percent increase in the number of wells from the February 1999 HRRCA to the proposed regulation. EPA states in Section 5.1.2 of the RIA & Revised HRRCA ". . .that the total number of sources (wells) is an important determinant of potential radon mitigation costs. . . " and ". . . it has been assumed in the mitigation cost analysis that each source out of compliance with the MCL or AMCL would need to install control equipment." It should be noted that in the RIA & Revised HRRCA, EPA equates "sources" with "wells". The proposed regulation represents a 4 percent increase in the cost of the regulation from $373 million per year to $408 million per year. This does not properly reflect the 75 percent increase in the number of wells impacted by this regulation. CWA requests that EPA properly calculate the cost of the radon regulation using the correct number of sources (wells).

CWA believes that EPA has underestimated the cost of the proposed radon regulation in the following areas:

- Cost of treatment. While more wells may mean lower flows per well impacted per EPA's calculations, this still represents a significant increase in the number of treatment plants. See discussion above.
- Cost of monitoring. The increase from $11 million in the February 1999 HRRCA to $14 in the proposed regulation does not reflect the 75 percent increase in the number of wells. See discussion above.
- Land acquisition. EPA states in the proposed regulation that they are considering the cost of land acquisition for large water systems (only small systems were included in the February 1999 HRRCA). There is no supporting documentation in the proposed regulation stating what level of land acquisition EPA has included in the cost estimates. For California investor-owned utilities, 399 wells exceed the MCL, of which 74 percent require land at an average cost of $150,000. This equates to $44 million, in itself far exceeding the 4 percent ($33 million) increase from the February 1999 HRRCA to the proposed regulation. Additionally, only 39 percent of wells were sampled. These costs will increase.
- Aeration treatment off-eas permitting. EPA has incorrectly made the assumption that permits will not be required for aeration treatment facilities. The attached letter (Attachment B) from the South Coast Air Quality Management District in re-

sponse to an inquiry from the City of Riverside clearly indicates EPA's error on this matter. This letter also indicates the potential requirement for water utilities to perform their own dispersion modeling to provide evidence that a proposed aeration treatment plant would not ". . .pose a significant health threat" to the community.

• Aeration treatment off-eas treatment. EPA has incorrectly made the assumption that the California Of rice of Environmental Health Hazard Assessment (OEHHA) will not develop unit risk estimates from off-gassing at aeration treatment plants. Conversations with OEHHA staff indicate that they will have no choice but to develop such estimates when it becomes necessary to build such treatment plants. Written documentation of this opinion will be forwarded to EPA when obtained from OEHHA. Off-gas treatment will likely be required in California. EPA has not identified a BAT for off-gas treatment in this regulation. CWA requests that EPA do so prior to promulgation of this regulation.

• Chlorination costs. EPA's estimates for percentages of water systems disinfecting are based on the Community Water System Survey of 1995 as reported in the Docket support document titled "Geometries and Characteristics of Public Water Systems", dated August 15, 1999 and prepared by Science Applications International Corporation (SAIC). Approximately 50 percent of polled utilities (1,980) responded to the survey. After quality assurance checks, data from less than 1,500 community water systems were used for data analysis. This is out of more than 57,000 COOS's in the country (less than 3 percent). After reviewing the survey, a comprehensive and technical 20 page document, it is easy to see why EPA has incorrectly calculated the percentage of water systems disinfecting. The very systems lacking the desire or where-with-all to perform disinfection are obviously the ones who are least likely to return this complicated and lengthy survey to EPA. Given this obvious built-in bias, EPA could not help but misrepresent the facts. State regulatory agencies and water utilities have strongly stated disagreement with EPA on this issue, and EPA's own support document provides evidence that this disagreement is valid. CWA requests EPA to properly calculate disinfection requirements for this regulation.

• Iron and Manganese treatment. EPA has acknowledged its error in the February 1999 HRRCA. Unfortunately, the RIA & Revised HRRCA discusses sequestering Fe & Mn with polyphosphates. The California Department of Health Services (CDHS) does not recognize sequestering as "treatment" for high Fe & Mn, but requires oxidation/filtration.

• Mixed Systems. EPA states that the number of systems they have determined to be impacted by the proposed radon regulation does not include mixed systems, those that use both groundwater and surface water. CWA believes that this may be cause for a significant under-counting of the number of impacted systems and sources. The CWA radon survey found that many of our member utilities affected by the radon regulation are mixed systems. The chart below summarizes this.

CWA Radon Survey

System Size (population)	No. of Mixed Systems	No. of Systems Responding	Nof of Mixed Systems
1,001–3,300	6	30	20
3,301–10,000	2	21	10
10,001–50,000	10	34	23
50,001–100,000	8	16	50
>100,000	7	8	88

The water systems noted in the above chart all produce a minimum of 20 percent groundwater. Others that produce less than 20 percent were left out. CWA requests that EPA determine the number of mixed systems and include them in the cost estimates for the radon regulation.

• Annual household consumption. EPA has calculated radon treatment plant design capacity and associated O&M costs with an assumption that an average household uses 83,000 gallons of water per year. This is approximately 50 percent of what we know of in California and from other national organizations. CWA provides three examples. Attachment C is a typical 34 page water conservation education handbook used in middle schools in California. Page 17 references that "It is estimated that each person in the United States uses about 150 gallons of water a day". Using a conservative assumption of 3 persons per household, that equates to 450 gallons per day per household, or 158,400 gallons per year. This figure is approximately twice the assumption used by EPA. Attachment D is "Water Quality Glossary" from a doc-

ument produced by the National Association of Water Companies. This document states that "An acre-foot (325,861 gallons) supplies a family of 5 for 1 year". This figure is approximately four times the EPA assumption. More recent publications by Metropolitan Water District of Southern California (Attachment E) indicate that "one acre-foot of water represents the needs of two average families, in and around the home, for 1 year". This also is approximately twice the EPA assumption. There are probably hundreds of other references that reflect the same inaccurate assumption by EPA. CWA believes that EPA has under-estimated the average household use of water by at least 100 percent and requests that EPA appropriately adjust their calculations for treatment plant sizing and O&M costs in the proposed radon regulation.

CWA believes that the bulleted items above have lead to a gross under-estimation of the costs of the proposed radon regulation. CWA believes that EPA must make numerous re-calculations to properly determine the true costs of this regulation to enable a true cost-benefit analysis to be performed.

Additionally, CWA believes EPA must address the following issues in the proposed radon regulation:

- Radon is naturally occurring and ubiquitous to the environment in which we live. This makes radon unique to any other contaminant that has been regulated by EPA. People are exposed to radon virtually every minute of their lives. EPA should propose an MCL for radon in drinking water that properly reflects its minimal (1–2 percent according to the National Academy of Sciences) contribution to overall radon exposure.
- EPA has proposed a dual standard for radon. Utilities can either comply with the MCL or they can develop themselves or utilize a state Multi-media Mitigation (MMM) Program and comply with an alternative MCL (AMCL). This is precedent setting and potentially problematic. The NAS has expressed many concerns over the effectiveness of several components of the MMM programs in their "Risk Assessment of Radon in Drinking Water" published in 1999. CWA believes that EPA needs to address the NAS concerns and alleviate doubt about the various components of MMM programs before they base a National Primary Drinking Water Regulation on them.
- CWA believes that EPA continues to treat smokers inappropriately as a sensitive sub-population in this regulation. EPA estimates that 84 percent of the benefits of this regulation goes to smokers. EPA correctly states that smokers are members of the general population. This is likewise true for traditional members of sensitive sub-populations like immuno-compromised, infants and the elderly. EPA's argument is not persuasive. CWA believes that EPA should discount the benefits to smokers in the radon regulation.

CWA believes there are several serious problems with the proposed radon regulation that needs attention prior to promulgation. CWA respectfully requests that EPA consider the testimony provided in this comment letter and make the appropriate and necessary changes to make this regulation a responsible one that provides the best benefit to water utility customers.

Should you have any questions or require additional information, please feel free to contact me.

Very truly yours,

TED JONES, JR., *President,*
California Water Association.

STATEMENT OF ROGER D. MASTERS AND MYRON J. COPLAN

IMPLEMENTATION OF THE SAFE DRINKING WATER ACT

The authors of this submission (Dartmouth College Professor Emeritus Roger D. Masters and veteran chemist/chemical engineer Myron J. Coplan, PE), have been collaborating since 1997 on ecological analyses and statistical association between community use of silicofluorides for water fluoridation and increased prevalence rates of children with elevated blood lead as well as behavioral dysfunctions including learning disabilities, ADD/ADHD, violent crime, and cocaine use at time of criminal arrest. Preliminary reports of these ecological studies was published in the International Journal of Environmental Studies and Social Science Information. Our information has also been presented at scientific meetings, with growing acceptance.

Further studies are at an advanced stage of preparation. Using diverse datasets, (including comprehensive state-wide blood lead surveys for Massachusetts and New York and county-level data for NHANES III as well as New Jersey data on osteosarcoma and a National Institutes of Justice study of cocaine use by criminals

in 129 cities), results are almost always statistically significant at the level of better than 1000 to 1.

We are well aware that correlation is not peruse proof of cause. However, because the results of our original study have now been replicated in several different populations using data collected by national and state health agencies, the ecological statistics strongly indicate a need for further research. We have considered a number of hypotheses for how the use of silicofluorides for water treatment may cause adverse health and behavioral effects. One that has begun to have increasing credibility for us is the likely presence of small amounts of radionuclides in drinking water. The radioactivity may be due either to natural events or anthropogenic in origin.

USEFUL APPENDICES ENCLOSED

The following are included herewith to provide background and guidance:

A. Chart of nuclear decay phenomena associated with radon, illustrating why health risks from radioactive substances in water neither start nor end with radon;

B. Chapters from "Health Risks of RADON and Other Internally Deposited Alpha-Emitters", a compilation by the National Research Council;

C. Tables from "NSF–60", (regarded as the "bible" on tests for health safety of drinking water additives) showing what materials require tests for radioactivty;

D. A recent study of several radioactive Spanish waters illustrating the geologic and hydrologic complexity of radionuclides associated with radon.

NATURALLY OCCURING RADON IN WATER

It is commonly believed in the lay community that radon is only a hazard as a gas which seeps into buildings through cracks in basement floors and walls. While there is some appreciation of the fact that local geology is responsible in some vague way for the presence of radon as a gas in soil, until now little, if any, consideration has been given to health threats of water-borne radon.

Radon (222Rn), itself transient (3.8 days half-life), is a "marker" for both its "mother" radium and its own"progeny", radioactive lead (2'0Pb) and radioactive polonium, (typo). Thus, discussion of radon in water needs to consider a number of radionuclides.

(1). Where radon occurs in a geological formation there must also have been other radionuclides. So water contacting that formation would have been likely to pick up some of radon's "ancestors" (uranium and radium) and some of its longer-lived "descendants" (2?0Pb and 2'0po) along with radon itself.

(2). The "mother" radium atoms (226Ra) had to have been present for thousands of years before they decayed to radon, (222Rn) with release of one alpha particle each.

(3). Virtually all the radon atoms produced by this step, whether dissolved in water or trapped in the geologic formation as a gas, remain as such for only a few days before they decay in several steps into 210Pb.

(The 3.8 day "half-life" signifies that half the number of radon atoms produced at any one time decay into the next generation of radon progeny in 3.8 days. This doesn't mean that half decay all at once at the end of 3.8 days. Decay occurs one atom at a time with decreasing frequency if the original total number of radon atoms is not constantly replenished. The thing to bear in mind is that in the geological formation there is a virtually endless supply of latent "mother" radium atoms, which provide that source of replenishment because of their very slow decay rate (halflife of 1,600 years), and that they are backed up by 238uranium (half-life 4.5 billion years).

(4). After the "mother" radium decays into a 222Rn atom, the latter decays in five quick steps (less than an hour) to 210Pb. Over that interval the 222Rn atom and its progeny have created three alpha particles, a couple of beta particles and some gamma rays.

(5). The resulting radioactive lead atoms (210Pb) have a half-life of 22 years. This means that a fair number are still around after 50 years, even though half had decayed in the first 22 years). The decay course of 210Pb includes release of a beta particle creating 210Bi atoms. These also release beta particles in a matter of days becoming 210Po atoms. The radioactivity of these 210Po atoms is probably as important as that of radon.

POLONIUM IN THE ATOMIC AGE

Polonium (210Po) occurs in nature. But it is also one of the by-products of the production of nuclear materials for military use and power generation. It has been considered one of the most dangerous of the radionuclides to which man has know-

ingly exposed himself. In the early days of nuclear weapons and related developments, it was the subject of intensive study1–4 formechanism of exposure, routes of elimination, and health effects. It is stored in many tissues of the body because it behaves chemically like lead and calcium. 210Po decays over a few months, emitting alpha particles and gamma rays. It was considered to be 20 times more toxic than cyanide.

Some "experts" address the problems of radon in water on the assumption that this risk is due to natural causes, independent of any anthropogenic considerations. This view requires careful scrutiny. It may not be immediately obvious, but there is a long history of relationships between fluoridation and radioactive water. The current concerns about waterborne radon must take this into account since there are sources of water-borne radon besides those due to established and traditional hydrologic/geologic causes.

The nexus between radioactivity and fluoridated water was known shortly after the Curies discovered radionuclides in 1898 and named one of them Polonium. A 1906 reports noted that thermal mineral baths in Aachen contained fluoride (as silicofluoride) along with some unspecified radioactive substance. Although the species in which it is bound has not always been identified as silicofluoride, some form of fluoride has often been found to co-exist with "natural" radioactivity all over the world.6–8

By the same token, naturally occurring fluoride has been reported to be in the form of silicofluoride without necessarily noting the presence of radioactivity.9 Nevertheless, it is not a big leap to postulate that radon and "natural" fluoride in the form of silicofluoride coexist in US drinking water supplies, although very few people drink naturally fluoridated water at the level of 1 ppm. In Massachusetts towns where that occurs, (in the vicinity of Ware) the prevalence of child elevated blood lead was comparable to that found in large urban centers such Boston and Worcester which have big city problems that are clearly not associated with radionuclides.

However, when small rural communities which share a common geology providing naturally occurring fluoride, (such as the "Ware Cluster"), exhibit childhood blood levels several times as high as those in similar non-fluoridated towns, it is reasonable to suspect that the naturally fluoridated water may carry the same substances that are suspected as responsible for adverse health and behavioral effects associated with deliberately added silicofluorides. The Massachusetts "Ware Cluster" of child elevated blood lead suggests there is no reason to presume "natural fluoride" in a water supply to be innocuous, any more than it is logical to presume that "natural arsenic" in a water supply is innocuous.

RELEVANCE OF DELIBERATELY ADDED FLUORIDE

Over the past 50 years, the practice of adding fluoride to public water supplies has been expanded to include systems serving nearly 70 percent of the US population. There is an active plan to reach a goal of 100 percent. Paradoxically, except for UK Commonwealth nations and a few others, no other countries currently follow that practice. Meanwhile, 90 percent of US fluoridated municipal water is treated with a silicofluoride; less than 10 percent is treated with sodium fluoride, the agent first used after preliminary trials that were considered sufficient to establish the health safety of fluoridation.

Without questioning whether the experiments with sodium fluoride were adequate, the fact is that no tests were conducted for health safety of chronic human exposure to the silicofluorides. Today, over 140 million people are served by water systems that consume 200,000 tons of the silicofluorides per year. 10 And this has occurred without any evidence of health safety supported by tests conducted on any mammals (let alone humans) subjected to long-term chronic low level exposure to silicofluorides. This is not trivial because these fluoridating agents, (fluosilicic acid and sodium fluosilicate), may also carry small amounts of the same radionuclides that accompany water-borne radon from "natural" sources.

Silicofluorides are derived from "phosphate rock," a mixture of calcium phosphate, calcium fluoride, silica-bearing material (sand, clays) and a few percent of uranium and radium. Mining and processing this ore releases radon into the environment. In the 1970's80's about 75 percent of uranium produced in the US came from this ore. " During conversion of the rock to phosphoric acid and subsequent extraction of uranium from this acid, fluoridebearing gases are released along with radon. These gases are extremely toxic and cannot be released into the atmosphere. They are conducted to a "scrubber" where they are absorbed in a water spray or similar system. Local well water is often in short supply so a scrubber may variably be fed with well water or "gypsum pond" water to absorb the "offgases" from several stages of phosphate ore processing. 12

These man-made ponds may contain solutes derived from the initial phosphate ore and "inprocess" derivatives of this ore including radionuclides. The term "gypsum pond" reflects the fact that collect water draining from very large piles ("gypsum stacks", essentially small hills) of calcium sulfate, ("gypsum"). This product, known as "phosphogypsum" is an unavoidable by-product of treating the ore with sulfuric acid. As such, it is a wet "sludge" carrying residues of the main desired product, namely the phosphoric acid from which both phosphate fertilizer and uranium are eventually derived.

Rain washing through the gypsum stacks (hills), carries away some of the residual acid and a dilute stream of it is collected in the "gypsum pond." Thus, the scrubber product ("fluosilicic acid") is not just a solution of fluoride gases (HF and SiF4), radon released from the ore, and mists of radionuclide aerosols. On some occasions it will, of necessity, also include radionuclides (and other substances) from gypsum pond water.

Besides the nexus between fluoride and radon in both natural geology/hydrology and the industrial chemistry of silicofluoride and uranium derived from phosphate rock, a third matter calls for attention. Considerable documentation links people who were studying health effects of radionuclide exposure under the Manhattan Project, the AEC and the NRC with efforts to disseminate the idea that there are no health safety risks from drinking water treated with silicofluorides.

A 1957 report,13 published in the Journal of Dental Research by the authors of significant studies on Polonium and Uranium health effects1–4, 15 admits there had not been any actual studies of health effects studies of silicofluorides, but "guarantees" that it didn't matter because, (on theoretical chemical grounds), silicofluorides would be fully dissociated into free fluoride ion and silicic acid, at 1 ppm of fluoride.

According to this thesis, upon dissociation of the silicofluoride anion, fluoridated water would be "just like" sodium fluoride treated water. Since sodium fluoride treated water had been found safe, silicofluoride treated water would be equally safe. Therefore animal health safety studies of silicofluoride were not required. It is interesting that no mention was made of radioactive substances as possible contaminants of fluosilicic acid.

EPA and CDC chemists take the same position today, namely that silicofluorides dissociate into nothing but free fluoride and silicic acid. No mention is made of possible radioactive contaminants and there have still not been any tests for health effects in humans from chronic exposure to the silicofluorides. Indeed, although a Select Committee of the US Congress in 1952 had requested research on the effects of chronic exposure to fluoridated water, none has been conducted to date. Moreover, neither in 1957 nor 1999 did the "experts" take account of animal studies oft he 1930's 14 which showed profound adverse health effects to farm animals from exposure to silicofluorides as well as a difference between the metabolism of fluoride from sodium fluoride and that. From silicofluoride.

It is interesting that the 1957 "guarantee" of silicofluoride health safety was offered by people concurrently doing animal studies of radionuclide toxicity for the AEC1—3, 15 One wonders how they could have reached that conclusion without animal tests, especially since silicofluoride was an important by-product of uranium production.

This enigma persists. Supporters of fluoridation never say what agent is used to deliver the fluoride. This even applies to the staff of NIDR and Surgeon General. In fact, college chemistry professors, dentists, staff of the FDA and major academic dental research centers seem totally oblivious to the fact that silicofluorides are used and even state (erroneously, of course) that sodium fluoride or some other compound such as stannous fluoride or even fluorine gas is the fluoridating agent most widely used.

It is even more curious that the specifications for health testing of water additives embodied in a document widely known as NSF–60 (see enclosure "C") call for radioactivity tests for two rarely (if ever) used fluoridating agents (calcium fluoride and ammonium fluosilicate) but do not require such tests for the two most widely used agents, sodium fluosilicate and fluosilicic acid.

Because 140 million (or more) Americans are exposed to a likely anthropogenic source of radon and its associated radionuclides, it seems beyond question that a substantial program of animal testing and chemical studies is needed. Such research should be outside of the control of the bureaucracies that seem to have been oblivious to the problems, if not actually inclined to ignore them.

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AN ALLIANCE FOR DISCOVERIES IN HEALTH

July 12, 2000

The HONORABLE MICHAEL D. CRAPO *Chairman,*
Subcommittee on Wildlife, Fisheries and Drinking Water
Senate Office Building
Washington, DC 20510

DEAR SENATOR CRAPO: I write today in response to the Subcommittee's call for testimony regarding fluoridation of drinking water. Recent results of an oral health public opinion poll we commissioned indicate 99 percent of the American public feel their oral health is very important to their overall health (see enclosed graph.); and 97 percent of Americans indicated that the desire to prevent oral disease was an important factor in determining whether or not to get dental care (see enclosed graph).

According to a report by the Centers for Disease Control and Prevention, one of the top ten public health accomplishments of the last century was fluoridation of drinking water (see enclosed graph).

One way to achieve better oral health and prevent oral disease for our nation's citizenry is by supporting community water fluoridation. Oral Health in America: A Report of the Surgeon General notes:

Communities with fluoridated drinking water in the United States, Australia, Britain, Canada, Ireland and New Zealand show striking reductions in tooth decay—those with fluoridated drinking systems have 15–40 percent less tooth decay;

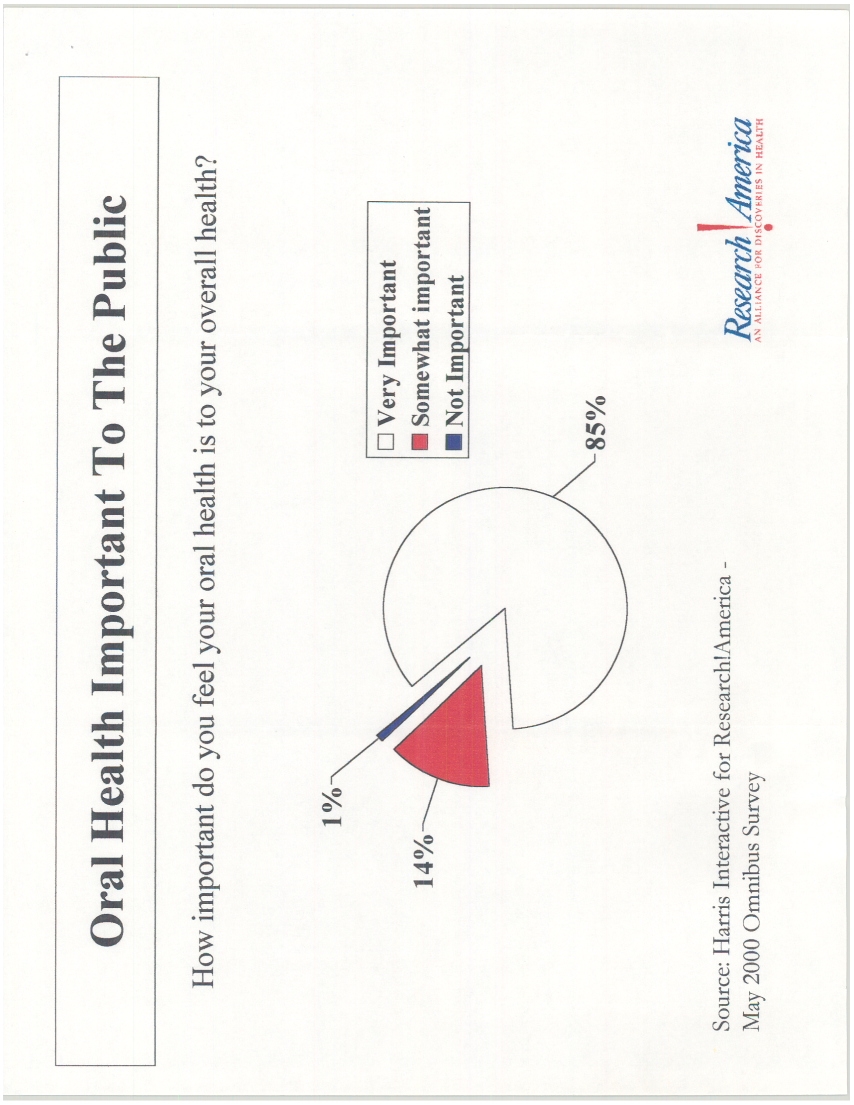
Honorary Board

Nearly all tooth decay can be prevented when fluoridation is combined with dental sealants and other fluoride products, such as toothpaste.

It would be a shame to take a step backward in progress by not utilizing this great public health breakthrough.

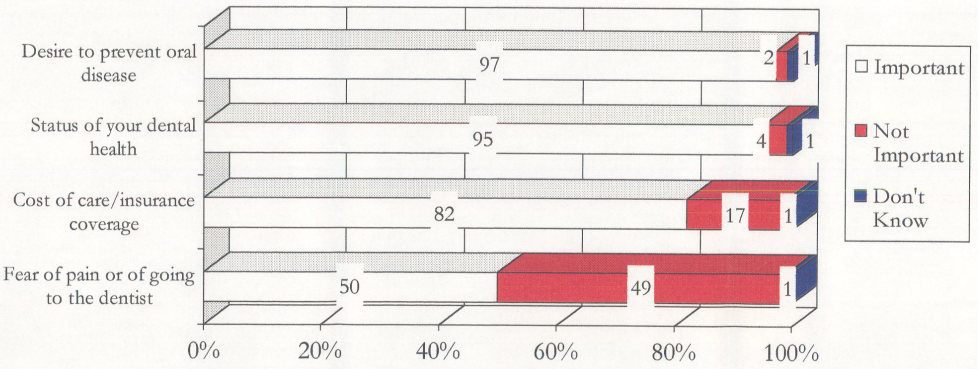
Sincerely,

PAUL G. ROGERS CHAIR, *Research! America.*



Disease Prevention & Oral Health Status Determine Whether To Get Dental Care

For each of the following, please tell me how important of a factor it is in determining whether or not you get dental care.



Source: Harris Interactive for Research!America - May 2000 Omnibus Survey

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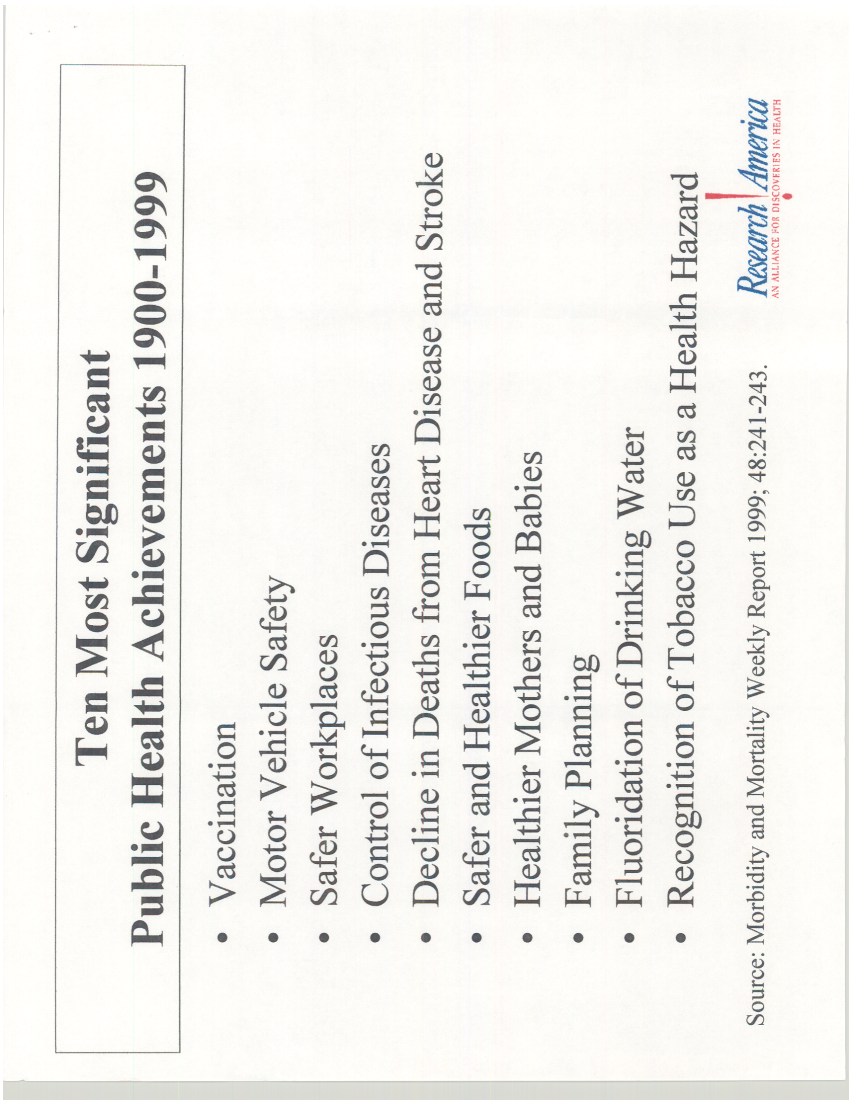
AN ALLIANCE FOR DISCOVERIES IN HEALTH



FITZWILLIAM VILLAGE WATER DISTRICT,
P.O. Box 12 Fitzwilliam NH 03447, June 13, 2000.

Senate Committee on Environment and Public Works
Senate Office Building
Washington DC 20510

DEAR SIRS: It is my understanding that you will be holding a hearing on June 29 on the proposed EPA Radon in Water Rule. The following are our comments that we wish to present at that hearing and be made a part of the record of the hearing.

We have already filed a comment with the EPA which clearly states our opposition to the Radon in Water Rule and the reasons we feel it to be an ineffectual program. Rather than reiterate those arguments, we would like to take this opportunity

to address the issue of some inequities in the distribution of costs if and when the EPA Radon Rule goes into effect.

1. The Inequity of Random Selection of Who Pays the Costs

Under the proposed EPA rule, a public water system will fall into one of three categories.

A. Those with less than 300 pico curies of radon per liter in their water will have to take no action.

B. Those with between 300 and 4000 pico curies of radon per liter will be able to use the MMM program to-educate their customers as to the dangers of and treatment for radon in the air in their homes.

C. Those with above 4000 pico curies of radon per liter will have to treat their water for radon. This will be an expensive process costing each water system thousands to hundreds of thousands of dollars.

The category into which a water system falls is entirely determined by the chance location of the water system and where they have happened to have drilled their wells, In effect, they have participated in a well drilling lottery. There will be some winners and some losers. The winners won't have to do anything or will be able to escape with a relatively inexpensive public relations effort. The losers will typically have to pay thousands of dollars up front to install treatment equipment and more down the line to maintain this equipment. The EPA makes no provision to fund any of this cost. The states where the wells are located are under no obligation to provide any assistance.

Is this situation an equitable one? Should there not be some form of financial assistance made available to those systems with the heaviest financial burden?

2. The Inequity of State Subsidies

The EPA makes a provision in their proposed rule whereby the individual states can assume the burden of providing those water systems who qualify for the MMM program with a statewide MMM program they can participate in. This assistance represents a subsidy for those systems who would otherwise have to develop their own more expensive programs. Thus not only are those systems with the heaviest financial burden receiving no assistance, they can watch as those systems with a relatively light burden are financially assisted by their state governments! Is this an equitable arrangement?

3. The Inequity of Costs for Smaller Water Systems

Water systems are businesses. They provide a service for fees which they collect from their customers. If and when the EPA Radon in Water rule goes into effect, many large and small water systems will have to treat their water for radon. The cost per capita for the larger systems will be generally lower than the cost per capita for the smaller systems. As an example, we estimate that our users will end up paying about $1000. per household for radon treatment. A small city having to treat for radon might have costs that run in the $10. to $50. per household range. Thus if and when the Radon in Water rule goes into effect, it will have the same effect as a business tax that lays a disproportion of its financial burden on small businesses. If such taxes are inequitable, why are EPA predicted expenses any different?

We feel that the above items represent serious inequities in the distribution of the cost of the Radon Treatment program proposed by the EPA. We hope you will consider them in your recommendations.

Sincerely,

FRANK BEQUAERT,
JAMES DUGAN,
JOHN FITZWILLIAM.

RICHARD DIPENTIMA, MANCHESTER HEALTH DEPARTMENT,
Manchester, NH 03101, July 7, 2000.

Dear Sirs: For the record, my name is Richard DiPentima, RN, MPH, Deputy Public Health Director, Manchester NH Health Department. I have been working in public health for over 25 years including positions at the local, State and Federal level. Over the years I have witnessed the great public health benefits of water fluoridation as well as the great harm that occurs as a result of not providing fluoridation of community water supplies.

The benefits and safety of fluoridation have been shown by over fifty years of practical experience and countless studies conducted by reputable mainstream scientists. This does not include the experience of individuals and communities that have benefited for far longer through consumption of naturally occurring fluoridated

water. The vast majority of the scientific, medical, dental and public health community strongly support expanding the practice of fluoridation to prevent dental disease. The benefits of fluoridation in terms of reducing dental disease and saving billions of dollars has been well documented. The U. S. Centers for Disease Control and Prevention has listed community water fluoridation as one of the ten great achievements of the 20th Century!

Not unlike the practices of immunization of children, pasteurization of milk and chlorination of water supplies, fluoridation has its critics. While these critics are few in number, they often are quite active and vocal in their opposition. Unfortunately, these critics do not always rely on sound science, truth or adhere to accepted standards. The goal of these critics is to produce fear, doubt and undue concern among the public by claiming that fluoridation is responsible for everything from AIDS to violence. Unfortunately, these critics have been all to successful in promoting propaganda over science.

I urge the committee to review two recently released reports that may add to your appreciation of the scope of the oral health crisis in America. First, the Surgeon General's Report, "Oral Health in America" released in May 2000. Second, The GAO Report released in April 2000 "Oral Health-Dental Disease is a Chronic Problem Among Low-Income Populations." Both these documents will provide support for the need to continue and expand the availability of community water fluoridation. A retreat from this very important public health practice will have profound health and economic implications. At a time when health care costs continue to rise and millions of Americans lack access to dental care, the last thing we should do is curtail disease prevention activities.

Thank you for providing me an opportunity to provide my comments. If you have any questions please contact me.

RICHARD DIPENTIMA, *RN, MPH, Deputy Public Health Director,*
Manchester Health Department,
795 Elm Street, Suite 302
Manchester, NH 03101.

STATEMENT OF RICHARD A. CASTRO, CHAIRMAN, PUBLIC SERVICE BOARD OF THE CITY OF EL PASO, TEXAS

On May 24 of this year, the Administrator of the Environmental Protection Agency signed a rule entitled National Primary Drinking Water Regulations: Arsenic and Clarifications to Compliance and New Source Monitoring. The proposed rule (Arsenic Rule) as written will have a major and profound impact on the city of El Paso and on many other western cities. The purpose of my testimony this day is to make known the significance of the proposed rule to El Paso and to describe certain deficiencies in the rule as proposed.

Let me preface my testimony by stating emphatically that the El Paso Water Utilities Public Service Board supports safe drinking water. Furthermore, we support the efforts of the EPA to protect the health of our citizens through this rulemaking effort. At such time as a limit is proposed based on sound science, El Paso will fully support the proposal and will implement treatment measures necessary to meet that limit. In the proposed rule, the EPA indicates that they are proposing a Maximum Contaminant Level (MCL) for arsenic of 0.005 milligrams per liter which is equivalent to 5 micrograms per liter; although, they are requesting comments on limits equivalent to 3, 10 and 20 micrograms per liter as well.

The service area of the El Paso Water Utilities presently includes approximately 695,000 people located within the city of El Paso and the areas of El Paso County surrounding the City. El Paso is located in the Chihuahuan Desert; and as such, is subject to limited availability of drinking water. We rely on a limited supply of groundwater for 55 percent of our drinking wager supply. Our groundwater resources contain arsenic from 3 to 30 micrograms per liter depending on location, depth and other geologic features.

Of the 139 wells utilized by the El Paso Water Utilities, 111 have arsenic in concentrations greater than or equal to 5 micrograms per liter. In order to provide arsenic removal treatment for those wells, the Citizens of El Paso would be required to provide $150 million in capital and an additional $8 million in annual operating expense. This cost represents a 40 percent rate increase for our customers. Moreover, the proposed rule is only one of many rules that the EPA will promulgate over the next few years. At the same time, El Paso Water Utilities is struggling to provide water to an ever-increasing population in this desert area. Just to supply the necessary water resources, our customers will see an 80 percent rate increase over the next 10 years riot including arsenic treatment costs. These are huge burdens

to our citizens because El Paso has one of the lowest per capita income levels in the nation.

Our analysis of the proposed rule shows the possibility that serious flaws have been incorporated into the science behind the rule. Rather than waiting for the completion of research work sponsored by the collective water utility industry, which will correct these flaws, the EPA is proceeding with the rule to meet a congressionally imposed deadline.

However, our main concern with the proposed rule is the estimated compliance cost calculated by the EPA. The compliance cost estimations seriously underestimate the cost of compliance with the proposed rule. The EPA cost fails to include all the necessary supporting requirements to modify a water system for arsenic removal. For example, many El Paso wells are not collected to a central point prior to introduction into the distribution system. In order to provide treatment, extensive changes must be made to the water distribution system and new reservoirs must be constructed. The EPA compliance cost estimate does not consider those costs or the cost to purchase land, extend wastewater lines to treatment sites, site preparation costs and other large supporting costs. Also, any treatment used to remove arsenic from water will result in the formation of a residual into which the arsenic is concentrated. That residual may have to be disposed of in accordance with applicable hazardous waste rules. The use of ion exchange, the preferred treatment methodology as described in the proposed rule, requires the use of significant amounts of salt and the disposal thereof. Last, the establishment of a lower drinking water MCL for arsenic will result in lower stream standards and an increased level of treatment at Superfund sites. None of these costs are adequately addressed EPA's compliance cost estimates.

El Paso would support an MCL of 20 micrograms per liter. Even this level will cost us several million dollars to implement, but would represent reduction to 40 percent of the current level. Until good-science based studies justify a lower limit, we are very much opposed to the proposed MCL of 5 micrograms per liter.

STATEMENT OF THE ASSOCIATION OF STATE DRINKING WATER ADMINISTRATORS

The Association of State Drinking Water Administrators (ASDWA) is pleased to provide written testimony on implementation of the Safe Drinking Water Act (SDWA) of 1996 to the Senate Committee on Environment and Public Works Subcommittee on Fisheries, Wildlife, and Drinking Water. ASDWA represents the state drinking water administrators in the 50 states and six territories who have responsibility for implementing the m?any provisions of the SDWA and ensuring the provision of safe drinking water. State drinking water programs are committed to providing safe drinking water and improved public health protection to the citizens of this nation. ASDWA's testimony will focus on the many successes that the states have achieved over the last 4 years as well as many of the disturbing trends that are emerging, and the challenges that remain.

States have been protecting drinking water for more than 25 years, in some cases going back decades to the early U.S. Public Health Service standards. Since 1974, states have adopted and been implementing standards for 20 inorganic chemicals including lead and nitrate; 56 organic chemicals including pesticides, herbicides, and volatile chemicals; total trihalomethanes; total and fecal coliform; as well as implementing treatment requirements for surface water systems for turbidity, Giardia, and viruses. In addition, states have developed technical assistance programs, conducted sanitary surveys, and addressed operator certification, training, enforcement, emergency response, and review of water utilities plans and specifications.

The 1996 reauthorization of the Safe Drinking Water Act contained numerous new requirements to continue to ensure safe drinking water in this country. These new requirements include: consumer confidence reports; revisions to the lead/copper rule; Stage 1 D/DBP rule; interim enhanced surface water treatment rule; source water assessments and delineations for all public water systems; unregulated contaminant monitoring requirements; a revised public notification rule; a long-term enhanced surface water treatment rule; a filter backwash rule; a radon rule; a rule to protect ground water; an arsenic rule; a radionuclides rule; Stage 2 disinfection by-products rule; long-term 2 enhanced surface water treatment rule; water system capacity development programs; and operator certification program revisions. In addition, the U.S. Environmental Protection Agency (EPA) is required to obtain data to make determinations on whether to regulate an additional five more contaminants every 6 years (see page 6).

The states were willing players and partners in the discussions leading up to reauthorization in 1996 with the specific understanding that a significant new man-

date such as this law, which encompasses sweeping new reforms and activities outside of the traditional drinking water program, must be accompanied by significant new resources and staff. While critical, resources alone are simply not enough. In addition, states need a reasonable regulatory schedule and the flexibility to allow states to shift staff and resources to new programs in a calculated and manageable fashion. Unfortunately, almost 4 years into implementation, the states are seeing disturbing trends emerge from EPA that are preventing the states from achieving full implementation of the law. In fact, these trends are resulting in a dilution of public health protection efforts and the forced prioritization of state program activities.

These trends include:

- Inadequate Funding and Unwillingness to Address Cumulative Costs and Program Integration
- Early Implementation
- Changing State Roles and Expectations
- Increasing Record Keeping and Reporting Burden

Each of these topics is discussed in more detail below.

Inadequate Funding and Unwillingness to Address Cumulative Costs and Program Integration

On average, states have historically provided 6S percent of the total funding for the drinking water program while EPA has provided only 35 percent, even though the SDWA authorizes EPA to fund up to 75 percent of the full costs of the program. Currently, about $271 million in state and Federal dollars is available to the state drinking water program. A Resource Needs Model, recently developed by the states and EPA, projects that state drinking water programs face a $100 million resource shortfall and a shortfall of almost 2,000 FTEs for fiscal year 2001. These shortfalls almost double through 2005 based on anticipated state workloads for the plethora of new regulations and programs being promulgated (see page 7).

To further compound the problem, EPA has not requested any increase in state PWSS program grants (current funding level is $90 million), that provides the reliable, sustainable base for state operations, since fiscal year 1996. In fact, the Agency has not even requested the full amount of $100 million as authorized in the SDWA. Although the Agency often looks to the drinking water SRF as a new source of funding for states, they do not fully recognize that states cannot hire permanent staff using a funding source that changes annually and the authority for which expires in 2003; that requires a 100 percent match of new state dollars; and that puts states in direct competition for the same pool of funding with water systems that have overwhelming infrastructure needs to improve public health protection.

The practical outcome of failing to provide any new PWSS funds is that state funding bases have been eroded over the years due to inflation and indirect and direct cost increases. In addition, the growing economy has made hiring and retaining staff more difficult as state salary levels become less competitive in the marketplace. The state drinking water programs have never been fully and adequately funded and are now challenged to meet enormous new mandates without the significant new money and staff needed to ensure full and effective implementation of the new programs as well as maintenance of the existing core programs.

The situation is further exacerbated by EPA's unwillingness or inability to fully address the cumulative costs to states for each of the very complex and comprehensive new programs and regulations being developed. There appears to be no acknowledgement that state program funding is finite and, in fact, already inadequate, nor a willingness to simplify and streamline regulations and provide adequate flexibility to reduce state implementation burdens. This attitude forces states to prioritize their activities based on available staff and resources and ensures that full implementation will likely not be realized.

The states were committed in 1996 to take on the new mandates of the SDWA with the understanding that resources, staff, and needed tools would be available to ensure full and effective implementation of the new program as well as maintenance of the existing program. States are still committed to the improved public health protection opportunities envisioned in the law but are growing increasingly frustrated and angry that barriers are being erected to preclude their achievement of these goals.

Recommendations: 1) EPA should work with the states to confirm the current staff and resources needed to fully implement the program; 2) EPA should work with the states and Congress to close the documented resource gap and ensure that adequate funding will be available in future years based on the individual and cumulative costs of new regulations and programs; 3) EPA must also work with states to streamline and simplify new regulations and programs to reduce increased bur-

den to the greatest extent possible; and 4) in the event that the gaps cannot be closed, EPA must be willing to engage the states in discussions on how to prioritize and manage the new mandates with existing or inadequate resources.

Early Implementation

The situation referenced above is further exacerbated by the Agency's continued insistence on early implementation of rule requirements prior to states adopting their own rules within the statutory framework of 2 years from the date of rule promulgation. This is especially troublesome with respect to the overwhelming number of rules EPA currently has out for review and the difficulty states and water systems will have complying with all of these new rules simultaneously. States need their rules in place in order to establish basic regulatory and enforcement authorities; to train operators and water system owners on Federal as well as state requirements; reprogram data management systems to accept new data reporting requirements, track compliance, and report to EPA; and ensure adequate laboratory capacity. Forty-nine of the 50 states have primacy and have the mechanisms in place to work with utilities within their state to achieve and maintain compliance. Inserting EPA Regions into the process, who are not onsite and do not have the resources, experience, and mechanisms in place to do much more than send letters and issue orders, greatly complicates the process and leaves the program in great disarray at the point when states must assume responsibility. This is a disservice to the states, the utilities, and the public across this country and brings into question the concept of primacy and state authority.

Recommendations: 1) The Agency's use of Memoranda of Understanding (MOU) prior to state rule adoption is not acceptable and the Agency must immediately cease all activities directed at forcing states to implement requirements before state rules are adopted; 2) EPA should forego all attempts to require EPA Regions to assume interim implementation activities.

Changing State Roles and Expectations

Of significant concern to ASDWA and the states is the expanding expectation of scale and scope being promoted by EPA that dramatically changes the state role from regulatory oversight to implementer of SDWA regulations. States have historically assured safe drinking water by conducting basic oversight and surveillance of water utilities and measuring utility compliance through performance measures such as compliance with public health standards of finished water. While some states have the capacity to be more involved in operations issues, for the most part, the daily operations and maintenance of utilities have primarily been left to the utility—using certified operators, licensed consulting engineers, and technical assistance from the states and other providers when needed. This has historically been the case because of resource and technical capacity limitations at the state level and liability issues associated with making process control decisions for the utilities that are regulated by the states.

This direction represents a significant change from the majority of current state practices and must involve a meaningful dialog with state drinking water administrators, environmental commissioners, public health agency directors, Governors, Congress, and legislative bodies. The majority of state drinking water programs currently do not have the resources or sufficient staff with the technical expertise to work with individual utilities on a one-to-one basis to help make decisions on operating practices. If the Agency wants to make this change, then the states, including appropriate legislative bodies, must have buy-in to this process and there must be assurance that adequate numbers of trained state staff and resources will be made available to meet these new expectations.

At a time when most citizens want government out of daily decisionmaking, EPA is establishing a structure to position government regulators to assume operational responsibility of our drinking water infrastructure. The Agency is not being honest with itself, Congress, and the public if it believes that state drinking water programs are currently in any position to fully implement these new provisions, even with a minimal oversight role, much less be able to assume a significant new role in water plant treatment, operations, and management decisionmaking.

Recommendations: 1) Congress needs to consider the fundamental role for government regulators to play; and 2) EPA needs to recognize that they are promoting a significant change in scale and scope of the program with expectations that states need to increase their day-to-day management role of water utilities. This shift needs to be more fully explored by the states and EPA, and additional funding made available to support this expansion of state responsibility and staff technical capacity if this change is accepted.

Increasing Record Keeping and Reporting Burden

Although ASDWA recognizes EPA's need to ensure, on the Federal level, that a rule is being implemented properly, EPA must recognize the increasing burden that is being placed on state data management programs with consideration for the number of upcoming rules. States, which should be EPA's partners in ensuring safe drinking water, are willing to submit necessary data elements to EPA to meet this need, but do not have the staff or resources to report extraneous data elements that are not necessary, and based on past experience, are typically not even used by the Agency. Therefore, prior to proposing a final rule, EPA must enter into a dialog with state drinking water program staff to evaluate what data must be collected by the water systems, what data must be reported to states, and the minimum data elements that must be reported to the Agency, and determine the impact these requirements will have on states and water systems. The cumulative costs and impacts of these continual data requests must also be evaluated to ascertain if collectively they are providing states and EPA with meaningful data linking rules to real public health improvements.

Successes

In spite of the many roadblocks, hurdles, and challenges that state drinking water programs have faced over the last 4 years, and indeed 25 years, states have attained a significant amount of success in implementing the provisions of the SDWA. For example,

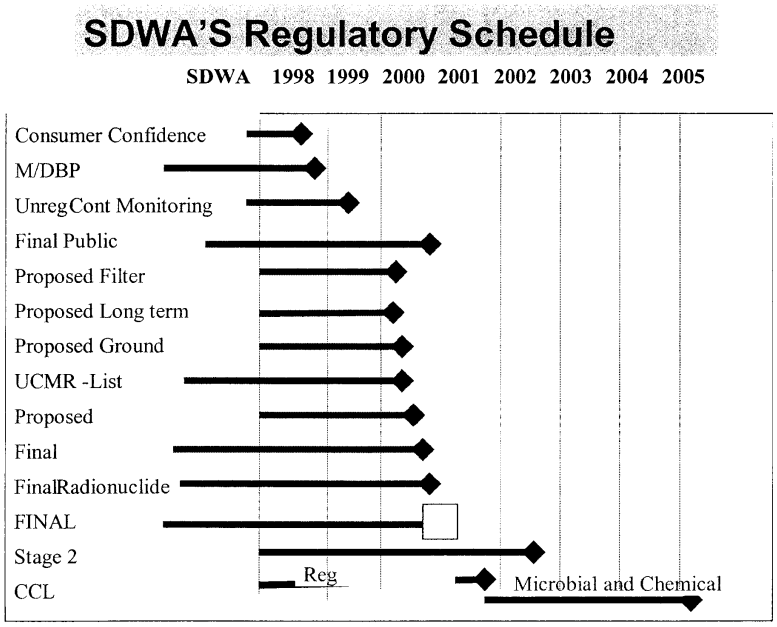
States have made significant progress in working with utilities using surface water supplies to install new treatment facilities to assure a much higher level of public health protection. Sources of lead from drinking water have been significantly reduced; the data and information about water system quality and compliance is now more readily available to the public through Consumer Confidence Reports, state compliance reports, the Envirofacts data base, and state web sites; the quality of water plant operators and water system capacity is being significantly improved; and an important source of funding for infrastructure improvements has been established in all states and loans are now being made to water systems to improve both their infrastructure and their ability to provide safe water to their consumers. States are also now beginning a very comprehensive and resource intensive effort to delineate and assess the quality of all source water being used for drinking water to ensure that local communities have the tools and information they need to protect their drinking water sources.

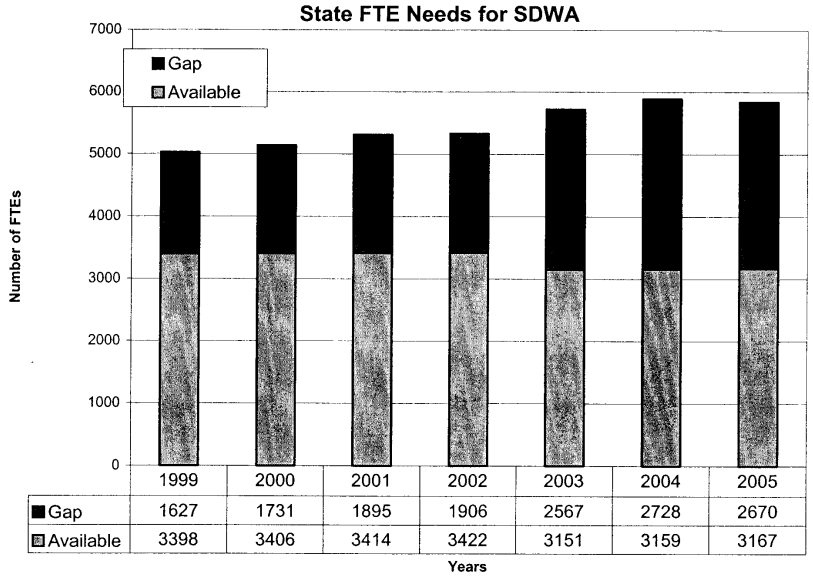
States intend to do all they can to meet their existing and new commitments, however, the road blocks and barriers being placed before and upon states are beginning to take their toll. More and more states are vocalizing their frustrations with the excessive, and in many cases unrealistic, expectations that are appearing in new regulations; the unrealistic expectations that EPA has for early implementation of the rules; and most critically, the lack of sufficient funding and staff to fully and effectively meet their own expectations as well as those of EPA, Congress, and the public.

The states are not interested in continuing to be the victims of GAO reports and IG investigations that find deficiencies in state programs when the staff, resources, and tools have not been made available for states to succeed. While quietly prioritizing and addressing implementation activities at the state and local level may meet the states' short-term needs, it is doubtful that ultimately it will meet the expectations of the public and Congress. States do not want to see the gains that have been made over the last 25 years eroded as focus and attention shifts from base, core public health activities to complex, new, and in many cases unimplementable regulations. The fundamental principles of the SDWA Amendments of 1996 are sound and, if correctly administered, have the potential to provide meaningful new public health protections. The states want the chance to succeed and they want the opportunity to help craft, as EPA's partners, the future direction of programs that will ensure the provision of safe drinking water in this country.

Upcoming Rulemaking Schedule

- **11/99 Proposed Radon Rule**
- **4/00 Proposed Long Term 1 Enhanced Surface Water Treatment Rule**
- **4/00 Proposed Filter Backwash Rule**
- **4/00 Radionuclides NODA**
- **4/00 Proposed Minor Changes to Stage 1 M/DBP Rule**
- **5/00 Proposed Ground Water Rule**
- **5/00 Proposed Secondary Standard for MTBE**
- **5/00 Final Public Notification Rule**
- **6/00 Proposed Arsenic Rule**
- **8/00 Final Radon Rule**
- **8/00 Final Filter Backwash Rule**
- **11/00 Final LT1**
- **11/00 Final Ground Water Rule**
- **11/00 Final Radionuclides Rule**
- **12/00 Final Secondary Standard for MTBE**
- **1/01 Final Arsenic Rule**





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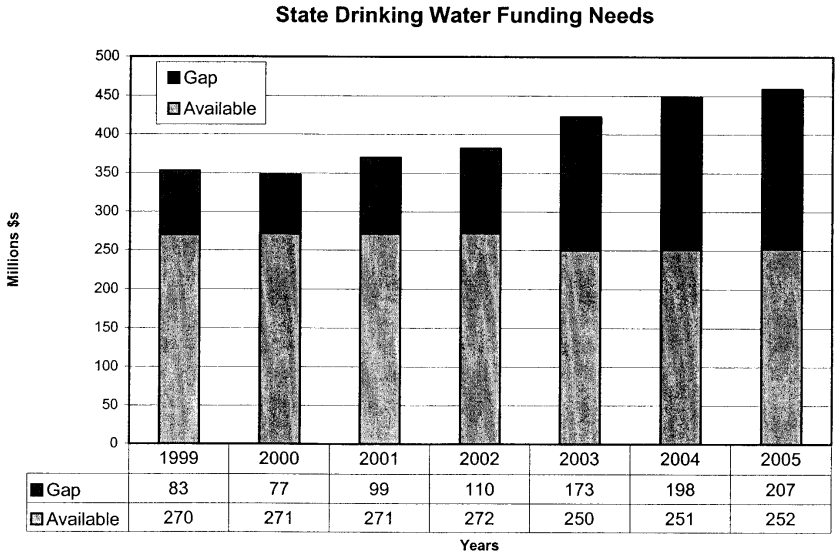

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