VACCINES—FINDING THE BALANCE BETWEEN PUBLIC SAFETY AND PERSONAL CHOICE

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

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VACCINES—FINDING THE BALANCE BETWEEN PUBLIC SAFETY AND PERSONAL CHOICE

TUESDAY, AUGUST 3, 1999

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 2 p.m., in room 2157, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Waxman, Morella, Shays, Mink, Mica, Norton, Cummings, Kucinich, Davis of Illinois, Terry, Biggert, Schakowsky, and Ose.

Also present: Representative Weldon of Florida.

Staff present: Kevin Binger, staff director; Barbara Comstock, chief counsel; Daniel R. Moll, deputy staff director; James Wilson, chief investigative counsel; David Kass, deputy counsel and parliamentarian; S. Elizabeth Clay, professional staff member; Mark Corallo, director of communications; Corinne Zaccagnini, systems administrator; Carla J. Martin, chief clerk; Lisa Smith-Arafune, deputy chief clerk; Phil Schiliro, minority staff director; Phil Barnett, minority chief counsel; Sarah Despres and David Rapallo, minority counsels; Ellen Rayner, minority chief clerk; Jean Gosa, minority staff assistant; and Andrew Su, minority research assistant.

Mr. BURTON. The Committee on Government Reform will come to order. I know we have a big crowd that wants to get in, but we'll have to have the door shut, so we can hear what's going on. Officer, will you shut that door, please? Thank you.

A quorum being present, the Committee on Government Reform will come to order. I ask unanimous consent that all Members' and witnesses' written opening statements be included in the record. Without objection, so ordered.

[The prepared statement of Hon. Doug Ose follows:]

August 3, 1999

Statement by Representative Doug Ose
Government Reform Committee Hearing on Vaccines and Public Safety

Mr. Chairman, I want to thank you for conducting this hearing on vaccines and public safety. I am pleased that the panel of witness appears to be a little more balanced, and I look forward to hearing their testimony this afternoon.

Mr. Chairman, numerous studies have shown that vaccines have dramatically reduced the incidence and devastating effects of numerous infectious diseases. In fact, these studies and research conclude that vaccines are among the greatest of medical accomplishments ever achieved. Millions of lives have been saved through vaccination and countless children have been sparred the pain and suffering of diseases like diphtheria, smallpox, and polio that plagued our nation only a generation ago.

The benefits of vaccines far outweigh the potential risk, and leading health organizations including the Centers for Disease Control and Prevention, the World Health Organization, and the American Academy of Pediatrics advocate immunization against a number of diseases.

Due to the success of widespread vaccination, some vaccine-preventable diseases are virtually unheard of today, and so few cases occur that the threat of these diseases seems to diminish over time. However, without continued routine immunization, epidemics of vaccine-preventable diseases would return, a far greater number of children would suffer unnecessarily, and the incidence of infant and childhood deaths would rise dramatically.

Scientific evidence indicates that side effects associated with vaccination are extremely rare. We cannot assume that events which occur following vaccination are necessarily caused by the vaccine. Millions of doses of vaccines have been safely administered to children and adults in this country and abroad and the benefits are well documented.

I would also like to welcome one of the witnesses, Mr. Rick Rollens, who will be testifying before our panel this afternoon. I look forward to hearing his testimony, and learning more about the work he is doing at U.C. Davis.

Mr. Chairman, I hope to hear a balanced perspective and debate on vaccine and public safety this afternoon, and I yield back the balance of my time.

Mr. BURTON. We will have more Members here shortly, but everybody is going to different hearings. This is a very, very busy week, as my colleagues all know.

I ask unanimous consent, at this point, that Representative Schakowsky be appointed to the minority vacancy on the Criminal Justice, Drug Policy, and Human Resources Subcommittee. Without objection, so ordered.

I ask for unanimous consent that Congressman Dave Weldon, who is one of the handful of physician Congressmen, join us on the stand and participate in our hearing today. Without objection, so ordered.

Mr. WAXMAN. Reserving the right to object.

Mr. BURTON. The gentleman reserves the right to object. State his reservation.

Mr. WAXMAN. Mr. Chairman, we really need to establish a policy when Members, who are not on our committee, are permitted to come and join us and ask questions. When we were in the majority, the policy we applied, whether it was a Democrat or a Republican, was that if the Member from outside the committee wanted to come and sit with the Members, they were certainly welcome to; but they were not permitted to ask questions because that wouldn't have been fair to other Members. That was the rule we applied, no matter what side of the aisle the Member was from.

I don't know what the policy is now. If the policy is to let any Member who wants to come and join a hearing, join us and ask questions, it could get out of hand. So, we ought to have a policy established.

Mr. BURTON. Well, I think a gentleman's agreement between you and I would probably suffice, at this point. What I would suggest is if you, Mr. Waxman, have a Member that would like to come and ask questions on a specific topic, I don't think we would have any objection on our side. The reason we have Dr. Weldon here today is because he is a physician. We're talking about issues relating to the health industry and he has some expertise and some background in this area.

Mr. WAXMAN. Well, Mr. Chairman, just to inquire further, and I don't—I'm not talking about this in any way personal to Mr. Weldon, but there are Members who have interest in hearings that this committee will have at one time or another. If you say you're going to let him come and you let someone on our side come, are we talking about one on each side? Or is it anybody who comes can come and—maybe what we could do, rather than work out a policy at this moment, is since we don't have many Members here, have an agreement that we'll let Mr. Weldon ask questions. But, I do think we need to think through this whole question.

We had the issue come up recently with one of our Members who wanted to attend a hearing, and we said, look, if it were a field hearing, that's one thing, if it's in a Member's district. But, since it's a hearing in Washington, we didn't think it was proper to have a Member come and ask questions because other Members then have to wait until they take their turn, either on the first or second round. So, we need to have a policy, apply it, no matter who's involved. And this is an issue that—we had a policy when we were

in the majority. I don't know what your policy is, but it sounds like for today, the question is Mr. Weldon.

Mr. BURTON. Well, I think the policy generally has been as the gentleman has stated. That's why I asked for unanimous consent that there be an exception made today. I think that we would make that exception, not as a general policy, but as an exception from time to time and we could do that for the minority. But, I'd be happy to sit down with the gentleman and try to work out some kind of a policy for future hearings.

Mr. WAXMAN. The only thing I want to point out is that once you've made an unanimous consent exception, then others are going to say why not an unanimous consent exception for me and it gets harder to say no to people. Once you start down that road, just realize that we're sending an invitation out to anybody who wants to show up for any hearing, and it's going to be tough to control in the future.

Mr. BURTON. Well, I understand. And as the chairman—and you may be chairman in the next Congress, who knows. I hope not; but, nevertheless, it could happen. [Laughter.]

But, if you're chairman in the next Congress, I will exceed to your wishes and, likewise, I hope you will mine. I will try not to make this a policy, but I will sit down with you to try to work it out, so that we can work with each other when we have exceptions like this that we'd like to have made.

The gentleman will withdraw his reservation?

Mr. WAXMAN. I'll withdraw my reservation.

Mr. BURTON. Thank you, very much, Mr. Waxman. Then, so ordered.

We're here today to expand upon the work of two of our subcommittees. Both the Subcommittee on Criminal Justice, Drug Policy, and Human Resources and the Subcommittee on National Security, Veteran's Affairs, and International Relations have conducted hearings on vaccine issues. I'm thankful to my two subcommittee chairs, Mr. Mica and Mr. Shays, for being so diligent in pursuing issues regarding safety, efficacy, and the mandating of hepatitis B and anthrax vaccines.

In this country and around the world, we have made a decision to vaccinate the entire population against dreaded infectious diseases. Children are required to receive numerous vaccines before they enter day care centers or schools. Vaccines that we now know contain mercury. Adults in certain professions are required to receive vaccinations for employment. This policy creates an inherent conflict between the interest of the individual and the community.

The tension between the individual risks and the public benefit is a classic ethical dilemma for public health. Some have described the current mandating of an increasing number of vaccines to children to be a good intention gone too far. Many of you may remember the polio crisis earlier this century. It was through the work of brilliant scientists, like Jonas Salk and Albert Sabin, and their colleagues, that the polio vaccines were developed. It was a mad dash to the finish line of licensing for the manufacturers of these vaccines, while polio, which caused so much illness and heartache, appears to have been eradicated. But, there are still cases of polio today, cases caused by the vaccine, itself. Jonas Salk spent the last

months of his life pleading with the government to stop the use of live vaccine, because of the cases of polio that it was causing.

Both the Food and Drug Administration and the Centers for Disease Control have adverse events monitoring systems. The FDA system, the Vaccine Adverse Event Monitoring System, is a passive monitoring system. Medical professionals, the pharmaceutical industry, and the public report adverse events. Over 11,000 adverse events were reported just last year. Over 5,900 adverse events have been reported so far this year, about one-sixth of those are considered serious. In all, 95,103 adverse events have been reported to this system since its inception. The former FDA Commissioner estimated that only 1 in 10 adverse events are reported, which means that we're talking about something close to 950,000.

Now, what is a serious event? It includes events that require hospitalization, events that cause disability, and events that kill. When asked about the safety of their vaccines, one pharmaceutical representative told my staff, everything has adverse events, including aspirin. To the academic or bureaucratic realm, the risk benefit ratio is numbers on a page. But to the parent of a child, who suffered a serious adverse event from a vaccine, that risk becomes a reality.

The risk was too real for the Nelson's, whose 1-month old daughter, Abbey, born healthy and hearty, died less than 1 month after coming home from the hospital. They later learned from the doctor, who performed the autopsy, that it was a death related to the hepatitis vaccine given to their daughter in the hospital when she was 2 days old.

To Rick Rollens, whose son acquired autism from a vaccine reaction, the risk was too great. The autism, vaccine linked, is very controversial. But, we have verified with current and former NIH neurologists that any injury to the brain can cause autism, including the shock to the neurological system by a vaccine. They will testify today.

To Michelle Clements, who is not able to be with us today, but who has submitted written testimony, whose son has spent at least 3 years in a coma, as a result of the DPT vaccine, the risk was too great.

We, as the government, can no longer keep our heads buried in the sand like an ostrich, pretending that there is no problem. On the flip side of this discussion is the need to protect the public at large from vaccine preventable diseases. I am not stating or implying that we should not have vaccines, because they are crucial to public health.

We will hear today from Carola Zitzmann, whose son was born in 1964 with severe disability, after being exposed to rubella during her pregnancy. We will also hear from Rebecca Cole, whose child died from chicken pox; and from Dr. Keith Van Zandt, a pediatrician, whose child is living with hepatitis.

In 1997, President Clinton directed Secretary Shalala to work with the States to develop an integrated immunization registry system and to require that all children in federally subsidized child care centers be immunized. This mass tracking of childhood vaccinations has created State registries that are tracking children from birth to grave. With these State systems reporting back to the

Federal level, we have instigated something the American people have strongly and loudly opposed, national medical tracking and invasion of the American public's privacy. One report stated that the long-term tracking strategy had three steps: first to notify families with a postcard when their child was late for a vaccine; second, if they did not comply, then a government official would call them on the telephone and remind them; and third, if they still did not comply, a government official would come and visit their home. I think that's going too far.

And what of attaching immunizations to Federal child care centers? Does this mean if your child has a medical or religious exemption, that he or she will not be allowed to access a federally subsidized facility? In our rush to vaccinate everyone, have we informed members of the public that they have choices? No, we have not. In our rush to vaccinate, do physicians and health care providers keep current in the medical literature, conscientiously reviewing medical histories, read package inserts and the Physician Desk References for contradictions, and clearly discuss these with their patients or their parents? Not very often. Have we become complacent in our protecting of our children, just so that we can meet some kind of a quota?

We will hear today also from Antonia Spaith, a Department of Defense civilian employee, who suffered serious adverse events after taking the anthrax vaccine and other vaccines. The mandating of anthrax vaccine in the military is a great concern to many in the Congress. I have joined my colleagues, Congressman Walter Jones, Ben Gilman, and others, in sponsoring legislation to stop the mandating of this vaccine.

From intense investigations, it has been learned that the decision to use this vaccine is fraught with errors. The adverse event rate is much higher than indicated and the military knows it. The research into its safety and efficacy does not provide any sense of security. We're using a vaccine that does not provide protection against strains of anthrax that would most probably be used, those that come through the air.

As we have learned at the subcommittee level, this issue is adversely affecting military readiness. We are losing a lot of members of our military, who choose to leave the military, rather than take this vaccine. Morale is low, as a result of the misinformation campaign, also on the lack of information on adverse event reports. We learned that there is fear in the ranks about reporting. We learned that the Department of Defense filters these reports before sending them to the FDA. We, also, learned that in complete defiance of regulations, the manufacturing facility was not inspected until 1996.

That means for 20 years, this manufacturing facility that produces the anthrax vaccine was not inspected, at which time it was learned that the quality control was deplorable. After 20 years of producing this vaccine, they found that the quality control was deplorable. No vaccine has been produced and distributed since that inspection, which means that we've stockpiled vaccines that are likely adulterated and still being given to our service members, while the plant is being updated. Yesterday, a member of my staff reviewed a test video being prepared by the military to show to its

members to inform them about this vaccine. It is full of intentionally misleading statements.

Now, in order to keep the pharmaceutical industry in the vaccine development business, Congress created what was supposed to be a no fault system for vaccine victims to receive compensation. There is concern that the Department of Health and Human Services has modified the injury compensation table, and in so doing, excluded those injuries that were most likely to apply to the program.

Now, we're pleased that Dr. David Satcher, the U.S. Surgeon General and Assistant Secretary for Health will be testifying on behalf of the Department of Health and Human Services. We're also pleased that Dr. Marcel Kinsbourne, Dr. Ronald Kennedy, and Dr. Samuel Katz will be testifying today, and we welcome them.

[The prepared statement of Hon. Dan Burton follows:]

Opening Statement

Chairman Dan Burton

Government Reform Committee
U.S. House of Representatives

"Vaccines:
Finding the Balance Between
Public Health and Personal Choice"

Tuesday
August 3, 1999
2:00 p.m.

2157 Rayburn House Office Building
Washington, D.C. 20515

We are here today to expand upon the work of our two of Subcommittees. Both the Subcommittee on Criminal Justice, Drug Policy, and Human Resources, and the Subcommittee on National Security, Veterans Affairs, and International Relations have conducted hearings on vaccine issues. I'm thankful to my two Subcommittee Chairs, Mr. Mica and Mr. Shays for being so diligent in pursuing issues regarding safety, efficacy, and the mandating of the Hepatitis B and Anthrax vaccines.

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This policy creates an inherent conflict between the interests of the individual and the community. The tension between individual risks and public benefit is the classic ethical dilemma for public health. Some have described the current mandating of an increasing number of vaccines to children to be a good intention gone too far.

Many of you may remember the polio crisis earlier this century. It was through the work of brilliant scientists like Jonas Salk and Albert Sabin and their colleagues that the polio vaccines were developed.

It was a mad dash to the finish line of licensing for the manufacturers of these vaccines. Wild polio -- which caused so much illness, appears to have been eradicated. But there are still cases of polio today -- cases caused by the vaccine. Jonas Salk spent the last months of his life pleading with the Government to stop the use of the live vaccine because of the cases of polio it was causing.

Adverse events

Both the Food and Drug Administration and the Centers for Disease Control have adverse events monitoring systems. The FDA's system, the Vaccine Adverse Events Monitoring System

(VAERS), is a passive monitoring system. Medical professionals, the pharmaceutical industry, and the public report adverse events. Over 11,000 adverse events were reported last year. And over 5,900 adverse events so far this year -- about one-sixth of those are considered serious. In all, 95,103 adverse events have been reported to this system since its inception. The former FDA Commissioner estimated that only one in ten adverse events are reported. What is a serious event? It includes events that require hospitalization, events that cause disability, and events that kill.

When asked about the safety of their vaccines, one pharmaceutical representative told my staff, **"everything has adverse events, including aspirin."**

In the academic or bureaucratic realm, the risk/benefit ratio is numbers on a page, but to the parent of a child who suffered a serious adverse event from a vaccine, that risk became a reality.

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Choice and Medical Privacy

In 1997, President Clinton directed Secretary Shalala to work with the states to develop an integrated immunization registry system and to require that all children in Federally subsidized child care centers be immunized. This mass tracking of childhood vaccinations has created state registries that are tracking children from birth to grave. With these state systems reporting back to the Federal level, we have instigated something the American people have strongly and loudly opposed -- national medical tracking -- an invasion of the American public's privacy.

One report stated that the long-term tracking strategy had three steps -- first to notify families with a post card when their child was late for a vaccine. Second, if they did not comply, then a Government Official would call them on the telephone and remind them, and third, if they still did not comply, a Government Official would visit their home.

And what of attaching immunizations to Federal Child Care Centers -- does this mean if your child has a medical or religious exemption that he or she will be not be allowed access to a Federally subsidized facility? In our rush to vaccinate everyone, have we informed members of the public that they have choices? No, we do not. In our rush to vaccinate, do physicians and health care providers keep current in the medical literature, conscientiously reviewing medical

histories and read package inserts and the Physicians Desk Reference for contraindications and clearly discuss these with their patients (or parents)? Not often.

Have we gotten complacent in protecting our children just so that we can meet a quota?

Anthrax

We will hear today from Antonio Spaith, a Department of Defense civilian employee who suffered serious adverse events after taking the anthrax vaccine, and other vaccines. The mandating of anthrax vaccine in the military is a grave concern to many in Congress. I have joined my colleagues Congressmen Walter Jones and Ben Gilman in sponsoring legislation to stop the mandating of this vaccine. From intensive investigations, it has been learned that the decision to use this vaccine is fraught with errors. The adverse event rate is much higher than indicated and the military knows it. The research into its safety and efficacy does not provide any sense of security. We are using a vaccine that does not provide protection against strains of anthrax that would most probably be used. As we have learned at the Subcommittee level, this issue is adversely affecting military readiness. We are losing vast numbers of our military who choose to leave the military rather than take this vaccine, morale is low as a result of the misinformation campaign on the lack of adverse events. We learned that there is fear in the ranks about reporting. We learned that the Department of Defense filters these reports before sending them to the FDA. We also learned that in complete defiance of regulations, the manufacturing facility was not inspected until 1996 (over 20 years without inspection) -- at which time it was learned that the quality control was deplorable. No vaccine has been produced and distributed since that inspection. Instead, we have stock-piled vaccines that are likely adulterated and being given to our service members while the plant is being updated. Yesterday, a member of my staff reviewed a test video being prepared by the military to show to its members to inform them about this vaccine. It is full of intentionally misleading statements.

National Vaccine Injury Compensation Program

In order to keep the pharmaceutical industry in the vaccine development business, Congress created what was supposed to be a no-fault system for vaccine victims to receive compensation. There is concern that the Department of Health and Human Services has modified the Injury Compensation Table, and in doing so, excluded those injuries that were most likely to apply to the program.

We are pleased that Dr. David Satcher, U.S. Surgeon General and Assistant Secretary for Health will be testifying on behalf of the Department of Health and Human Services. We are also pleased that Dr. Marcel Kinsbourne, Dr. Ronald Kennedy, and Dr. Samuel Katz will also be testifying today.

The hearing record will remain open until August 25th for all those who wish to make written submissions to the record.

Mr. BURTON. The hearing record will remain open until August 16th for all those who wish to make written submissions to the record.

[NOTE.—The information referred to is held in committee files.]

Mr. BURTON. I now recognize my colleague and ranking minority member, Mr. Waxman, for his opening statement.

Mr. WAXMAN. Mr. Chairman, there are a few triumphs in the annals of medicine like vaccinations. Vaccines have saved more lives than any other medical intervention in history. Today, they protect us from deadly infectious diseases which spread death, disability, and misery in other less fortunate parts of the world. Thanks to universal immunization, the United States has made tremendous progress against polio, diphtheria, whooping cough, and other diseases. According to UNICEF, these diseases kill 2½ million children and cripple 750,000 children worldwide every year. Without vaccinations, American children would also be vulnerable to similar catastrophic epidemics.

I don't think American parents would ever permit their children to be exposed to such extreme risks. But today we are becoming complacent about our success against infectious diseases. Unlike our parents and grandparents, we aren't terrorized every year by paralytic polio and whooping cough epidemics. This makes it easier to forget the value of vaccines and to focus on their potential risks. But, if children are frightened and parents discouraged about vaccines, we will quickly become vulnerable again to infectious diseases.

No one doubts that there are adverse reactions to vaccines. It is unfortunate that they happen and that children and adults suffer as a result. That is why I sponsored the National Childhood Vaccine Injury Act of 1986, which established the National Vaccine Injury Compensation Program. This program relies upon the best available science and medicine to provide an alternative to litigation for individuals who suffered specific vaccine related injuries.

Today we must continue to rely upon what science tells us about the benefits and risks of vaccines. We must continue to educate the public about vaccines, their benefits and risks. While everything we know about childhood vaccines tell us that their benefits far outweigh their risks, we must remain vigilant and continue epidemiological research into potential side effects.

There is a simple way to illustrate the importance of vaccination. Two hundred years ago, Edward Jenner developed the first small pox vaccine. I was inoculated against small pox; my children, who were born in the 1960's, were also inoculated. But those of you who were born in the 1970's do not have a small round scar that we bear on our shoulders because you didn't need the small pox vaccine. Small pox no longer threatens our children in our beds or whole communities with death. It's just a memory.

Today, we are tantalizingly close to eradicating the second communicable disease in history, polio. But until polio, meningitis, diphtheria, hepatitis, and other diseases are truly memories, our children and our families will continue to be at risk. Vaccination will remain an indispensable public health defense and it will be Congress's responsibility to continue to support and encourage universal vaccination.

Mr. Chairman, we will hear from families today who have suffered either adverse reactions to the vaccine or health problems they believe are linked to the vaccine. We will also hear from the families of those who have experienced the trauma and stigma of infectious disease. I'm sympathetic to all of our witnesses and look forward to their testimony.

Unfortunately, however, there are many witnesses that we will not hear from. The Democrats made a request for witnesses, but only half of those requests were granted. We requested to hear from a doctor who could have talked about efforts to vaccinate worldwide and the ravages of vaccine preventable diseases on children around the globe. We asked for a doctor to testify who has been doing vaccine studies since 1967 and who is an expert on reactions to the pertussis vaccine. And we asked to hear from a member of the board of directors of the American Academy of Pediatrics. But, these requests were denied.

Many other voices are missing from this discussion. For example, there is no representative from the State health agencies who actually mandate vaccinations and administer vaccine programs. There's no representative from the vaccine manufacturers who bear a large responsibility for vaccine safety. I deeply regret that these groups are not here today to provide us with balanced and informed testimony.

That's what hearings are supposed to be all about. We hear different points of view. And in the course of hearing different points of view, we can try to find out what the truth may be. But I'm sad that at this hearing we're not getting a balanced opportunity to get input from witnesses who have something very important to say.

Now, let me just point out to everybody what that would have entailed. Witnesses are given 5 minutes to testify. The Republican majority on this committee would not let us hear from somebody from the American Academy of Pediatrics for 5 minutes. The Republicans running this committee wouldn't let us hear from a doctor that has been doing vaccine studies since 1967 and is an expert on reactions to the pertussis vaccine for 5 minutes. The Republican leadership did not allow us to hear from a doctor who could have talked about efforts to vaccinate worldwide and the ravages of vaccine preventable diseases on children around the globe for 5 minutes.

But I wouldn't object to a colleague of ours, who is not even on this committee, to be able to ask questions for 5 minutes because I think people ought to be able to have an opportunity to say what they have to say. Although when we get Members who will hear that this is a committee they can all join at any moment to ask questions, we're going to have no time for witnesses, because the Members are going to be the only ones talking.

In conclusion, I wish to submit for the record the positions of leading medical and patient organizations in support of universal vaccination. I want to submit for the record a statement from the World Health Organization and the Pan American Health Organization, the American Medical Association, the Association of State and Territorial Health Officials, the American Nurses Association, the American Public Health Association, the American Academy of Family Physicians, the Children's Defense Fund, the American

Pharmaceutical Association, the Partnership for Prevention, the Bill and Melinda Gates Children's Vaccine Program, the Immunization Action Coalition, Every Child By Two, and the National Foundation for Infectious Diseases. So when we have a printed record of this hearing, we'll have a lot of different points of view in that record. It's just today, when the presentations are made to us orally, that we will not have the opportunity to hear from all of the witnesses that we requested.

I look forward to hearing the witnesses that are here today and I hope that will help us further our understanding about vaccinations and policies that would be best suited to help improve the health and safety of the children of this country.

[The prepared statement of Hon. Henry A. Waxman and the statements referred to follow:]

STATEMENT OF CONGRESSMAN HENRY A. WAXMAN
HOUSE GOVERNMENT REFORM COMMITTEE
"VACCINES: FINDING A BALANCE
BETWEEN PUBLIC SAFETY AND PERSONAL CHOICE"
TUESDAY, AUGUST 3, 1999 ~ 2154 RAYBURN HOB

Mr. Chairman, there are few triumphs in the annals of medicine like vaccination. Vaccines have saved more lives than any other medical intervention in history. Today, they protect us from deadly infectious diseases which spread death, disability, and misery in other, less fortunate parts of the world.

Thanks to universal immunization, the United States has made tremendous progress against polio, diphtheria, whooping cough, and other diseases. According to UNICEF, these diseases kill two and a half million children and cripple 750,000 children worldwide every year. Without vaccination, American children would also be vulnerable to similar catastrophic epidemics.

I don't think American parents would ever permit their children to be exposed to such extreme risks. But today, we are becoming complacent about our success against infectious diseases. Unlike our parents and grandparents, we aren't terrorized every year by paralytic polio and whooping cough epidemics.

This makes it easier to forget the value of vaccines and to focus on their potential risks. But if children are frightened and parents discouraged about vaccines, we will quickly become vulnerable again to infectious disease.

No one doubts that there are adverse reactions to vaccines. It is unfortunate that they happen, and that children and adults suffer as a result. That is why I sponsored the National

Childhood Vaccine Injury Act of 1986, which established the National Vaccine Injury Compensation Program. This program relies upon the best available science and medicine to provide an alternative to litigation for individuals who suffered specific vaccine-related injuries.

Today, we must continue to rely upon what science tells us about the benefits and risks of vaccines. We must continue to educate the public about vaccines, their benefits and risks. While everything we know about childhood vaccines tells us that their benefits far outweigh their risks, we must remain vigilant and continue epidemiological research into potential side effects.

There is a simple way to illustrate the importance of vaccination. Two hundred years ago, Edward Jenner developed the first smallpox vaccine. I was innoculated against smallpox. My children, who were born in the 1960s, were also innoculated.

But those of you who were born in the 1970s do not have a small, round scar that we bear on our shoulders — because you didn't need the smallpox vaccine. Smallpox no longer threatens our children in their beds or whole communities with death. It is just a memory.

Today, we are tantalizingly close to eradicating the second communicable disease in history — polio. But until polio, meningitis, diphtheria, hepatitis and other diseases are truly memories, our children and our families will continue to be at risk. Vaccination will remain an indispensable public health defense and it will be Congress' responsibility to continue to support and encourage universal vaccination

Mr. Chairman, we will hear from families who have suffered either adverse reactions to the vaccine or health problems they believe are linked to the vaccine. We will also hear from the families of those who have experienced the trauma and stigma of infectious disease. I am sympathetic to all of our witnesses and look forward to their testimony.

Unfortunately, however, there are many witnesses that we will not hear from. The

minority made a number of requests for witnesses, but only half those requests were granted. We requested to hear from —

- a doctor who could have talked about efforts to vaccinate world-wide, and the ravages of vaccine-preventable diseases on children around the globe;
- a doctor who has been doing vaccine studies since 1967 and who is an expert on reactions to the pertussis vaccine; and
- a member of the board of directors of the American Academy of Pediatrics.

But these requests were denied.

Many other voices are missing from this discussion. For example, there is no representative from the state health agencies who actually mandate vaccinations and administer vaccine programs. There is no representative from the vaccine manufacturers, who bear a large responsibility for vaccine safety. I deeply regret that these groups are not here today to provide us with balanced and informed testimony.

In conclusion, I wish to submit for the record the positions of leading medical and patient organizations in support of universal vaccination, including the World Health Organization and Pan American Health Organization, American Medical Association, the Association of State and Territorial Health Officials, American Nurses Association, the American Public Health Association, the American Academy of Family Physicians, the Children's Defense Fund, the American Pharmaceutical Association, the Partnership for Prevention, the Bill and Melinda Gates Children's Vaccine Program, the Immunization Action Coalition, Every Child by Two, and the National Foundation for Infectious Diseases..

###

PREVENTING DISEASE

Why immunization?

Because:

- Immunization, together with vitamin A supplements, is the most cost-effective health intervention.
- Immunization will be able to prevent almost all the infectious diseases that kill and handicap children.
- Prevention is cheaper than cure. Half a billion US dollars are spent on measles immunization every year to prevent two million deaths in over 190 countries. But the cost of treating measles cases in four countries alone is over one billion US dollars a year.
- Prevention is better than cure. Even successful treatment of a disease does not prevent the suffering of the child or the disruption for the family. Meanwhile, avoiding the need for treatment limits the spread of antibiotic resistance.

DEPARTMENT OF VACCINES AND OTHER BIOLOGICALS

World Health Organization
Geneva
1999

Achievements

	1974	Today
Number of child deaths prevented by immunization	Under one million	Over three million
Children immunized through the EPI	5%	Over 80%
Number of immunization contacts	31 million	Over 1 000 million
Number of vaccines used in immunization programmes in developing countries	two (smallpox and tuberculosis)	nine (diphtheria, whooping cough, tetanus, tuberculosis, measles, yellow fever, polio, hepatitis B and Hib)

DEPARTMENT OF VACCINES AND OTHER BIOLOGICALS

World Health Organization
Geneva
1999

WHO WE ARE

The Global Programme for Vaccines and Immunization

Our Mission

A world in which all people are immunized against vaccine-preventable diseases.

How we are organized

The Vaccine Research and Development Unit

Securing the development of new vaccines and of new vaccination strategies

We are currently accelerating:

- development of vaccines against the two major killers of children: diarrhoeal diseases and acute respiratory infections.
- evaluation of vaccines against meningitis to prevent epidemics in Africa.
- research for more effective vaccines against tuberculosis.
- development of diagnostic tools for use in disease control.
- epidemiological studies on vaccine-preventable diseases.
- development of new vaccine delivery systems to simplify and reduce the cost of immunization programmes.

DEPARTMENT OF VACCINES AND OTHER BIOLOGICALS

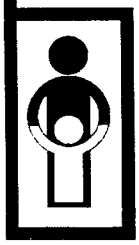
World Health Organization
Geneva
1999

The Vaccine Supply and Quality Unit

Ensuring high quality vaccines at affordable prices

We work with governments and individuals to:

- ensure that the over four billion doses of vaccine used every year are safe, potent, and effective.
- train key personnel from National Control Authorities, vaccine producers, and vaccine procurement staff.
- forecast the quantity of vaccines needed world-wide.
- develop new financing methods and affordable pricing strategies.
- lower technical barriers to accessing technologies for new vaccines.



DEPARTMENT OF VACCINES AND OTHER BIOLOGICALS

World Health Organization
Geneva
1999

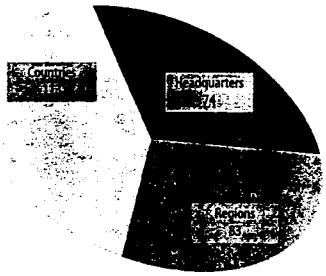
The Expanded Programme on Immunization

Ensuring that the vaccine reaches the people

We provide guidance and support to:

- Increase and maintain immunization coverage.
- Develop immunization policy.
- Meet global targets for the eradication, elimination, or control of diseases.
- Conduct disease surveillance.
- Strengthen the quality of immunization services, through :
  - maintenance of a cold chain for the safe transport and storage of vaccines
  - training health workers and managers at all levels
  - focusing attention on the need for injection safety.

270 GPV staff world-wide



Figures as of December 1997

DEPARTMENT OF VACCINES AND OTHER BIOLOGICALS

World Health Organization
Geneva
1999

American Medical Association
Physicians dedicated to the health of America

1101 Vermont Avenue, NW
Washington, DC 20005

Statement

For the Record

to the

Committee on Government Reform
U.S. House of Representatives

Re: Risk vs. Benefit of Vaccinations

August 3, 1999

Division of Legislative Counsel
202 789-7426

Statement

for the Record

of the

American Medical Association

to the

Committee on Government Reform

U.S. House of Representatives

RE: RISK VS. BENEFIT OF VACCINATIONS

August 3, 1999

On behalf of its 300,000 physicians and medical student members, the American Medical Association (AMA) appreciates the opportunity to provide feedback on the issues pertaining to vaccinations and vaccines that your committee plans to consider on August 3, 1999.

Immunization is perhaps the most significant public health story of this century. Through the successes of vaccination programs in the United States and throughout the world, many diseases that sent waves of fear through the communities of our previous generations are now under control, and in the case of smallpox, eradicated. The United States rates of diseases such as polio, *Haemophilus influenzae* disease, diphtheria, congenital rubella, measles, mumps, and tetanus are 99% lower than at any other time in history because of vaccination.

Ironically, because of this remarkable success, the public no longer perceives the threat of these diseases as real. Many Americans cannot remember seeing a case of measles, or polio, or

mumps, and the pain, suffering, and death in some cases, that these diseases caused to children and adults. Instead, we are now constantly bombarded by news media reports regarding the adverse reactions, both real and perceived, that are linked to the vaccines that have done so much for the betterment of public health. In the absence of the deadly diseases, it is now newsworthy to cover the risks associated with vaccination. Anti-vaccine forces, fueled by the news media and greatly empowered by the new information age, are focusing public attention on the risks and alleged adverse events associated with vaccines, rather than on the significant benefits that vaccinations have provided.

The AMA would like to point out that vaccinations do more than just protect the health of the child being vaccinated. Vaccinations also protect the health of the community in which the child resides. When vaccination levels are high, children who are not protected directly by vaccination are indirectly protected because they are not exposed to the disease. These include very young infants and children with medical conditions that prevent vaccination. In fact, a recent scientific study published in the *Journal of the American Medical Association* indicated that those who did not receive measles vaccine due to philosophical or religious reasons were 35 times more likely to contract measles, and could potentially increase the incidence of measles in their community by as much as 30%. The negative impact of decreased vaccination coverage on the public health of the United States is enormous. The return of these diseases would cause increased illness, disability, and death. The dollar cost would also be great, with increased physician visits, hospitalizations, treatment, and time lost from work.

The AMA recognizes that while vaccines are extremely safe and effective, none are 100 percent safe or effective. However, there are no safer or more effective alternatives for the long-term prevention of these communicable diseases. Thus, the AMA encourages the public to become fully informed about the risks and benefits of the vaccinations by talking to their physicians, and fully supports the law requiring the distribution of vaccine information statements prior to the administration of the vaccine.

With regard to vaccine safety, the AMA serves as a liaison member to the Advisory Committee on Immunization Practices (ACIP), and we remain committed to ensuring that vaccines are safe. ACIP recommendations are made following detailed analysis of the scientific data available on the vaccine. The AMA believes that any purported claims of adverse reactions to a vaccine should be subject to the same rigorous scientific evaluation to determine if a causal association to the vaccine exists and to ensure the continued safety of the vaccine. Thus, any claim of an adverse event to a vaccination would be subject to further research to maintain the United States' excellent record of preventing death and disease by providing the safest possible vaccination program.

The AMA is aware of efforts that are in place to monitor for potential adverse events from vaccination. As part of this effort, physicians, parents, and patients are encouraged to report any potential adverse reaction to the Food and Drug Administration's Vaccine Adverse Event Reporting System (VAERS). Unfortunately, data from this database can be misinterpreted to suggest significant risk of adverse reactions to particular vaccines.

It is not possible to determine the number of adverse reactions simply by examining the number of VAERS reports associated with that vaccine. This is because the VAERS database is used to examine overall trends and identify unusual occurrences for further scientific study, not to quantify the numbers of case reports. VAERS will accept all reports of health effects that follow vaccination, regardless of whether they are correlated to the vaccine or not. Thus, many of the VAERS reports have a coincidental rather than causal relationship with vaccination.

The AMA is committed to maintaining the major public health benefits of vaccinations and has developed very strong policies to ensure the continued provision and maximum safety of the vaccination program. The AMA advises that all children should be appropriately immunized and endorses the recommendations developed by the ACIP which are also supported by the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP). In addition, the AMA supports state legislation that requires children entering middle or junior high school to be adequately immunized according to the current national standards and endorses the National Adolescent Coverage Goals for the years 2000 and 2002. We also endorse laws that require insurance companies to provide coverage for immunization schedules that are endorsed by the ACIP, the AAP, and the AAFP.

The AMA believes that sound public education, based on proper scientific data, on the issues surrounding vaccination is important and encourages improving public awareness of current immunization guidelines. The AMA encourages state and local medical societies to work with state and local health departments to identify and eliminate barriers to immunization. We will continue to work with the Public Health Service, including the Centers for Disease Control and

Prevention and the National Vaccine Program Office, and with the AAP and the AAFP to complete the development and implementation of a national vaccine strategy that will assure age-appropriate immunization for children by their second birthday. In this regard, the AMA recently adopted policy supporting a national network of immunization registries, provided privacy and confidentiality for vaccine recipients are ensured.

In conclusion, the AMA strongly supports vaccination as an important public health strategy that cannot be compromised. We believe that critical public health decisions must be made on the basis of well-conducted scientific research and established scientific fact and not on anecdotal case reports. AMA policies on vaccination are firmly based on the abundant scientific data supporting it as one of the most important public health interventions of this century. The benefits of appropriately administering vaccines as part of a national immunization strategy far outweigh the risks, alleged or otherwise, associated with vaccination.

The AMA appreciates the Committee's consideration of this written testimony and looks forward to working with Committee members on this issue in the future.

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
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ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS (ASTHO)

STATEMENT FOR THE RECORD REGARDING THE RISKS AND BENEFITS OF VACCINES AND RELATED VACCINATION POLICIES

Submitted to the House Committee on Government Reform
August 3, 1999

The Association of State and Territorial Health Officials (ASTHO) represents the state health agencies of the United States and its territories. ASTHO is dedicated to formulating and influencing sound national public health policy. We are pleased to provide this statement to the House Government Reform Committee in support of immunizations and the ongoing role of state health departments in preventing the occurrence of vaccine-preventable disease.

Benefits of Immunization

Immunization is a vital public health tool and one of the most effective means of public health promotion and disease prevention. Prior to the institution of routine immunizations, vaccine-preventable diseases were a major cause of morbidity and mortality in children. Widespread vaccination of children has resulted in dramatic decreases in vaccine-preventable disease in the United States. In recent years, most of the diseases for which vaccines are routinely administered in childhood have become increasingly rare in the United States.

State Role in Immunization Requirements

Policies for vaccine requirements, including school and daycare entry laws, are made almost exclusively at the state level. States consider vaccines on an individual basis, and employ a rigorous decision-making process which allows for both expert and public input. Many states call together groups of experts to guide policy formation, and all state health departments work closely with state legislatures and some with state boards of health to enact policies which serve to protect the public's health.

States also seek specific immunization guidance from experts on the national level. The Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP) all provide guidance and advice on the use of vaccines. Vaccine recommendations are made through a careful, deliberative process which includes expert testimony, scientific data, and public input. While vaccine manufacturers play a role in this process, advisory committees must operate under conflict of interest laws.

ASTHO supports this approach and believes that vaccination implementation authority must be maintained at the state level. We are confident in the integrity of this process, and continue to support careful state consideration of recommendations put forward by the ACIP, AAP and AAFP.

Vaccine Safety

No medication, including vaccine, is without risk. While vaccines are proven effective in preventing incidence of disease and widespread immunization policies equally effective in preventing deadly disease outbreaks, rare adverse events to vaccination do occur. For this reason, we must continue to do everything possible to ensure that vaccines are as safe as possible and that providers and parents are educated about the risks and benefits of vaccines.

ASTHO supports the continued study of vaccine safety issues and the continued development of safety improvements in vaccines and vaccine delivery techniques. We further recommend that the federal government publish, distribute and regularly update vaccine information forms (such as the Vaccine Information Sheets currently produced by the Centers for Disease Control and Prevention) explaining the risks and benefits of individual vaccines and the availability of compensation for vaccine-related injuries. Surveillance of vaccine-related injuries through the Vaccine Adverse Effects Reporting System (VAERS) and the Vaccine Safety Datalink (VSD) is an important part of the support system to encourage high utilization of vaccines and ensure vaccine safety.

Philosophical Exemptions

While most states allow religious exemptions from childhood immunization requirements, and all states allow medical exemptions, only a minority of states (15 in 1998) allow philosophic or personal exemptions. Studies have shown that children exempted from vaccination requirements are more likely to develop vaccine-preventable disease, and when increased numbers of exempted children mix with nonexemptors, the risk of incidence of preventable disease increases in the nonexemptors as well.

ASTHO believes that wider adoption of these exemptions is inconsistent with good public health policy and is contrary to efforts to improve childhood immunization coverage. We support the right of states to pursue appropriate policies and legislation. However, we urge states considering philosophic exemptions to consider the public health impact of such exemptions and to make the criteria for exemption as strict as possible if such exemptions are adopted.

Position Statements

Childhood Immunizations

Summary: The American Nurses Association recognizes the importance of immunizations to the health of individual children and the community as a whole, and of the pivotal role nursing plays in assuring immunizations. The fulfillment of the immunization goal is a major undertaking that cannot be realized without the full endorsement of all professional nurses. For that reason, ANA will strive to attain the highest rate of immunization coverage in order to insure maximum protection overall for the general population.

Background

With the development and use of vaccines to prevent common communicable childhood diseases, the United States realized one of the most significant improvements in health status in the nation's history. Public health nurses provided the first major efforts to assure wide distribution of vaccine to children in community settings.

In recent years, the re-emergence of disease outbreaks has signaled the nation that immunization status has diminished to precarious levels. Decreased levels of disease protection are a consequence of inadequate support for the core public health functions by an ineffective health care system. Barriers created by cost, access, eligibility requirements and institutional rules have combined with a general malaise about the necessity for protection. As a result, there is a national complacency in regards to immunization of young children. This critical situation must be rectified so as to attain the Healthy People 2000 goal of a 90% immunization rate by 1996. Complacency of the American public related to immunization status has been replaced by a growing uncomfortable realization that children are again at risk for significant disease or death. Diverse factors have contributed to a reduced level of national protection from communicable diseases. These factors include:

- Legal challenges regarding efficacy, and adverse reactions. The risks of adverse reactions or outcomes associated with vaccines has assumed a heightened level of importance to the general public. The development of the Vaccine Information Statements (VISs), is in response to the need for informed consent related to those concerns.
- Lack of state and local leadership to address uniform day care and school entry laws. There has been limited opportunity and/or political will to critically examine the benefits and/or risks associated with immunizations. Thus the lack of leadership and essential appropriations for surveillance and enforcement has severely handicapped the system.
- Decreased private sector involvement. There has been low motivation in the private sector to have children immunized. Historically, the

cost of privately purchased vaccines has been a major contributor to the reluctance of private providers to continue or expand the service. As a result, fewer and fewer parents utilize the private sector for immunization protection. Frequently, the private provider refers parents to the public health clinic for necessary immunizations.

- Fragmented services which lack a comprehensive tracking/reminder system. The multi- health care delivery system in the United States fosters complex fragmented services. At any given time, an individual could obtain immunization from approximately four (4) different providers. Those being private physicians, federally qualified health centers, or city or county health departments. This fragmentation is compounded with an ineffective recordkeeping system that fails to compile a complete health record and follow-up with recall for the child's next appointment.
- Missed opportunities to immunize due to lack of practice standards. These missed opportunities occur as a result of not appropriately immunizing during certain health visits. Providers are encouraged to follow Standards for Pediatric Immunization Practices that address valid contraindications, the need for simultaneous injections and the need to assess and immunize at every health visit encounter. These encounters include both sick and well child office visits, children seen in emergency departments and inpatient hospitalizations.
- Decreased access to health care systems. Access to health care involves two essential components, availability and affordability of services. Private providers frequently limit the number of Medicaid patients that they include in their practice or require a well child visit in order to receive immunizations. Non-insured and under-insured infants and children are often referred to public health departments. Public clinics are frequently viewed as not "user friendly" with long waits and limited hours of operations. Cultural and language barriers exist within both sectors.

The public sector has become the primary source provider of vaccines for children. While the demand for immunizations in public clinics has increased, the numbers of nurses staffing clinics has remained static. Public clinics' capacity to serve is further eroded by data requirements for maintenance of immunization records. There is resistance to interagency service collaboration. Many clinics have limited hours of operation which is frequently identified as a barrier to access to immunizations and other primary care services.

Role of the Nurse

The American Nurses Association supports the critical role of public health nurses in improving access to vaccines for all children. Due to the complex nature of the U.S. health care system and the diversity of the population, many families need assistance in accessing immunization and other primary care services. Areas for which nurses can offer unique perspectives are:

- developing strategies to remove patient, provider and system barriers to care

- facilitating linkage of families to primary care providers
- designing outreach activities specifically aimed at hard to reach populations such as those who are geographically, culturally and socioeconomically at risk
- educating individuals and communities about the importance of immunizations
- encouraging partnerships among community groups, churches, fraternal organizations and Corporate National Services to assist families in entering the health care system on time
- collaborating with public/private organizations to pilot and implement innovative projects
- fostering data collection that supports research based practice

The American Nurses Association supports:

- development of culturally sensitive educational programs to motivate parents and communities to reprioritize immunizations as a basic component of comprehensive primary health care
- development of improved infrastructure for childhood immunizations which includes electronic tracking systems that identify and recall children in need of immunizations and provide a mechanism for the transfer of immunization data between multiple providers of care
- increased funding to insure the availability of nursing personnel in local clinics and health departments
- formulation of public policy that minimizes immunization exceptions and clearly delineates enforcement strategies
- professional education programs to ensure that providers are knowledgeable about current immunization schedules and valid and invalid contraindications that are consistent with the recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP)
- pharmaceutical research and development of new and refined vaccines to decrease number and severity of untoward effects
- collaboration among professional groups, governmental agencies, managed care operations and acute care facilities to integrate immunizations into their health programs by following established standards for pediatric immunization practice
- establishment of local coalitions within each state with broad, diverse community representation to advance a public/private partnership for immunization programs
- the development of strategies for delivery of primary care to children, whether public or private, which create opportunities and procedures for identifying those at risk for vaccine-preventable disease and to facilitate timely delivery of immunizations

References

- American Academy of Pediatrics (1991). Report of the Committee on Infectious Diseases.
- Anderson, D.C. (1992). Striehm ER Immunization. Journal of the American Medical Association, 268:20, 2959-2963.
- Centers for Disease Control and Prevention (1989). General Recommendation on

Immunization. Morbidity and Mortality Weekly Report, 38(13):205-14, 219-27.
- Centers for Disease Control and Prevention (1993). Standards for Pediatric Immunization Practices. Morbidity and Mortality Weekly Report, 42 (RR-5).
- Cutts, F.T., Orenstein, W.A., Bernier, R.H. (1991). Causes of Low Preschool Immunization Coverage in the United States. Annual Review of Public Health, 13:385-98.
- Freed, G.L., Bordley, C., and Defriese, G. (1993). Childhood Immunization Programs: An Analysis of Policy Issues. The Milbank Quarterly, 71 (1), 65-96.
- McConnochie, R.M., Roghmann, K.J. (1992). Immunization Opportunities Missed Among Urban Poor Children. Pediatrics, 89:1019-26.
- Orenstein, W.A., Atkinson, W., Mason D., Bernier, R.H. (1990). Barriers to Vaccinating Preschool Children. Journal of Health Care for the Poor and Underserved, 1:315-30.
- Pete, G. (1992). Childhood Immunizations. New England Journal of Medicine, 327:25, 2794- 1800.
- The National Vaccine Advisory Committee (1991). The Measles Epidemic: The Problems, Barriers, and Recommendations. Journal of the American Medical Association, 266: 1547-52.
- U.S. Department of Health and Human Services, Public Health Service. (1990). Healthy People 2000: National Health Promotion and Disease Prevention Objectives. Washington, DC: Department of Health and Human Services, (91-50213).
- U.S. Department of Health and Human Services, Public Health Service. (1993). Standards for Pediatric Immunization Practices. Washington, DC: Department of Health and Human Services, (535-765).

Effective Date: March 30, 1995
Status: New Position Statement
Originated by: Congress of Nursing Practice
Adopted by: ANA Board of Directors

Past House Action:
1972 - Protecting the Rights of Children and Adolescents
1985 - Federal Programs Affecting Women's and Children's Investment in the Future
1993 - The Future of America's Children

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NEWS

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A Statement from Executive Director Mohammad N. Akhter, MD, MPH
August 3, 1999

The American Public Health Association expresses its strong and continued support for universal vaccination against preventable diseases. Immunizations have been proven among the safest and most cost-effective health measures ever implemented. For every dollar spent on a measles-mumps-rubella vaccine, more than $16 is saved in direct medical costs.(1) Similarly compelling cost-benefit data exist for other vaccines, and they reflect not only dollars saved, but unnecessary suffering and death prevented.

A recent issue of the *Morbidity and Mortality Weekly Report* describes the toll taken on America's people before vaccinations were widely available:

> (I)n 1900, 21,064 smallpox cases were reported, and 894 patients died. In 1920, 469,924 measles cases were reported, and 7575 patients died; 147,991 diphtheria cases were reported, and 13,170 patients died. In 1922, 107,473 pertussis cases were reported, and 5099 patients died.(2)

By contrast, in 1998 there was one case of diptheria, 6,279 cases of pertussis, 89 cases of measles and none of smallpox, as the disease was eradicated in 1977.(2) These remarkable reductions in rates of illness and death are attributable to vaccination campaigns.

Public health professionals understand that a very small percentage of the population may experience allergic responses or other negative health effects from vaccinations. Long ago, APHA called for the establishment of a national compensation system to, at a minimum, alleviate the financial burden of such events. Furthermore, the Association continues to advocate the highest safety standards in vaccine development, manufacture, and distribution, in order to limit such potential adverse effects. In spite of science's best efforts, a small number of reactions may still be experienced. These occasions – like any crisis of health - are truly devastating for those affected directly, their families and other loved ones. However, it is important to remember that serious consequences will result for many, many more people if we reduce our immunization activities. Vaccine-preventable diseases can cause widespread blindness, deafness, brain damage, mental retardation, heart defects, sterility, miscarriage, paralysis, and death.

Taking into account that the benefits of vaccination against childhood diseases far outweigh the risks, we commend national policymakers for their ongoing support for universal immunization. APHA continues to advocate for the elimination of all vaccine-related adverse events, as well as the scourge of infectious disease, in America and around the world.

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(1) "A Cost-Benefit Analysis of the Measles-Mumps-Rubella (MMR) Vaccine", Battelle, 1994.
(2) "Achievements in Public Health, 1900-1999: Impact of Vaccines Universally Recommended for Children -- United States, 1990-1998", *MMWR*, April 2, 1999.

STATEMENT of the American Academy of Family Physicians

Submitted

To The

House Government Reform Committee

Regarding

"Vaccines: Finding the Balance Between Public Health and Personal Choice"

August 3, 1999

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On behalf of the 88,000 members of the American Academy of Family Physicians, I would like to submit the following statement for the record on "Vaccines: Finding the Balance Between Public Health and Personal Choice."

Background

The Academy deeply appreciates the opportunity to present the views of America's family physicians on an issue that has significance not only for the health of our country's children, but for society at large. We have been a leader in the effort to increase the level of immunization programs that focus on infants and children, as well as in activities to ensure the safety of these vaccines. While vaccines carry with them a small risk, the Academy views the decrease in the occurrence of many, childhood, preventable diseases as a major public health victory of this century.

In addition, the Academy has a long record of support for immunizations in our state and federal legislative efforts. Specifically, in our policies on "Access to Health Care," policies that articulate our support for universal health insurance coverage, we advocate for a defined, comprehensive benefits package emphasizing preventive and primary care services. These benefits include a category referred to as a "Basic Benefits Package," benefits for which no patient cost sharing should be required. Childhood immunizations are included in this section. In brief, Academy policy calls for the provision of free immunizations, underscoring their importance in health care services.

Finally, the Academy has made immunization issues a priority because family physicians have touched the lives of so many US families. Patients make 186 million office visits to family physicians each year--83 million more than any other specialty. In addition, family physicians currently see one out of every five children in the United States, visits that frequently include immunizations.

Recommended Childhood Immunizations

The Academy works with the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP) to produce, each year, the *Recommended Childhood Immunization Schedule* for the United States. In addition, the Academy has a member who serves as a liaison to the ACIP. This document, published each January in the medical journals of the AAFP, AAP and in the Centers for Disease Control and Prevention (CDC) publication *Mortality and Morbidity Weekly Reports* is the definitive source for health care providers nationwide. It is produced through an ongoing review of available scientific studies, as well as reports on the safety and administration experience of the immunizations. It is updated yearly and additional recommendations are made as needed.

In addition, the Academy makes recommendations for periodic health examinations, which were most recently revised in July, 1999. These recommendations describe AAFP policy for a number of health interventions, including childhood vaccines, and assist physicians making clinical decisions.

While the Academy is saddened that even one child may suffer an adverse reaction to a vaccine, we believe that the advantages to community-wide immunization programs far outweigh the small risk involved with their use. Our members include physicians who treated

polio victims who died or were disabled for life. They remember the climate of fear each summer, the empty swimming pools, the closed parks. We believe the American public may not recall the widespread suffering only a few decades ago from many diseases rarely even heard of today because of vaccines, when evaluating the present-day risk of vaccines.

Vaccine Science Changes Over Time

Nevertheless, the Academy realizes that the science surrounding vaccines changes over time. As stated above, the *Recommended Childhood Immunization Schedule* is updated annually, and changes are made during the year if necessary.

For example, in the year 2000 schedule, the Academy intends to recommend that all four doses of poliovirus vaccine be inactivated poliovirus vaccine (IPV), a dose given by injection. This will change the current recommendation, which gives providers the option of using oral polio vaccine (OPV) for the third and fourth dose. The Academy now believes the exclusive use of IPV is sufficient to prevent the reemergence of polio, it does not carry the risk of vaccine associated paralytic polio associated with OPV.

Further, the Academy has made two changes to the 1999 schedule this year in response to new data. Specifically, the Academy agrees with the Public Health Service guidance regarding infant hepatitis B immunization, which calls for balancing the very rare risk for newborns that might exist from thimerosal against the risk of infection with hepatitis B. As a result, we now recommend a delay in initiating this vaccine. The current schedule recommends the immunization be made at birth, but the new recommendation delays this until infants are two to six months old. When they are better able to withstand any occasional adverse reaction to thimerosal.

Finally, the Academy has reviewed information from the Centers for Disease Control and Prevention regarding a possible increased rate of intussusception among infants who have received rotavirus immunization compared to those who have not received this vaccine. Based on this information, the Academy recommends that rotavirus vaccine not be used until additional information can be obtained and analyzed. Prior to the recommendation for suspension of use, our policy stated that the decision to use rotavirus vaccine was to be made by the parent or guardian in consultation with their physician or other health care provider

Conclusion

The Academy appreciates the opportunity to provide the committee with our views and policy on childhood immunizations. While we share the grief of families who have been affected by adverse events related to vaccines, we stand by Academy recommendations for childhood immunizations because of the enormous benefit to public health. We would be pleased to assist you on this important issue.

All documents referenced in this statement are available on the Academy's website at aafp.org.

American Academy of Family Physicians
The doctors who specialize in you ®

This section of the AAFP Reference Manual contains definitions, policies, and position statements of the American Academy of Family Physicians relating to the clinical practice of medicine. In the past, the three sections of the Reference Manual were published seperately. This section was previously published as AAFP Positions on the Clinical Aspects of Medical Practice.

Child Immunization

The Academy believes that the best control of communicable disease is prevention, and that the best prevention for the serious infectious and communicable diseases of childhood (diphtheria, pertussis, tetanus, polio, measles, mumps, rubella, Haemophilus Influenzae type b, and hepatitis B) is immunization with approved available effective biological agents. Continued effort is required to achieve and maintain high percentage coverage of children.

While there are finite, serious risks for a few individuals involved as a result of receiving immunization materials, the benefit to the general public is to save lives and prevent serious disabilities to larger numbers of people. The Academy supports recommended immunization schedules for all children. Patients and their parents should be informed of the types of risks involved and the reasons for continuing immunization programs. (1984) (1992)

Children's Defense Fund

August 3, 1999

The Honorable Dan Burton, Chairman
House Committee on Government Reform
2157 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Burton:

Enclosed with this letter is a statement of the Children's Defense Fund for inclusion in the record for today's hearing on "Vaccines: Finding a Balance Between Public Safety and Personal Choice".

The mission of the Children's Defense Fund is to *Leave No Child Behind®* and to ensure every child a *Healthy Start,* a *Head Start,* a *Fair Start,* a *Safe Start,* and a *Moral Start* in life and successful passage to adulthood with the help of caring families and communities.

As part of our work to ensure that children receive a healthy start in life, we have been strong proponents of policies and programs which have helped improve the immunization status of children and which have led to reduced incidence of immunization preventable diseases.

As the House Government Reform Committee considers testimony and statements for submission for the hearing record, we encourage careful deliberation on proposals which would change the current policies and practices which have clearly helped improve the health status of millions of children.

Thanking you in advance for inclusion of our statement in the hearing record, I am,

Sincerely,

Gregg H. Haifley
Health Division Deputy Director

enclosure

cc: The Honorable Henry Waxman, Ranking Member

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STATEMENT OF THE CHILDREN'S DEFENSE FUND

House Government Reform Committee Hearing on
"Vaccines: Finding a Balance Between Public Safety and Personal Choice"

August 3, 1999
Rayburn House Office Building Room 2154

The Children's Defense Fund (CDF) would like to take this opportunity to submit for inclusion in the hearing record this statement on the importance of immunizations for children to maintain their good health and to prevent communicable diseases.

CDF is keenly aware of the public health benefits of immunizations. Published medical and epidemiological research, federal survey data, and programmatic data from a variety of public health programs consistently show that increasing immunization rates are associated with lower rates of vaccine-preventable diseases. In other words, immunizations protect individual children as well as their communities from preventable illnesses.

Between 1992 and 1997, immunization rates among children increased dramatically. As immunization rates rose, the incidence of vaccine-preventable illnesses decreased. For example, the number of cases of measles in 1997 was the lowest since it became a reportable disease in 1912. The incidence of *Haemophilus influenzae* type b (Hib) invasive disease - which can cause ear infections or meningitis - has declined more than 95 percent since the vaccine was introduced and added to the standard series of immunizations for young children (Teitelbaum and Edmunds, *MetLife Statistical Bulletin*, 1999).

Between 1985 and 1992, children who had been exempted from vaccines for medical, religious, or philosophical reasons were 35 times more likely to contract measles than children who had been vaccinated (Salmon, Haber, Gangarosa et al., *Journal of the American Medical Association*, July 7, 1999). Individuals who are not immunized may create risks for their

communities if they become sick and then transmit a contagious but preventable disease to friends and neighbors. This is of course the transmission process by which epidemics can start.

It is vitally important for public policy makers to find a reasonable balance of risks to individuals with the risks to their communities where personal health and public health interests intersect. No vaccine is entirely safe or risk-free, and there are certain medical circumstances, such as chronic illnesses, in which exemptions from vaccinations are justified. However, vaccines cause fewer medical complications than do vaccine-preventable illnesses such as measles, mumps, rubella, polio, diphtheria, tetanus, pertussis, and Hib. In fact, high immunization levels in communities benefit some unvaccinated individuals who might face medical risks from contracting a vaccine-preventable illness, such as those who are already ill. In such cases, the only protection for individuals without immunity is a high immunization rate in their community.

Successful federal and state immunization policies and practices in recent years include:

- Making vaccines more accessible to Medicaid, uninsured, and underinsured children;
- Conducting outreach and public awareness campaigns;
- Extending public clinic hours;
- Establishing immunization appointment reminder and immunization status systems; and
- Coordination with programs such as WIC (the Women, Infants and Children nutrition program).

The result of these and other related activities is significant improvement in immunization rates. Concurrent advances in science and technology and the increasing availability of safe and effective vaccines have improved the health status of millions of American children.

Recognizing that there is a certain amount of risk associated with vaccinations, Congress created the Vaccine Injury Compensation Fund. Congress has acknowledged the importance and the necessity of having a strategy to address those rare and sometimes devastating cases of adverse vaccine reactions. This system assures that, where there is an established causal link

between a vaccine and an adverse reaction, there is a system for compensation (inadequate as compensation may be relative to the life altering medical consequences). This system has the beneficial effect of assuring vaccine development, availability, and inclusion in standardized immunization schedules to the benefit of millions of children.

As committee members hear testimony suggesting retreat from routine immunizations, we urge awareness of the likely profound consequences, including increased risk of disease and death among children. Vaccines already must withstand rigorous scrutiny for efficacy and safety before becoming part of the routine immunization series for children. Those who challenge the clear individual and public health benefits of routine vaccinations should be held to a very high standard as they advocate policies that would jeopardize the health of individuals and their communities.

We thank the Committee for accepting these comments for inclusion in the record.

References

Salmon DA, Haber M, Gangarosa EJ, Phillips L, Smith NJ, Chen RT. Health Consequences of Religious and Philosophical Exemptions from Immunization Laws: Individual and Societal Risk of Measles. *Journal of the American Medical Association*, 1999, 282(1), 47-53.

Teitelbaum MA, Edmunds M. Immunization and Vaccine-Preventable Illness, United States, 1992 to 1997. *MetLife Statistical Bulletin*, 1999, 80(2),13-19.

APhA

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The National Professional Society of Pharmacists

August 2, 1999

The Honorable Dan Burton
Chairman
Committee on Government Reform
2157 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Burton:

The American Pharmaceutical Association (APhA), the national professional society of pharmacists, is writing to provide input on the issues of vaccines being considered at the hearing entitled "Vaccines: Finding a Balance Between Public Safety and Personal Choice" on August 3, 1999. APhA represents the third largest and most accessible health profession comprised of over 230,000 pharmacy practitioners, scientists, students and also pharmacy technicians.

APhA strongly supports the nation's system of vaccination for children and adults. The contribution of vaccines to individual and public health is remarkable, as demonstrated both by their efficacy and cost-effectiveness. The eradication or near eradication of diseases which historically have stricken children and adults in terrifying epidemics speaks to the power of these biologics and the importance of their proper use. No longer do parents fear the warm months of summer when the threat of polio and its deadly effects hung over most of our communities. Common childhood diseases, such as measles, mumps and diphtheria, rarely spread through whole schools in epidemic fashion causing considerable disability and tragic childhood death.

Pharmacists are encouraged to serve as vaccine advocates, facilitators of age-appropriate vaccination and vaccine providers. Their availability in many underserved rural and urban locations positions them as key agents in our war against vaccine preventable illness. In our publications and educational material, as well as in the attached *Guidelines for Pharmacy-Based Immunization Activities,* are recommendations related to many aspects of immunization use, including vaccine safety. Pharmacists are encouraged to educate the public about immunizations, their benefits and risks, and to disseminate vaccine information statements. They are also educated about FDA's Vaccine Adverse Event Reporting System (VAERS) and the injury compensation system. This training and the services provided by pharmacists provide the public an additional and highly accessible health care provider, working in tandem with physicians, nurses and health professionals to make the nation's system of vaccine delivery as safe and effective as possible.

APhA appreciates this opportunity to provide comments to the Committee and believes that the critical personal and public health value of vaccination can not be compromised. Maintaining a credible system, trusted by the American public and health professionals that serve them, and one grounded on the most rigorous scientific evidence must remain one of our nation's highest priorities.

Sincerely,

John A. Gans, PharmD
Executive Vice President

GUIDELINES FOR PHARMACY-BASED IMMUNIZATION ADVOCACY

Guideline 1 - Prevention

Pharmacists should protect their patients' health by being vaccine advocates.

(a) Pharmacists should adopt one of three levels of involvement in vaccine advocacy:
(1) Pharmacist as educator (motivating people to be immunized);
(2) Pharmacist as facilitator (hosting others who immunize);
(3) Pharmacist as immunizer (protecting vulnerable people, consistent with state law).

(b) Pharmacists should focus their immunization efforts on diseases that are the most significant sources of preventable mortality among the American people, such as influenza, pneumococcal, and hepatitis B infections.

(c) Pharmacists should routinely determine the immunization status of patients, then refer patients to another appropriate provider for immunization.

(d) Pharmacists should identify high-risk patients in need of targeted vaccines and develop an appropriate immunization schedule.

(e) Pharmacists should protect themselves and prevent infection of their patients by being appropriately immunized themselves.

Guideline 2 - Partnership

Pharmacists who administer immunizations do so in partnership with their community.

(a) Pharmacists should support the immunization advocacy goals and other educational programs of health departments in their city, county, and state.

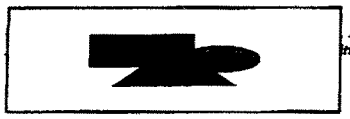
(b) Pharmacists should collaborate with community prescribers and health departments.

(c) Pharmacists should assist their patients in maintaining a medical home, including care such as immunization delivery.

(d) Pharmacists should consult with and report immunization delivery, as appropriate, to primary-care providers, state immunization registries, and other relevant parties.

(e) Pharmacists should identify high-risk patients in hospitals and other institutions and assure that appropriate vaccination is considered either before discharge or in discharge planning.

(f) Pharmacists should identify high-risk patients in nursing homes and other facilities and assure that needed vaccinations are considered either upon admission or in drug regimen reviews.



August 1997
tution Ave. NW Washington, DC 20037

Guideline 3 - Quality

Pharmacists must achieve and maintain competence to administer immunizations.

(a) Pharmacists should administer vaccines only after being properly trained and evaluated in disease epidemiology, vaccine characteristics, injection technique, and related topics.

(b) Pharmacists should administer vaccines only after being properly trained in emergency responses to adverse events and should provide this service only in settings equipped with epinephrine and related supplies.

(c) Before immunization, pharmacists should question patients and/or their families about contraindications and inform them in specific terms about the risks and benefits of immunization.

(d) Pharmacists should receive additional education and training on current immunization recommendations, schedules, and techniques at least annually.

Guideline 4 - Documentation

Pharmacists should document immunizations fully and report clinically significant events appropriately.

(a) Pharmacists should maintain perpetual immunization records and offer a personal immunization record to each patient and his or her primary care provider whenever possible.

(b) Pharmacists should report adverse events following immunization to any appropriate primary-care providers and to the Vaccine Adverse Event Reporting System (VAERS).

Guideline 5 - Empowerment

Pharmacists should educate patients about immunizations and respect patients' rights.

(a) Pharmacists should encourage appropriate vaccine use through information campaigns for health care practitioners, employers, and the public about the benefits of immunizations.

(b) Pharmacists should educate patients and their families about immunization in readily understood terms.

(c) Before immunizing, pharmacists should document any patient education provided and informed consent obtained, consistent with state law.

References:

Center for Disease Control and Prevention Standards for Pediatric Immunization Practices, MMWR 1993;42(RR-5):1-13
National Coalition for Adult Immunization. Bethesda, Maryland:NCAI 1995

Today's **Solution** *for Tomorrow's* **Health**

July 28, 1999

William L. Roper, MD, MPH, [illegible]
Jonathan E. Fielding, MD, MPH, MBA, [illegible]
Donald M. Vickery, MD, [illegible]
John R. Seffrin, PhD, *Treasurer*

The Honorable Richard Schweiker, *Chairman Emeritus*

Susan L. Polan, PhD, *President*

The Honorable Henry A. Waxman
2204 Rayburn HOB
Washington, DC 20515-0529

Dear Representative Waxman:

I understand that on August 3, 1999, the Committee on Government Reform will be holding a hearing entitled "Vaccines: Finding a Balance Between Public Safety and Personal Choice." The hearing will provide an opportunity to review the role of vaccines and illuminate issues regarding research, the safety and efficacy of vaccines, adverse events reporting and injury compensation, and the education of health care personnel and the public on vaccines. The enclosed packet contains information that I hope will help you to make an informed decision on these very important issues.

Vaccines are undoubtedly one of the greatest health achievements of the twentieth century. Smallpox has been eradicated, poliomyelitis has been eliminated in the Western Hemisphere, and measles and Haemophilus influenzae type B (Hib) disease have been reduced to record low numbers of cases. The decline in these deadly diseases is due largely to the success of vaccines.

However, the current rarity of these once common diseases does not mean that they no longer pose a serious and deadly threat. For example, over a five year period in the former Soviet Union, declining levels of vaccine coverage for both children and adults resulted in an increase of diphtheria from 839 cases in 1989 to nearly 50,000 cases and 1,700 deaths by 1994. There have already been at least 20 imported cases of diphtheria in Europe and two cases in U.S. citizens working in the former Soviet Union. Because infectious diseases do not respect international borders, it is essential that the U.S. maintains and improves its current immunization levels in order to protect the health of its population. Vaccinating our armed forces against the potentially deadly infectious agents that they may face in today's changing military environment is one important way to protect our citizens from deadly disease. This issue and the research surrounding it should be given full attention and review.

I hope that you will look to Partnership for Prevention if you need any further information about vaccine policy. Please do not hesitate to contact Susan Polan or Sarah Knab at the Partnership office (202/833-0009) if you have any questions.

Sincerely,

Bill Roper

William L. Roper, MD, MPH
Chairman

Partnership for Prevention is a national nonprofit organization committed to increasing the priority, resources, knowledge and incentives for disease prevention and health promotion policy.

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Written Statement from the
Bill and Melinda Gates Children's Vaccine Program
PATH, Seattle, WA

Vaccines: Finding a Balance Between Public Safety and Personal Choice

August 3, 1999

Thank you for this opportunity to make a statement about immunization and the value of vaccines worldwide. PATH, the Program for Appropriate Technology in Health, is an international, non-profit, 501(c)3 organization active in over 85 countries. Among other projects, PATH implements the Bill and Melinda Gates Children's Vaccine Program with funding from the William H. Gates Foundation. The Program works to ensure that all children receive the full benefits of new, life-saving vaccines without undue delay and to strengthen and improve existing immunization activities. More information is available at www.ChildrensVaccine.org.

We would like to begin with some brief, general comments about immunization. We will then explain how a changing world is increasing public anxiety about vaccines, and increasing the need to allay misplaced fear and to defend and justify immunization programs.

We feel that there is ample evidence supporting the following statements about immunization:

- **Global immunization programs currently save two to three million young lives per year.** They also prevent about 750,000 cases of blindness, paralysis, and mental disability annually.

- **Immunization is one of the world's most cost-effective health interventions.** By preventing disease, treatment and hospitalization costs are avoided and lost productivity is minimized. Society saves at least $2, and as much as $29, for every dollar spent on immunization. After providing adequate nutrition, there is no more efficient expenditure of health dollars than on immunization.

- **The vast majority of health care providers and parents value immunization.**

- **Global immunization is the greatest public health success story in history.** Since the early 1980's, global immunization efforts have resulted in unprecedented progress in preventing childhood disease and death. In only ten years, a massive effort raised coverage rates from 5% of children worldwide in 1980 to a reported 80% in 1990.

- **Immunization contributes to alleviating poverty** by enabling more children to stay in school (which leads to better jobs), increasing productivity by allowing parents to work instead of caring for sick children, freeing up resources that otherwise would have been spent to treat disease, and reducing disabilities leading to decreased economic productivity.

- **It is safer to vaccinate than not to vaccinate.** Serious medical problems resulting from immunization are rare. In most cases, the risk of a serious medical problem resulting from vaccination is far lower than the risk of suffering from the disease.

- **We are always at risk of epidemics when immunization levels drop.** When political and economic chaos caused disruptions in immunization in the former Soviet Union, the incidence of diphtheria increased from 2,000 cases in 1990 to 47,000 in 1994. The disease soon spread to other European countries, forcing an expensive effort to halt the epidemic. Effective, routine immunization would have reduced expense and human suffering.

- **Scientifically unproven hypotheses, irresponsibly sensationalized in the media, can contribute to drops in immunization coverage, and increased levels of disease across the globe.** Global communications allow for rapid dissemination of even the most preposterous rumors. If given sufficient exposure, this misinformation can have disastrous impact.

- **Believing that something is true does not make it true.** It is important to remember that most "side effects" which are reported to occur following an immunization are not caused by the immunization, even though some parents and anti-vaccine groups may believe this to be the case.

It has been pointed out that vaccines are victims of their own success. As vaccine preventable infectious diseases disappear from public view due to immunization, rare incidences of serious adverse events following immunization loom large in the public's mind. People forget the toll previously taken by disease. Even worse, common diseases of unknown etiology are attributed to immunization even though there is no scientific proof of a cause and effect relationship between immunization and the disease.

The last few decades have seen significant changes in the flow of information between research science, public health, the media, the public, the legal system, and anti-immunization groups. The traditional scientific model of generating and testing hypotheses under the watchful eyes of peers, and only then announcing results, has been replaced. Today scientists increasingly go to the media before or simultaneously with publication, or even without publication. The issue can become a topic of public debate before the scientific process could possibly generate data to support or reject the hypothesis. But even if the hypothesis is disproved, the public has already seen images of damaged children linked to the vaccine and the (non-)issue can be exploited by anti-vaccine groups, liability lawyers, and elements of the media who thrive on this type of controversy.

Scientific hypotheses must be given free airing, but editors also must have responsibility for proper precautionary wording when, for example, an author recommends stopping a national immunization program based on a hypothesis but without sufficient evidence. Too many lives are at stake! Recent examples include hypotheses that measles-mumps-rubella vaccines may cause inflammatory bowel disease and autism, vaccination associated with diabetes mellitus,

and hepatitis B vaccine associated with multiple sclerosis. We do not yet know how much damage may have been done, and how many individuals will suffer from preventable diseases due to misinformation and speculation on these issues.

We end with a question: If society and the vaccine industry are medico-legally responsible for compensating those who are truly damaged by vaccines, why are the media and anti-vaccine groups not held legally responsible for the consequences of promulgating misinformation on the safety of vaccines—when such misinformation results in damage to health? Perhaps we will see such lawsuits in the future when vaccine coverage declines (as in the unfortunate case of pertussis immunization in the United Kingdom, Italy, Germany, Sweden and Japan), the disease returns, and society is forced to learn a harsh lesson once again.

For more on this topic, please see the article on which much of the statement was based: Kane, M.A. Commentary: Public perception and the safety of immunization., Vaccine 16 (1998) S73-75.

Immunization Action
COALITION

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August 3, 1999

Representative Daniel Burton, Chairman
Committee on Government Reform
United States House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Burton:

I respectfully request that this letter be included in the official record for the hearing on vaccine safety and U.S. vaccine policy that is before the Committee on Government Reform today, August 3, 1999.

The Immunization Action Coalition, of which I am the executive director and medical director, believes in vaccinating all people of all ages against all vaccine-preventable diseases. Over 5,000 health professionals actively support our mission. At least twice a year we send an emphatic and clear message through our publications *NEEDLE TIPS* and *VACCINATE ADULTS!* to approximately 500,000 health professionals reminding them to vaccinate all people of all ages against all vaccine-preventable diseases.

I am writing to give input into three important questions concerning vaccines on which the Committee on Government Reform is taking testimony today.

ARE VACCINES SAFE?
Millions of dollars and millions of hours are spent by the Centers for Disease Control and Prevention, the Food and Drug Administration, the American Academy of Pediatrics, the American Medical Association, the American Academy of Family Physicians, the American College of Physicians, the Vaccine Adverse Events Reporting System, the vaccine companies, and countless other agencies and scientific groups to make sure our vaccines are safe. I choose to trust the recommendations of these thousands of experts whose work it is to make sure vaccines are safe.

ARE VACCINES EFFECTIVE?
Vaccines save lives. Consider the following vaccine-preventable disease statistics:

- 15,520 people died of diphtheria in 1921. In 1997, no one died of diphtheria.
- 10,314 people died of measles in 1923. In 1997, 2 people died of measles.
- 9,269 people died of pertussis in 1923. In 1997, 6 people died of pertussis.
- 511 people died of tetanus in 1947. In 1997, 4 people died of tetanus.
- 1,000 people died of Hib disease in 1986. In 1997, 7 people died of Hib disease.

Deaths from vaccine-preventable diseases have decreased dramatically through the use of vaccines. (See attached tables.)

I have also enclosed 19 personal stories and case reports collected by the Immunization Action Coalition of people who suffered or died from vaccine-preventable diseases. Three of the stories are highlighted below:

- **Story #3: Family remembers hepatitis B victim as a girl with promise**
  A. J. is dead. No one knows how A. J. got hepatitis B virus infection. Imagine if there had been a law that she needed to be vaccinated before attending school. She'd be alive today. Ask her family if they wish there had been a hepatitis B vaccination school entry law. After A. J. died, the demand for hepatitis B vaccination by students in her school increased dramatically.

  Hepatitis B virus is a silent disease that anyone from birth through old age can contract. It is not just a disease of adults. Prior to the implementation of routine infant hepatitis B immunization, it was estimated that 35,000 children were infected with hepatitis B virus annually in the United States.

- **Story #11: Measles outbreak associated with an unvaccinated population**
  A measles outbreak occurred in a religious community in St. Paul, Minnesota, in 1996. Shortly after the outbreak, most of the unvaccinated children and young adults in this religious community subsequently chose to receive two doses of MMR vaccine.

- **Story #10: Pertussis claims the lives of two infants**
  Families who make decisions not to vaccinate their children sometimes don't know that their children can infect others including younger siblings who are not old enough to be vaccinated. The two infants who died were too young to be vaccinated. Pertussis (whooping cough) is a disease that can be contracted at any age, but it is particularly dangerous and life threatening for infants because their airways are so tiny.

Commenting on the pertussis outbreak that led to the death of these two infants in Santa Cruz County, California, public health chief Betsy McCarty, RN, MS, said, "People who think they are doing the right thing by not getting their children vaccinated, couldn't be more mistaken. This is as important as putting your kid in the car seat, seeing they have enough to eat, and locking up the poisons."

WHY DO STATES NEED SCHOOL VACCINATION LAWS?
This is a question that arises over and over again. All states have mandatory vaccination requirements for certain vaccines at school entry. Here are some reasons why states have vaccination laws:

- Diseases spread in closed, crowded environments such as schools.
- Unvaccinated schoolchildren are at greater risk of contracting vaccine-preventable diseases which are sometimes deadly.
- Unvaccinated schoolchildren can bring vaccine-preventable diseases home to younger children in their families and neighborhoods who may be too young to be vaccinated.
- Unvaccinated schoolchildren put children who are medically unable to be vaccinated (e.g., children with HIV infection) at risk for these diseases.
- Unvaccinated schoolchildren pose a risk to children whose parents chose to vaccinate them but who are in the category of children who did not respond to the vaccine.
- Unvaccinated schoolchildren can start school outbreaks which disrupt education, increase absenteeism, and lead to loss of income for parents who must stay home with their sick children.

Public health policy concerning the use of vaccines has made it possible for people in the United States and around the world to live longer, healthier lives. There is no doubt in my mind that the work of the Immunization Action Coalition has helped perpetuate the excellent health of this nation by promoting the use of safe and effective vaccines for children and adults.

Sincerely,

Deborah L. Wexler MD

Deborah L. Wexler, MD
Executive Director

Comparison of Maximum and Current Reported Deaths from Vaccine-Preventable Diseases, U.S.

This table compares the maximum number of deaths from vaccine-preventable diseases reported in one year vs. the number of deaths reported in 1997 (the most current year for which vaccine-preventable disease death statistics are available)*

Disease	Maximum Reported Deaths (year reported)	Reported Deaths in 1997	Percent Decrease
Diphtheria	15,520 (1921)	0	100%
Measles	10,314 (1923)	2	99.98%
Mumps	25 (1968)	0	100%
Pertussis	9,269 (1923)	6	99.94%
Polio (wild)	3,145 (1952)	0	100%
Rubella	31 (1947)	0	100%
Tetanus	511 (1947)	4	99.22%
Haemophilus influenzae invasive disease (type B)	1,000 (1986)	7	99.3%

* Data provided by the U.S. Centers for Disease Control and Prevention, Atlanta, GA.

Cases of Vaccine-Preventable Diseases in the United States Reduced Dramatically in 20th Century Thanks to Vaccines!

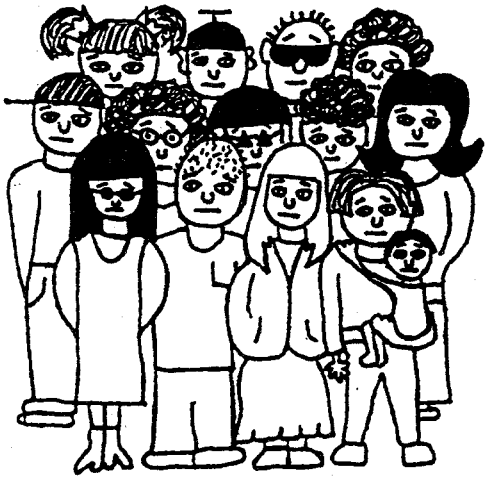
Baseline 20th Century annual morbidity and 1998 provisional morbidity from nine diseases with vaccines recommended before 1990 for universal use in children — United States.

Disease	Baseline 20th Century Annual Morbidity	1998 Provisional Morbidity	% Decrease
Smallpox	48,164[1]	0	100%
Diphtheria	175,885[2]	1	100%[3]
Pertussis	147,271[4]	6,279	95.7%
Tetanus	1,314[5]	34	97.4%
Polio (paralytic)	16,316[6]	0[7]	100%
Measles	503,282[8]	89	100%[3]
Mumps	152,209[9]	606	99.6%
Rubella	47,745[10]	345	99.3%
(Congenital Rubella Syndrome)	823[11]	5	99.4%
Haemophilus influenzae type b	20,000[12]	54[13]	99.7%

[1]Average annual number of cases during 1900-1904.
[2]Average annual number of reported cases during 1920-1922, 3 years before vaccine development.
[3]Rounded to nearest tenth.
[4]Average annual number of reported cases during 1922-1925, 4 years before vaccine development.
[5]Estimated number of cases based on reported number of deaths during 1922-1926, assuming a case-fatality rate of 90%.
[6]Average annual number of reported cases during 1951-1954, 4 years before vaccine licensure.
[7]Excludes one case of vaccine-associated polio reported in 1998.
[8]Average annual number of reported cases during 1958-1962, 5 years before vaccine licensure.
[9]Number of reported cases in 1968, the year reporting began and the first year after vaccine licensure.
[10]Average annual number of reported cases during 1966-1968, 3 years before vaccine licensure.
[11]Estimated number of cases based on seroprevalence data in the population and on the risk that women infected during a childbearing year would have a fetus with congenital rubella syndrome.
[12]Estimated number of cases from population-based surveillance studies before vaccine licensure in 1985.
[13]Excludes 71 cases of *Haemophilus influenzae* disease of unknown serotype.

Adapted from MMWR, Vol. 48, No. 12, April 2, 1999, p. 248

The Immunization Action Coalition presents . . .



Unprotected People

Stories of people who died or suffered from vaccine-preventable diseases

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Item #R2057 (3/99)

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Unprotected People #1
Haemophilus influenzae type b

A mother's experience with *Haemophilus influenzae* type b

Written by Peggy Archer, RNC, BSN. Reprinted from "Michigan Immunization Update," winter 1998, a publication of the Michigan Department of Community Health.

In 1989, the *Haemophilus influenzae* type b vaccine was relatively new and not yet routine. I was aware of the vaccine's availability, but, busy mom that I was, I had not yet made the trip to the health department to get the immunization for my two-year-old daughter, Sarah. I will always regret that bit of procrastination and the anguish that it caused.

As a registered nurse, I felt confident treating Sarah's colds and sniffles without calling our pediatrician. I did not become alarmed when, late one March evening, Sarah's mild upper respiratory infection progressed to a croupy cough and fever. I gave her a tepid bath and acetaminophen to control her fever, and to relieve her croup I transformed our bathroom into a steam room and sat holding her until I was convinced she was feeling better. Vaporizer at her bedside, I tucked her in with the thought that we would see the pediatrician in the morning. I settled into bed, only to be awakened within the hour by my worried husband. Sarah's breathing was becoming more labored and my concern began to grow. It was clear that Sarah needed immediate medical attention in a hospital emergency room.

As we left the house, my husband, Eric, grumbled a bit about taking a child to the emergency room in the middle of the night, to be seen for a simple cold. It was at that moment that I knew what was wrong with Sarah. It was as if God wanted to override any feelings of doubt instilled by Eric's lack of a sense of urgency. As I prepared our daughter for the ride, I told Eric that she could be suffering from epiglottitis, a condition in which the epiglottis becomes so inflamed that it can completely block the airway. He must have seen the panic in my eyes, because he didn't ask questions. In moments, we were speeding toward the hospital. The 25-minute drive seemed like hours as I watched Sarah's condition deteriorate before my eyes. Even in the dim light of our car I could see her color changing from pink to pale blue and then a dusky blue. Unable to swallow the copious secretions pooling in her mouth, she began to drool. As she struggled to breathe, I began to wonder what implements I had in my purse with which I could perform a tracheotomy.

The emergency physician confirmed my suspicions of epiglottitis. A pediatrician and an ear, nose, and throat specialist were summoned and agreed that Sarah should be taken to surgery immediately for intubation and possible tracheotomy. The pediatrician explained that Sarah was in serious condition most likely due to infection with the *Haemophilus influenzae* type b (Hib) bacteria. Finally, he added that her illness could have been prevented by vaccination. I was overwhelmed at the thought that my negligence caused this to happen.

The anesthesiologist who was to assist the other physicians arrived in the emergency department. I had worked with him on several occasions and knew him to be confident and unexcitable. As he quickly and quietly assessed Sarah, a look of extreme concern came over his face. He became anxious and began to pace as we waited for the staff to prepare Sarah for the operating room. She was in worse condition than I had thought, and I was terrified that I might lose her.

After leaving Sarah's side, I sought support from friends in the familiar Special Care Nursery where I worked as a staff nurse. Just as Eric and I arrived on the unit, a colleague gave us the upsetting news that there were problems in the operating room. Sarah's throat was so swollen that they could not get her intubated. Their last hope before doing a tracheotomy was to try an extra small tube, the size that we used

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in the nursery for the tiniest of premature infants. Overcome with worry, Eric and I headed for the chapel to pray. That is where we were an hour or so later as the surgical team wheeled our little girl past us, on the way to the Intensive Care Unit. My eyes were so full of tears that it took a few moments for me to recognize that she did not have a tracheotomy. The tiny endotracheal tube had been successfully placed, and she was put on a ventilator for respiratory support.

Eric and I sat by Sarah's bedside still fearful for her life. Blood cultures confirmed that *Haemophilus influenzae* type b was the cause of her illness. The pediatrician's admonishment rang in my ears. "This wouldn't have happened if she had gotten the Hib vaccine." I was overcome with guilt as I watched the ventilator pump oxygen into Sarah's tiny lungs. In addition to large doses of antibiotics, the nurses injected her IV with a drug that would temporarily paralyze her, preventing her from becoming restless and dislodging the airway she so desperately needed. I was familiar with the drug, so I knew Sarah could still feel every poke and procedure, but was unable to respond. Knowing that I could have prevented her from going through such torture was almost unbearable.

Thirty-six hours later, the swelling had subsided enough so that the tube could be removed, and Sarah was placed in a humidified oxygen tent. Like most kids, she showed incredible resilience and was discharged on the fifth day. Sarah is 10 years old now and has no memory of the terrible ordeal that her parents will never forget.

I recently began working in a pediatric clinic, and have encountered parents who refuse to immunize their children due to fear of a severe reaction. Perhaps if these same parents are made aware of children like Sarah, who nearly lost her life to a vaccine-preventable illness, they will reconsider their decision not to immunize.

Unprotected People #2 Hepatitis B

Parent of child with HBV testifies about importance of hepatitis B vaccination

A parent whose son is chronically infected with the hepatitis B virus delivered the following testimony in 1997 at a public hearing on the implementation of a hepatitis B school entry law.

The parent spoke on a personal level of the pain her entire family has suffered because of one family member's chronic illness. She concluded by urging parents to learn as much as they can about hepatitis B so that they can make truly informed decisions regarding school immunization and how to best protect their children. The testimony is as follows:

I'm here to talk about my family. I'm not here to add to the list of statistics related to immunization issues. I'm here to personalize them, to bring them to a level that you can relate to from the heart rather than from a business, political, or clinical standpoint. My husband and I have three young children. One is a hepatitis B carrier. Although he is asymptomatic, biopsies at ages 3 and 4 confirmed that he already has cirrhosis. He did not respond to a 7-month course of interferon, a form of chemotherapy, and no other treatment has been available for him.

There is a four-letter "F" word which we try to shield our children from. It's something they shouldn't know anything about at such a young age. The word is Fear. Fear of social repercussions, fear of financial ruin, fear of sickness, death and loss.

You may have noticed that I have not provided our family name. I can't. The first thing hepatitis B families learn, usually after rejection by friends or family, is to go to extreme lengths to protect their child's privacy. We desperately want to reach out for comfort when we learn our child has an incurable illness, but we can't. Local hospitals offer support groups for parents of children with cancer, but no help is available for parents of children who have life-threatening infectious diseases.

We feel an overwhelming need to warn daycare workers, teachers, Sunday school caretakers, babysitters, playmates and their parents that extra care needs to be exercised if our child scrapes his knee, bites or is bitten, has a bloody nose, and so on. We want to tell everyone to get the shots. Yet we agonize over the negative consequences of "telling"....Will our child be treated fairly? Will he be ostracized on the playground? Will we ever find a babysitter? Will they have any friends or will our children be singled out as the kids to avoid? Will information given to the school nurse in confidence wind up as the topic of conversation at a PTA meeting? There are discrimination and disability laws that guarantee our child a public education, but there are no laws to protect my child's heart....

My husband and I attended a school meeting regarding one of our other children. During casual conversation, a mom mentioned that she'd heard that there was a child with hepatitis B in our school district. She went on to tell the other concerned parents that she had visited the school superintendent in an effort to identify the child so that she could better protect her son. We sat paralyzed in silence, waiting for glances to turn in our direction (they didn't!), and all I could think was, get your kid the shots if you want to protect him. We supervise our child's play, we coach his soccer games, we are there as much as possible in order to protect other people's children. But it's obviously impossible to continue this vigilance as the children grow older. A neighbor tried to bandage our child's bleeding cut and I body slammed her away. She thinks I'm overprotective. She has no idea I was protecting her. No one else should have to live with this virus. It's preventable.

We worry about our ability to provide the best care for our child. His interferon treatment cost well

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over $20,000 and only a portion was covered by insurance. We are self-employed and we watched our health insurance premiums triple. We can't change carriers because we fear he could become sick or need a transplant during the "pre-existing condition exemption period" with a new policy. If no cure or control is found in the very near future, the likelihood that he will need a transplant is high. We have been warned that transplant and post-transplant care will most likely ruin us financially, and it is only a temporary solution. The virus would eventually attack the new liver as well. We wonder whether we will be able to afford to put our children through college, how we will manage to retire.

I call this virus "IT." Capital I, capital T. Stephen King fans will understand why. IT invades our lives, our thoughts, our spiritual beliefs, no matter what defenses we erect. I watch my happy children playing and IT reminds me that we will soon have to tell my son that he has a serious illness. Whenever he doesn't feel well, I wonder, "Is this IT"? How long will IT allow him to play the sports he loves? How will IT affect his school performance? The quality and length of my son's life are frightening unknowns, but statistics related to the progression and characteristics of this disease make it difficult to be optimistic. You can all look at your young children and fantasize about their senior proms and weddings. I cannot.

My son is a leader. He is clever, creative, charming. He is very protective of our other children and they look up to him. I fear the effect IT will have on his siblings, worry about how they will deal with their brother's illness, or worse. I fear that I will watch my child die, the worst possible thing that can happen to a parent. Doctors and parents have no control over the course this illness chooses within our children's bodies. However, the availability of the hep B vaccine allows us to control the spread of the disease to others. No other family should ever have to experience this pain. Three shots can prevent IT.

Hepatitis B is transmitted primarily through blood and sexual contact with infected persons. There are young, asymptomatic carriers who have not yet been diagnosed. Infected children will be socializing with and dating your children. It is clear to me that those of you who oppose immunizing our state's children are well informed about vaccine composition and side effects. I beg you to learn as much about the hepatitis B virus and disease progression as well. Only then will you be able to make a truly informed decision regarding school immunizations and how to best protect your children.

Signed,
A Parent

Unprotected People #3
Hepatitis B

Family remembers hepatitis B victim as a girl with promise

By Molly Guthrey, Staff Writer, St. Paul Pioneer Press. *Originally printed Saturday, Aug. 6, 1994. Reprinted with permission.*

The family huddled quietly on the eve of their child's funeral in a home cloaked with almost tangible sorrow.

The North Minneapolis house used to be filled with 15-year-old Arkesha Johnson's easy peals of laughter. But on Thursday, it was painfully silent with grief-stricken relatives.

Terry Johnson, the girl's mother, sat at the kitchen table, her shoulders hunched as she talked about her daughter's sudden death from hepatitis B. She spoke softly and her eyes still had a glaze of shock about them, as if her mind was still trying to process her eldest daughter's death six days earlier.

Known to friends and family as Kesha, she was an honors student who excelled at math and science and who would have been a junior this fall at South High School in Minneapolis. She had a boyfriend and a best friend. She loved Janet Jackson and rap music and gospel music, too. She dreamed of becoming a surgeon or a pediatrician and planned to attend college—maybe Temple University—on grants and scholarships.

She was determined to be a success in life. Renee Johnson, one of her aunts, was so sure of her niece's academic talents that she was convinced that someday she would watch as Kesha was awarded the Nobel Prize after discovering a cure for cancer or AIDS.

Now, the family is trying to cope with the death of all those dreams surrounding their Kesha.

"I think any time you lose a child, you feel shock, hurt and pain, everything pretty negative rolled up into one," Renee Johnson said.

Kesha died on July 29 of hepatitis B, family members said, after being diagnosed about two weeks before. Until then, she had been a seemingly healthy and active teenager – but then she started having stomach pains. She was nauseated and throwing up on July 14, the day her mother took her to the Hennepin County Medical Center.

The doctors ran some tests and found her liver badly damaged, family members said. They wouldn't let Kesha go home again, even to pack. She was transferred to the University of Minnesota Hospital, where her illness quickly worsened as family members tried to assimilate what was happening.

She never went home again.

She was removed from life support on July 29 as about 40 family members and close friends filled the room and cried. Only her aunt could bear to watch as Kesha stopped breathing. Some left the room, sobbing.

"I knew Kesha's spirit had already left us," said Renee Johnson.

She was the same Kesha they loved for the first nine days in the hospital, before the disease overtook her body and her mind. She giggled and watched television, visited with friends and family and hoped for the best.

None of them thought she would die. Family members said she was put at the top of a transplant list.

"There was always hope," said Kim Johnson, an aunt from Chicago. "We didn't think it would happen like this. The doctors had hoped it wouldn't. It was just so sudden."

There were so many relatives visiting that they filled up two waiting rooms. The operators at the university received hundreds of calls from well-wishers.

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Family members said they have been told by doctors that it is rare for a person to be overcome so quickly by hepatitis. They're not sure how she caught the disease or why it happened so fast.

Hepatitis B is a highly infectious virus that attacks the liver. Infection can lead to severe illness, liver damage and sometimes death. Nationally, about 300,000 acute cases and 6,500 deaths occur annually, health officials say.

Last year in Minnesota, there were 77 cases of hepatitis B reported in Minnesota, 56 cases involving people aged 15 to 39. The infection has slowly been declining in Minnesota since 1988. Deaths are rare, health officials said.

"It is often a silent disease," said Dr. Deborah Wexler, of the St. Paul-based Hepatitis B Coalition. "This is a perfect example of why every child in the United States needs to be vaccinated against hepatitis B."

Last year, Minnesota became the first state in the nation to recommend that all adolescents be immunized against the hepatitis B virus. State health officials took the step after they discovered the disease was becoming more prevalent among adolescents 15 and older.

At her funeral on Friday at St. John's Missionary Baptist Church on Morgan Avenue, Kesha looked a little bit like an angel in her casket, dressed in a cream dress with sparkly rhinestones sprinkled across her chest, resting in a bed of white velvet.

It was a girlish casket, brown with tiny pink flowers etched onto the sides.

It was a simple service, filled with simple words and songs and prayers. The choir she used to sing with sang for her. Her friend Cornell Washington also sang a song about their friendship, a cappella. He bowed his head to compose himself for minutes before he began.

"You never miss a good friend until she's gone," the boy sang in a shaky voice from the front of the church. "Life goes on, but it's not the same."

And her family and friends bowed their heads and began sobbing openly as the boy's song for Kesha filled the small church.

Unprotected People #4
Varicella (chickenpox)

Three fatal varicella cases in unvaccinated young women

Three fatal varicella (chickenpox) cases in young adult women were reported to the Centers for Disease Control and Prevention by state health departments during January-April 1997. All three women were susceptible to varicella, unvaccinated, and infected by exposure to unvaccinated preschool-aged children who had contracted varicella. These three cases appeared in the Morbidity and Mortality Weekly Report (MMWR), *May 16, 1997, vol. 76, no. 19 and are reprinted below.*

NOTE: There are approximately 100 deaths and 10,000 hospitalizations from varicella each year in the United States. The CDC's Advisory Committee on Immunization Practices (ACIP) recommends that all susceptible children (12 months of age and older) and all susceptible adults be vaccinated.

Case 1: Death of a 23-year-old woman
On January 19, 1997, a 23-year-old woman in good health had onset of a classic varicella rash. In early January, her 2- and 5-year-old unvaccinated children had had varicella. On January 22, she had onset of shortness of breath and hemoptysis. When she was admitted to a local hospital on January 23, a chest radiograph indicated diffuse alveolar density consistent with varicella pneumonia, and treatment was initiated with oxygen and intravenous acyclovir. Her condition worsened, and she required intubation several hours after admission. Because of increasing respiratory distress, she was transferred to a referral hospital where treatment continued with oxygen, antibiotics, and intravenous acyclovir. On January 31, her rash became hemorrhagic, and she developed disseminated intravascular coagulation (DIC) and renal failure, followed by progression to multiple system failure; she died on February 2. Varicella zoster virus was cultured from skin lesions and from a tracheal aspirate.

Case 2: Death of a 25-year-old woman
On March 11, 1997, a 25-year-old woman in good health had onset of a classic varicella rash, fever, and headache. Her 4-year-old unvaccinated child had had onset of a varicella rash on February 23. On March 12, the woman had onset of cough, and on March 13, shortness of breath. On March 14, she sought care at a local emergency department (ED) because of increasing respiratory difficulty and confusion. Chest radiograph indicated bilateral infiltrates consistent with varicella pneumonia, and arterial blood gases indicated hypoxemia. Varicella encephalitis and pneumonia were diagnosed; she was admitted to the hospital, and treatment was initiated with oxygen and intravenous acyclovir. Four hours after admission, her respiratory difficulty increased, and she required intubation. On March 15, a computerized tomography of the brain revealed severe, diffuse cerebral edema, and she developed renal failure and coma. On March 16, she was transferred to a referral hospital for renal dialysis; an electroencephalogram indicated absence of electrical brain activity, and repeat chest radiographs indicated diffuse infiltrates. She died on March 17.

Case 3: Death of a 32-year-old woman
On April 3, 1997, a 32-year-old woman with Crohn's disease sought medical evaluation at a local ED because of onset of abdominal and back pain. On March 7, therapy was initiated with 40 mg prednisone daily for an exacerbation of her Crohn's disease. By April 3, her steroid therapy had been tapered to 20 mg prednisone daily. On physical examination, she had mild, generalized abdominal tenderness with no specific signs or abdominal guarding. She was afebrile, and a white blood cell (WBC) count was normal. A benign abdominal syndrome was presumptively diagnosed, and she was discharged.

Her symptoms persisted, and on April 4, she sought medical evaluation at the office of her health-care provider. Findings on physical examination were unchanged. Although an abdominal radiograph, ab-

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dominal and pelvic ultrasounds, and a WBC count were normal, because of her underlying medical condition, she was referred for surgical consultation. On April 5, the abdominal pain persisted, and she returned to the ED for evaluation. A WBC count was 15,000/mm3 (normal: 3200-9800/mm3), and she was admitted to the hospital. Diagnoses of colitis and ileitis with possible perforation and intraabdominal abscess were considered, and treatment was initiated with broad-spectrum antibiotics. On physical examination, a maculopapular, vesicular rash with crusted lesions was observed on her trunk, head, and neck. Varicella was presumptively diagnosed, and she was placed in isolation. The patient reported that she had had onset of a mild macular, nonpruritic rash on her back on April 3 and that she had been exposed on March 12 and 13 to her 4-year-old unvaccinated niece with varicella. On April 6, the vesicles became hemorrhagic, and she began bleeding from intravenous sites. She rapidly developed hypotension and DIC, and died from shock the same day. On autopsy, evidence of viral inclusion bodies in multiple organs was consistent with varicella, and varicella was determined to be the cause of death.

Unprotected People #5
Polio

"I awoke one morning unable to walk"

One day, three-year-old Sharon Karber awoke unable to walk. It was 1953. Polio had reached epidemic proportions in the United States, and Sharon had become another polio victim. This is her personal story which originally appeared in "Michigan Immunization Update," spring 1997. It is entitled, "Through a child's eyes: a child's polio experience." As Sharon says, "this is a true story told through the eyes of one child who experienced a crippling vaccine-preventable disease and was rehabilitated. Not everyone was as lucky." Today, Ms. Karber, a registered nurse, is a nurse consultant at the Michigan Department of Community Health. Here is her story:

Through a child's eyes: a child's polio experience
Contributed by Sharon Karber, RN, MSN, Nurse Consultant, Michigan Department of Community Health

For me and my family, the crippling effects of polio will never be forgotten. It was the spring of 1953, and a polio epidemic was occurring in Michigan and the rest of the country. During that year, 2,346 polio cases were diagnosed in Michigan, and, at almost three years of age, I became one of those statistics. I awoke one morning unable to walk and had to be admitted to Mary Free Bed Rehabilitation Hospital in Grand Rapids, where I spent the next seven months.

I recall seeing my parents through a glass door during my stay at the hospital. As I learned later in life, polio patients were quarantined in order to both protect the polio patients from acquiring respiratory infections from visitors and in order to contain the spread of polio to those with whom they might have contact. Eventually it became normal to see my parents only on weekends because they had to travel two hours, one way, to see me. Rehabilitation therapy during those seven months included hot packs to my legs, whirlpool treatments, passive leg exercises and learning to walk with braces and crutches. I was discharged from Mary Free Bed Hospital after seven months of therapy under the condition that my mother would continue to administer my leg exercises. This meant that three times a day she would place me on the kitchen table and massage, stretch and strengthen my leg muscles.

Grade school years were very difficult because of my braces and crutches. It was impossible to run and play like other kids. I required leg surgeries (including four weeks in a cast) every summer until I was 12 years old in order to correct deformities, reposition muscles, and reattach tendons for better leg and foot control. Eventually I graduated from needing braces and crutches, but then came the mis-mate orthopedic saddle shoes. I remember pleading with my mother to buy me regular shoes but the answer was always "no," because the shoes had to be orthopedically built and had to accommodate a two shoe-size difference in foot size.

Junior high school was my first normal school experience. I had at last reached my maximum ability where nothing further could be done to improve the functioning of my legs. I was now able to compete in gym class, wear normal shoes, and cheerlead with the best of my peers. My residual physical limitations were minimal, but what a long road I had traveled with that polio villain!

My experience with this disease was nothing compared to what my parents endured seeing their child go through years of physical limitations and rehabilitation. Until the day my mother died, tears would always come to her eyes when she told her side of this story. To write my story now, as an adult and as a mother, makes my heart ache for my mother, who suffered emotionally because of my disease. Physically losing parenting responsibilities of her youngest child and then having that once-normal child return physically disabled from a disease that a

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vaccine could have prevented (had it been discovered earlier) caused terrible guilt for her. I strongly believe my rehabilitation and level of functioning today would not have been possible without her unending devotion in performing my daily leg exercises, compliance with years of physician visits and consents for numerous surgeries.

Today, I have my own family and am a nurse consultant for the Michigan Department of Community Health working with the Immunization Division. My life has come full circle as I now spend much of my time as a strong advocate for immunizations. I believe the work I do to educate health care providers in Michigan about the importance of vaccinating all children on time will help prevent potentially devastating diseases. It is my hope that no child will ever have to suffer any disease that can be prevented by vaccines. This is a true story told through the eyes of one child who experienced a crippling vaccine-preventable disease and was rehabilitated. Not everyone was as lucky.

Unprotected People #6
Hepatitis B

"All of the horrors that I endured could have been avoided"

U.S. Congressman John Joseph Moakley from Massachusetts was gravely ill with hepatitis B virus infection but fortunately received a successful liver transplant. Today, Congressman Moakley is a great advocate for hepatitis B vaccine. As he writes in the following letter, "All of the horrors that I endured could have been avoided if I had had available to me the very safe and effective vaccine against hepatitis B that now exists." Here is Congressman Moakley's story:

Don't Hesitate: Vaccinate!
Contributed by Joe Moakley, Member of Congress of the United States, House of Representatives, 9th District, Massachusetts

In the early 1980s, I was diagnosed with hepatitis B. It has never been determined where or how I contracted the virus. It may have been during a Congressional fact finding trip to China at that time. That is one of the very frightening facts about hepatitis B. While risk factors have been identified that are associated with viral transmission, up to 40% of the cases of hepatitis B in adults have no known risk factors associated with them.

By 1995, I was told by my doctors that I had about two months to live. In my case, the hepatitis B virus had led to cirrhosis of the liver and this vital organ had deteriorated beyond function. I was terribly ill. I had no strength and I had become severely jaundiced. But I was lucky; a liver transplant saved my life. Today I am happy, healthy and so grateful that I have been able to celebrate 25 years in the United States Congress.

Unfortunately, more than 1,250,000 Americans have hepatitis B, and up to 6,000 Americans every year die from the complications associated with the hepatitis B virus. All of the horrors that I endured could have been avoided if I had had available to me the very safe and effective vaccine against hepatitis B that now exists. The three shot series over a period of four to six months can protect most people from the agony of this disease.

I strongly encourage everyone to check with their provider about immunization against hepatitis B for themselves and for those they love. There is no reason for anyone to suffer from this totally preventable disease.

Item #R2057-F (11/98)

Unprotected People #7 Tetanus

Montana newborn of an unvaccinated mother contracts neonatal tetanus after application of nonsterile clay to the umbilical cord

A case report of neonatal tetanus was published in Morbidity and Mortality Weekly Report (MMWR) *on November 6, 1998, in an article entitled "Neonatal Tetanus – Montana, 1998." The article states that "the findings indicated that tetanus occurred after application of nonsterile clay to the umbilical cord."*

The editorial note includes mention of the Center for Disease Control And Prevention's Advisory Committee on Immunization Practices (ACIP) recommendation to give a booster dose of Td to previously vaccinated pregnant women who have not received a Td vaccination within the preceding 10 years, and unvaccinated or partially vaccinated pregnant women should complete the primary series of three doses of Td.

The article and editorial note are printed below:

Neonatal Tetanus — Montana, 1998

Neonatal tetanus (NT) is a severe, often fatal disease caused by a toxin of Clostridium tetani, a ubiquitous spore-forming bacterium found in high concentrations in soil and animal excrements. NT is associated with nonsterile delivery and umbilical cord-care practices for newborns of mothers with antitoxin levels insufficient to protect the newborn by transplacental transfer of maternal antibody. In 1997, NT accounted for an estimated 277,400 deaths worldwide (1) but is rare in the U.S. During 1995-1997, of 124 tetanus cases reported in the United States, only one occurred in a neonate (2,3). This report summarizes the investigation in March 1998 of an NT case by the Missoula City-County Health Department (MCCHD) and the Montana Department of Health and Human Services (MDHHS). The findings indicated that tetanus in a newborn of an unvaccinated mother occurred after application of nonsterile clay to the umbilical cord.

On March 21, 1998, a 9-day-old newborn, who had no previous medical problems, was taken to a hospital by her parents who reported a 10-hour history of an inability to nurse and difficulty in opening her jaw. Her parents also had noticed a foul-smelling discharge from her umbilical cord during the preceding 1-2 days. No other symptoms were noted by the parents. On admission, the newborn had trismus, increased general muscle tone, and hyperresponsiveness to external stimuli. The umbilical cord was covered with dried clay, which when retracted revealed a foul-smelling yellow-green discharge. Culture from the umbilical cord grew several anaerobic (*C. perfringens, C. sporogenes*) and aerobic (Staphylococcus, Streptococcus, and Bacillus sp.) bacterial species. NT was diagnosed based on the clinical characteristics.

The newborn was treated with tetanus immune globulin (500 units intramuscularly) and penicillin G (300,000 U/kg/day intravenously) for 10 days. On March 24, she required mechanical ventilation and remained ventilated for 12 days. She was discharged on April 10, with no apparent neurologic sequelae and was developing normally on follow-up at age 7 months.

The mother, a 32-year-old non-Hispanic white woman born in the United States, had never been vaccinated because of her family's philosophic beliefs. She had no complications during her pregnancy and was attended throughout her pregnancy by a licensed "direct-entry" midwife* from her community. The newborn was delivered in a local hospital by cesarean section. While in the hospital, she received standard umbilical cord care with isopropyl alcohol. The newborn was discharged at 3 days of age. For home umbilical cord care, the parents applied a "Health and Beauty Clay" powder provided by the midwife. This clay powder was applied to the umbilical cord up to three times daily with a clean cotton-tipped swab. The family lived in a rural area in a house adjacent to a horse pasture. Although the newborn and her mother stayed primarily indoors, the family's dog often ran between the house and the pasture.

The "Health and Beauty Clay" was a bentonite clay from Death Valley, California. According to the manufacturer, it had been sold for 21 years as a cosmetic product without reported adverse health outcomes. The manufacturing process of the clay did not include

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sterilization. The clay was shipped in 2-lb. containers, sold by weight in a local store, and dispensed to local midwives in smaller containers. The midwives would further aliquot the clay into 2-oz., presumably clean vials for distribution to their patients. The use of the clay for umbilical cord care was common among local direct-entry midwives because they believed it accelerated drying of the umbilical cord.

On April 9, MCCHD distributed a health-care advisory to more than 60 health-care providers in the area that emphasized the importance of tetanus toxoid vaccination, particularly for pregnant women, and cautioned against using nonsterile products for umbilical cord care. Following this case, use of clay for umbilical cord care was discontinued by midwives in the community. The mother of the case-patient has since been vaccinated with tetanus and diphtheria toxoids (Td), but as of October 1998 has not initiated vaccination for her infant because of concern about potential adverse effects.

Reported by: B Goode, Missoula City-County Health Dept, Missoula; K Caruso, Community Medical Center, Missoula; J Murphy, A Weber, J Burgett, Montana Dept of Health and Human Svcs. Child Vaccine-Preventable Disease Br, Epidemiology and Surveillance Div, National Immunization Program; and an EIS Officer, CDC.

Editorial Note: In the United States, NT is rare. Tetanus-associated deaths among children aged less than one year, an indicator for NT deaths (most tetanus deaths in this age group are caused by NT), declined from 64.0 per 100,000 population in 1900 to 4.5 by the 1940s. By 1967 in the United States, NT incidence was less than 0.01 per 1000 live-born infants.** This decline is associated with improvements in birth practices and increased levels of population immunity following the initiation of routine tetanus toxoid vaccination since the 1940s. Since 1972, 31 cases of NT have been reported to CDC. Of these cases, only five (16%) mothers had a history of ever having received tetanus toxoid, and only one was known to have received more than one dose.

Factors contributing to this case include the lack of maternal vaccination, the anaerobic conditions and *C. tetani* contamination of the umbilical cord resulting from the application of a nonsterile clay, and the potential exposure to *C. tetani* spores from the nearby horse pasture. The case described in this report is the first since 1984 in an infant of a mother born in the United States and with philosophic objections to vaccination. Since 1984, only two other cases of NT have been reported, both in infants of unvaccinated or inadequately vaccinated mothers born outside of the United States (3,4). The case in this report was the first NT case and one of only four tetanus cases reported from Montana since 1965.

Vaccination with tetanus toxoid during pregnancy is safe and effective in preventing NT (5). The ACIP recommends giving a booster dose of Td to previously vaccinated pregnant women who have not received a Td vaccination within the preceding 10 years, and unvaccinated or partially vaccinated pregnant women should complete the primary series of three doses of Td (6,7).

To prevent NT cases in the United States, health-care professionals should review and update the vaccination status of childbearing-aged women and particularly those who are pregnant. In addition, targeted education regarding the importance and safety of tetanus vaccination is needed among parents and direct-entry midwifery groups, and parents and health-care providers should avoid appiying nonsterile products to the umbilical cord of newborns, including products that create anaerobic conditions. Unless all women giving birth are vaccinated appropriately with tetanus toxoid, even hospital-born infants in the United States are at risk for developing NT, especially if unconventional practices of umbilical cord care are followed.

* Direct-entry midwives are a group distinct from certified nurse midwives; in Montana, they are licensed to attend women during uncomplicated pregnancies, labor, and postpartum periods.

**Data on NT incidence per 1000 live-born infants were not available until the 1960s.

References

1. Expanded Program on Immunization. WHO/EPI Information System.Geneva, Switzerland: World Health Organization, Sept., 1998; document no. WHO/EPI/GEN/98.10.
2. Bardenheier B, Prevots DR, Khetsuriani N, Wharton M. Tetanus surveillance – United States, 1995-1997. In: CDC surveillance summaries (July). MMWR 1998; 47(no.SS-2): 1-13.
3. Craig AS, Reed GW, Mohon RT, et al. Neonatal tetanus in the United States: a sentinel event in the foreign-born. Pediatr Infect Dis J 1997;16:955-9.
4. Kumar S, Maledi LM. A case of neonatal tetanus. South Med J 1991;84:396-8.
5. Galazka AM. Tetanus: the immunological basis for immunization. Geneva, Switzerland: World Health Organization, Expanded Program on Immunization, 1990; document no. WHO/EPI/GEN/93.13.
6. CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1994;43(no. RR-1):20-1.

Unprotected People #8
Varicella (chickenpox)

Story #8: Five varicella deaths that could have been prevented

The following five stories of varicella-related deaths appeared in the fall/winter 1998-99 issue of NEEDLE TIPS.

Editors' note: *We hear many stories from parents about physicians who are not encouraging varicella vaccination. We hope that the following reports of deaths secondary to varicella infection will motivate clinicians to recommend this vaccine for all their susceptible patients. There are approximately 100 deaths (half of these in children) and 10,000 hospitalizations each year in the U.S. from varicella. These deaths and hospitalizations are preventable. Please recommend varicella vaccine to your susceptible patients of ALL ages.*

Cases 1, 2, and 3 below were reprinted from the MMWR, *May 15, 1998, vol. 47, no. 18. Cases 4 and 5 were reprinted from* Michigan Immunization Update, *winter 98, vol. 5, no. 1.*

Case 1: Death of a 21-month-old

On February 28, 1997, a previously healthy, unvaccinated 21-month-old boy developed a typical varicella rash. He had no reported exposure to varicella. On March 1, he was taken to a local emergency department (ED) with a high fever and was started on oral acetaminophen and diphenhydramine. On March 3, his primary-care physician prescribed oral acyclovir. On March 4, his mother noted a new petechial-like rash. The next morning, his primary-care physician noted lethargy, a purpuric rash, and poor perfusion. He was transferred to a local ED. Fluid resuscitation and intravenous ceftriaxone were initiated, but the child continued to deteriorate rapidly, requiring intubation, mechanical ventilation, and inotropic support with dopamine. Blood cultures were negative for bacterial pathogens. Laboratory tests indicated disseminated intravascular coagulation and severe dehydration. Approximately 1.5 hours after arrival at the ED, he was transported to a tertiary-care center. Within 10 minutes of arrival, he suffered cardiac arrest and died. The death was attributed to varicella with hemorrhagic complications.

Case 2: Death of a 5-year-old

On December 21, 1997, a 5-year-old unvaccinated boy with a history of asthma was taken to a local ED with a fever of 104.5 F (40.3 C) and a typical varicella rash in multiple stages of healing. The child was treated with antipyretic and antipruritic medications and discharged.

That evening, the boy developed mild dyspnea and was treated at home for a presumed asthma attack with metered-dose inhalers and one dose of oral prednisone. He returned to the ED on December 22 with shortness of breath and a 4-hour history of abdominal and leg pain. On presentation to the ED, one of the patient's siblings had active varicella and another had recently recovered from varicella. Physical examination revealed numerous chickenpox lesions, one of which appeared infected. He was tachypneic, and his extremities were mottled consistent with peripheral septic emboli. Chest and abdominal radiographs revealed a right pleural effusion, pneumonia, and mild ileus. Thoracostomy produced pleural fluid containing gram-positive cocci, confirmed 8 hours later to be group A Streptococcus (GAS). A peripheral blood sample revealed gram-positive cocci. He was admitted to the hospital and treated with intravenous ceftriaxone, nafcillin, and acyclovir.

After admission, his breathing became labored and his extremities increasingly mottled. He rapidly developed hypotension, obtundation, and bradycardia. Despite efforts at cardiopulmonary resuscitation, the child died five hours after arriving at the ED. A postmortem examination attributed the death to GAS septicemia, pneumonia, and pleural effusion, complicating varicella infection.

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Case 3: Death of a 23-month-old
On December 14, 1996, a previously healthy, unvaccinated 23-month-old boy developed fever and a typical varicella rash. Approximately 1-2 weeks earlier, his unvaccinated 4-year-old sibling had contracted varicella. He was taken to his physician on December 17 because of persistent fever and cellulitis of the left foot, and he was hospitalized on December 19 for failure to improve on an unspecified outpatient antibiotic regimen. Because his condition deteriorated despite intravenous methicillin and ceftriaxone, he was transferred to a regional hospital on December 21. Sepsis, possible viral meningoencephalitis, and mild pleural effusion were diagnosed. A cerebrospinal fluid examination revealed lymphocytic pleocytosis, and blood and urine cultures grew penicillin-resistant Staphylococcus aureus. Antibiotics were changed to nafcillin and gentamycin, and intravenous acyclovir was added on December 23. On December 24, the child developed an aortic insufficiency murmur, and an echocardiogram revealed a 9x9 mm vegetation on the aortic valve, consistent with bacterial endocarditis. Serial echocardiograms displayed growth of the vegetation and development of a pericardial effusion. He was transferred to a cardiac surgery center on December 26. While awaiting surgery, he developed refractive heart failure secondary to staphylococcal endocarditis. He became incoherent, probably secondary to a major embolic neurologic event, and died on January 8, 1997.

Case 4: Death of a 35-month-old
In March 1997, a 35-month-old unvaccinated, previously-well male child presented to the local hospital emergency room with gastrointestinal bleeding and onset of shock. He was transferred to a larger hospital and admitted to its pediatric intensive care unit (PICU). On admission to the PICU the child had a seizure, followed by rapidly progressive multisystem failure. The child died 2.5 hours after admission. Autopsy determined that the cause of death was chickenpox and associated complications (causes of death noted in the hospital medical record were cardiac arrest secondary to profound hypotension, possible myocarditis, massive gastrointestinal hemorrhage, and varicella infection). This child had onset of varicella eight days prior to admission (an unvaccinated older sibling had onset of varicella three weeks prior) and was seen by a physician at that time.

Case 5: Death of a 42-year-old
In early 1997, a 42-year-old male presented to a hospital emergency room complaining of epigastric pain. A physical exam noted rash consistent with chickenpox. The patient stated all three of his children had been diagnosed with chickenpox in the previous three weeks. His previous medical history included severe chronic emphysema and chronic bronchitis, which was being managed with steroids under a physician's care. During the course of his hospitalization he developed varicella-related pneumonia and septic shock. The patient died three days after admission. According to a sibling, the patient was thought to have had chickenpox in childhood, but this could not be documented.

Unprotected People #9 Hepatitis B

"I was at no risk for ever having hepatitis B!"

The following letter is written by a 35-year-old woman who contracted hepatitis B virus (HBV) infection. This mother of three children, like at least one third of people who contract hepatitis B, had no known risk factors for HBV infection. We are printing her story because, as she says, "I hope my story helps convince people to get their children and themselves immunized. No one should have to go through what I went through."

The letter is as follows:

I am a married 35-year-old woman and a stay-at-home mother of three young daughters — ages 4, 7, and 10. I live in a small town on the New Hampshire seacoast. I've always been extremely healthy and active.

Last November 12th, I woke up and my joints were aching, especially my hips, knees, and ankles. I had just started an intense walking program, so my first thought was that I had "overdone" it. Each day, I felt progressively worse, and I finally made a doctor's appointment after suffering for about a week.

At the doctor's, I described my symptoms. He said that he thought my symptoms indicated "stress." He took some blood work to rule out rheumatoid arthritis and sent me home with a prescription for ibuprofen and the advice that I should consider going on antidepressants to eliminate the symptoms of "fibromyalgia." I felt devastated because I was sure something was wrong with me.

I continued to feel worse and worse every day. I began to feel more nauseated and exhausted than I can describe. Worse yet, my doctor had made me feel that it was "in my head" even though I told him that I did not feel depressed and was under very little stress!

After getting sicker and sicker, I finally made another appointment ten days later. The nurse practitioner took one look at me and noticed how jaundiced I looked. Also, my stools had become pasty looking and my urine quite dark. I thought I was just dehydrated from not eating for so long. She took blood work to determine if I had hepatitis and what type. I knew absolutely nothing about hepatitis at this point. I was just relieved that I had a diagnosis for what was wrong with me. She then described the ABC's of hepatitis.

I immediately assumed that I had hep A because I am in a category not considered "at risk" for the other types. Two days later, she called back with the results that I had hepatitis B. I felt as if my whole world had caved in.

My husband had to be tested. During the two days that we had to wait for the results, I felt that everything I believed about my marriage had to be a lie. When the results came back negative on my husband, he had to receive immunoglobulin because I had potentially infected him. I then had my two older daughters begin the vaccination series (my youngest had completed the series).

During the approximately six weeks that I felt so sick with this infection, I was so ill that I couldn't even take care of my kids. This whole experience was so incredibly demoralizing and humiliating. I believe that most people know nothing about hepatitis — I know I didn't. If I had known that I had even the minutest chance of becoming infected with hep B, I would have run to my doctor's to get immunized. I've never felt so ill.

I can't describe how it felt to have to wait for six months to finally have the blood work done to rule out the chance that I had become a chronic carrier. No amount of reassurance from the nurse practitioner could convince me that my chance was minimal that I would be chronic. After all, I was considered at no risk for ever having hep B at all!

In June, I received my blood work results and the knowledge that I am completely recovered from

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hep B. I thank God for that. But I'm still dealing with the after effects of what I went through. My husband and I went to a counselor to deal with the stress that this whole situation placed on our marriage and how angry my husband felt because I hadn't trusted him. I feel sick at the thought that during the time of my acute infection, I could have infected my children or my husband.

This virus has such a stigma attached to it! I stopped telling anyone that I had been infected with hepatitis B.

If my story makes even one person reconsider and have their child or themselves immunized, then it will make me feel better.

Over one third of all people who are infected each year with hepatitis B are in the "no risk" category for infection. I'm one of them, and even a year later, I'm trying to put my horrible experience behind me. No one should ever have to suffer through being infected with this virus — it is totally preventable with a series of three shots. "No risk" living is a meaningless term. If you go to a dentist, borrow a toothbrush, get your ears pierced, get a manicure, or engage in countless other mundane activities, you could become infected.

I hope my story helps convince people to get their children and themselves immunized. No one should have to go through what I went through.

Unprotected People #10 Pertussis

Pertussis claims the lives of two infants

The deaths of two infants from pertussis were reported in the "San Francisco Chronicle" on July 2, 1998. The article reports that the pertussis victims were a 2-month-old boy who died on April 4, 1998, and a 2-month-old girl who died one month later.

The newspaper article entitled, "Bay Area Rash of Whooping Cough Cases: Unvaccinated children help spread the disease," leads off by saying, "Whooping cough, the childhood scourge that just won't go away, has increased in worrisome numbers in the San Francisco Bay Area."

At the time of the article's publication (July 2, 1998) there were, according to state epidemiologist Cynthia O'Malley, PhD, 198 cases of whooping cough in California, most of them concentrated in the Bay Area.

The article ends with this powerful statement from Santa Cruz County public health chief Betsy McCarty, RN, MS: "People who think they are doing the right thing are not getting their children vaccinated. They couldn't be more mistaken. This is as important as putting your kid in the car seat, seeing they have enough to eat, and locking up the poisons."

To read the entire article from the San Francisco Chronicle's website, go to: **www.sfgate.com/cgi-bin/article.cgi?file=/c/a/1998/07/02/MN20754.DTL**

Unprotected People #11 Measles

Measles outbreak associated with an unvaccinated population

Although the information in the article entitled, "An Outbreak of Measles Associated with an Unvaccinated Population," is two years old, it highlights the timeless fact that members of unvaccinated communities, such as the religious community in which this outbreak occurred, continue to be victims of vaccine-preventable diseases.

This Minnesota story on a measles outbreak appeared in the February/March 1996 issue of the Minnesota Department of Health's Disease Control Newsletter. *Shortly after the outbreak, most of the unvaccinated children and young adults in this religious community consequently chose to receive two doses of MMR vaccine.*

The "Outbreak Summary" section of the article is reprinted here in its entirety:

"In early 1996, two measles cases were reported to the Minnesota Department of Health (MDH). After a major resurgence of measles both nationally and in Minnesota during 1988-1991, Minnesota had been measles-free since July 1992. During the course of the 1996 case investigations, additional cases that had gone undetected by the medical community were identified with rash onsets dating back to December 6, 1995. During this outbreak, 14 laboratory-confirmed cases and 13 probable cases were reported to MDH. Of the 27 cases, two were Wisconsin residents. The last known rash onset was January 29, 1996. The majority of cases (17; 63%) occurred in persons 20-29 years of age, three were over 30 years of age, six were 10-19 years of age, and one case was an 18-month-old child. All but one of the cases were associated with a religious community whose members live in the St. Paul area and operate a community school. It is not clear how the virus entered this community. Of the 25 Minnesota residents, 22 had not received vaccination against measles. One (an 18-month-old infant) had a documented history of receiving measles-mumps-rubella (MMR) vaccine; one (a 25-year-old) had a probable vaccination history; and for one (a 35-year-old), the vaccination history remains unknown.

"Many of the children and young adults (70%) in the religious community had not been immunized before onset of this outbreak; most have since received two doses of MMR. Two of the laboratory-confirmed cases occurred outside the religious community in a 35-year-old receptionist at a medical clinic where one of the cases had been treated, and in a 44-year-old woman residing in Hennepin County. This second case had no apparent association or exposure to the religious community."

Unprotected People #12
Varicella (chickenpox)

Child dies of varicella encephalitis

IAC EXPRESS received the following case report via e-mail from a Canadian physician describing the death of a 3½-year-old boy from varicella encephalitis. At the time of his death, a vaccine against varicella was not yet available in Canada.

The physician's e-mail is reprinted as follows:

A 3½-year-old boy developed chickenpox April 5, 1998. His 7-year-old brother had it at the same time. The younger child had a mild case with relatively few lesions.

Four days before admission the 3½-year old became sleepy and developed a headache. Two days later he developed increasing lethargy, vomiting, drowsiness and disorientation. He was taken to our community hospital on April 11. He had a lowered level of consciousness, responding slightly to pain. The next morning he had shaking movements, probably due to acute herniation of the brain due to swelling. He became comatose, was transferred to a major medical center, and pronounced brain dead on April 13. Life support was discontinued, and he died. The autopsy confirms a diagnosis of varicella encephalitis.

At the time of his illness, varicella vaccine was not available in British Columbia.

A footnote: the mother of this child was devastated by his death. She has refused to set foot in our hospital again because of the unbearable memories, and plans to deliver the child she is now carrying in another city.

Dr. Kirsten Emmott
Comox, British Columbia
Canada

Unprotected People #13
Hepatitis A

Virus saps grad in her peak weeks

The following article appeared in the daily newspaper. The Spokesman-Review, *on June 7, 1998. It is reproduced with permission from* The Spokesman-Review, *(Spokane, WA) Copyright 1998. By Cynthia Taggart, staff writer.*

Just thinking about how she got sick nauseates Allison Jester all over again.

"To know how I got it is just disgusting," the Lake City High senior says, cringing.

She's thin, hardly a presence inside jeans not designed to be baggy. She tires so quickly that her days are a series of naps. That's what hepatitis A does. It's cleaned Allison out and broken her down, scared everyone around her and changed her life. And she did nothing to cause it.

Sometime in March, food or water she ingested was contaminated with infected feces.

It could have happened in Seattle or Bellingham, where she was checking out colleges. It could have happened after golf team practices at any burger joint that offers immediate relief to gnawing stomachs.

It could have happened at a grocery store or even a friend's house. Allison will never know. By the time she was diagnosed three weeks ago, the virus had incubated inside her for two months. Tracking its origin was impossible.

When the virus reached maturity, it devoured Allison's liver like a starving lion.

As her senior year began to culminate in stage productions, golf championships, debate tournaments, academic projects and pre-graduation bonding parties, Allison fell ill.

It began with nausea, fever and aches, which Allison interpreted as the flu. She had a major role in the school production of "Noises Off" and willed herself to make it through rehearsals.

"I didn't want to give that part up," she says.

She forced herself through school, although she fell asleep in the auditorium during a special activity. She was so sick that she had to quit a high school golf tournament after the fourth hole.

By the weekend, her stomach refused to hold anything. Her mother, Patti, began to suspect hepatitis after she noticed Allison's urine was unnaturally dark.

Doctors didn't agree with Patti and gave Allison an anti-nausea shot. But Allison continued to vomit the rest of the day until dehydration became a worry.

"I felt like I was going to die," she says. "I had never felt so sick."

Her parents took her to Kootenai Medical Center's emergency room that night. Patti sensed her diagnosis was right when blood test results sent nurses scurrying to warn everyone about Allison's infected body fluids. Hepatitis A zeroes in on the liver, weakening it so much that it can't process medications.

There's no treatment. The virus has to run its course, which varies from weeks to months. Most people fully recover.

Ingesting fecal-contaminated food or water is the only way to catch the A virus, unlike the more dangerous but slightly less common hepatitis B virus. Hepatitis B most often is transmitted through sexual contact.

Food servers who don't wash their hands after using the bathroom spread hepatitis A. Unwashed shellfish from contaminated water can carry the virus. Drinking water contaminated with sewage is another way to catch it.

Hepatitis A is so common that 152,000 cases are reported in this country each year. Forty cases already have been reported to Panhandle Health District

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through May this year, which equals the total number of cases in North Idaho in 1997.

The number of hepatitis A victims is rising so fast that public health agencies have launched a national campaign promoting good hygiene–the best prevention.

Allison's parents, younger sister and uneasy friends got immune globulin shots to boost their immune systems. Some friends panicked and stayed away from Allison. She tried to explain that the virus isn't spread through casual contact.

Doctors prescribed rest. Allison quit the play and her two jobs. School moved to her home. More than anything else, she wanted to compete in a national debate tournament in St. Louis, Mo., on June 14. She was one of four students from Spokane and North Idaho to qualify.

"I was willing to give up everything to do that," she says.

Changing her senior project to accommodate her illness broke Allison's heart. She'd planned to photograph herself on a difficult rock climb in Post Falls. But she was in the hospital the weekend she scheduled the climb.

"I'll do that climb this summer for sure," she says.

Her appetite and energy are growing. She still wilts quickly beyond her house, but mustered the strength to march in Saturday's graduation ceremony.

"We've lamented that she's not been able to enjoy the last few weeks of her senior year," says Patti, who, like Allison, doesn't waste energy stewing over the unfairness of it all. "This is a special time of her life."

Allison will go to the national debate tournament, perhaps a touch more philosophical than she was before her illness.

"The hardest part was realizing I couldn't do everything I wanted," she says. "But it's made me step back a little. The little things don't matter. Things come your way you don't expect. You just deal with it."

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Unprotected People #14
Rabies

Man without history of a bat bite dies of rabies

An article entitled "Human Rabies — Virginia, 1998" was published in the February 12, 1999, issue of the MMWR. The article is a case report of a 29-year-old incarcerated man who did not have a definitive history of an animal bite was eventually diagnosed with rabies and subsequently died.

The "Editorial Note" states: "Since 1990, 27 human rabies cases have occurred in the United States (an average of three cases per year). Although 20 (74%) have been attributed to bat-associated variants of the rabies virus, a definitive history of a bat bite was established for only one of these cases."

The "Editorial Note" further states that "medical personnel should consider rabies as a diagnosis in any case presenting with the acute onset and rapid progression of compatible neurologic signs, regardless of whether the patient reports a history of an animal bite. Although early diagnosis cannot save the patient, it may help minimize the number of potential exposures and the need for postexposure prophylaxis.

The entire article is reprinted below:

Human Rabies — Virginia, 1998

On December 31, 1998, a 29-year-old man in Richmond, Virginia, died from rabies encephalitis caused by a rabies virus variant associated with insectivorous bats. This report summarizes the clinical and epidemiologic investigations by the Virginia Department of Health and CDC.

On December 14, 1998, an inmate at the Nottoway Correctional Center in Nottoway County, Virginia, developed malaise and back pain while working on a roadside clean-up crew. He sought medical care at the prison on December 15, complaining of muscle pains, vomiting, and abdominal cramps, and was treated with acetaminophen. His clinical signs progressed to include persistent right wrist pain, muscle tremors in his right arm, and difficulty walking. On December 18, the patient was sent to a Richmond emergency department, where he had a temperature of 103°F (39.4°C). He initially was alert and oriented but had visual hallucinations. During the next 12 hours, he became increasingly agitated and less oriented. Physical examination revealed anisocoria, increased tone in the right forearm, and hyperesthesia over the entire right side of the body. Intoxication with anticholinergic agents such as pesticides or jimson weed was considered; however, toxicology studies were negative.

The patient's condition worsened, with hypersalivation, priapism, and wide fluctuations in body temperature and blood pressure. He was intubated and heavily sedated on December 20. Laboratory findings included a white blood cell count of 20,800/uL (normal: 3700-9400/uL), myoglobinuria, and a compensated metabolic anion gap acidosis with renal insufficiency. Peak creatine phosphokinase levels were 130,900 U/L (normal: 50-450 U/L), indicating rhabdomyolysis. Analysis of cerebrospinal fluid (CSF) showed a white blood cell count of 57/uL (normal: 0-5/uL), protein levels of 128 mg/dL (normal: 12-60 mg/dL), and glucose levels of 46 mg/dL (normal: at least two thirds of a concurrent serum glucose value, which was approximately 136 mg/dL). A computed tomography scan of the patient's head revealed no abnormal findings.

A diagnosis of rabies was first considered by the patient's physician on December 20. Samples sent to CDC for testing on December 21 included a nuchal skin biopsy, which tested positive for rabies virus by direct fluorescent antibody test on December 22, and saliva and skin, which were positive by reverse-transcriptase polymerase chain reaction (RT-PCR) assay on December 23. The sequence of the amplified RT-PCR product showed greater than 99.7% DNA homology to a rabies virus variant associated with eastern pipistrelle bats (Pipistrellus subflavus) and silver-haired bats (Lasionycteris noctivagans). Serum and CSF samples obtained December 21 contained rabies virus neutralizing antibody titers of 1:50 and 1:36, respectively, by rapid fluorescent focus inhibition test (RFFIT). A serum sample obtained December 28 showed a ra-

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bies virus neutralizing antibody titer of 1:1200 by RFFIT. After the removal of all sedatives, the patient showed no purposeful movement and loss of brainstem reflexes. He died December 31.

Postexposure prophylaxis (PEP) was administered to 48 persons who possibly had contact with the patient's saliva between December 4 (10 days preceding the first clinical signs of illness) and death. Of the 48, 29 were prison inmates who reported possible contact with the patient's saliva, either while caring for him during his illness or through shared cigarettes or drinking and eating utensils. Three family members who visited the patient at the prison on December 6, 15 health-care providers, and the pathologist who conducted the autopsy also received PEP.

Family members, friends, and prison staff reported the patient had not indicated any contact with or bite from an animal in recent months, and prison medical records did not document evidence of a bite or scratch. The patient lived at a work center that housed up to 160 inmates in two separate dormitories. He had worked around the prison on a farm repairing fence lines and feeding cattle, in a paper recycling facility, and along roadsides cleaning up trash and debris. No evidence of bats was found within the prison or on prison grounds, although inmates reported occasionally seeing bats flying near the outdoor lights in the summer. Several stray cats were reported to occasionally approach inmates at the facility; however, the patient was not known to have handled them.

The patient had been incarcerated at Nottoway for approximately 6 weeks after transfer from another correctional unit. At the other correctional facility, the patient worked inside the prison and on a road crew cutting brush and picking up trash along highways. No evidence of bats was found in the prison, and inmates reported that they had never seen bats inside the facility. Prison staff and inmates reported that they did not recall the patient ever being bitten by an animal while working, and that he usually did not handle small animals found by the road crews.

Editorial Note: This report describes the only case of human rabies diagnosed in the United States during 1998 and the first case in Virginia since 1953. A definitive history of an animal bite could not be established for this patient, and the most likely explanation is an unrecognized bat bite occurring either at the farm or recycling facility or while the patient was working on a road crew. Because the incubation period for rabies varies from several weeks to several months, he may have contracted rabies before his transfer to Nottoway.

Since 1990, 27 human rabies cases have occurred in the United States (an average of three cases per year). Although 20 (74%) have been attributed to bat-associated variants of the rabies virus, a definitive history of a bat bite was established for only one of these cases. Of the 20 attributed to bat-associated variants, 15 (75%) have been caused by the same eastern pipistrelle/silver-haired bat variant responsible for the death described in this report. Although bat-associated rabies virus variants theoretically can be secondarily transmitted from terrestrial mammals, an unrecognized bat bite is the most likely explanation for these cases.

The reasons for the preponderance of human rabies cases associated with the eastern pipistrelle/silver-haired bat virus variant remain speculative. Epidemiologic findings suggest that it can be transmitted following minor, undetected exposures. Insectivorous bats, such as those implicated in the human rabies deaths in the United States, have small teeth that may not cause an obvious wound in human skin. Accordingly, it is important to treat persons for rabies exposure when the possibility of a bat bite cannot be reasonably excluded. In all cases where bat-human contact has occurred, the bat should be collected and tested for rabies if possible. If the bat is not available for rabies testing, the need for PEP should be assessed by public health officials familiar with recent recommendations.

The total of 48 persons who received PEP after contact with the patient described in this report is similar to the mean of 49.8 persons who received PEP after exposures to human rabies cases during 1990-1997. Consideration of rabies before the patient's death may have minimized the number of hospital staff that received PEP in this case.

Although this patient did not exhibit classic hydrophobia, other typical clinical signs, such as hypersalivation, hallucinations, priapism, paresthesias, muscle spasms, and autonomic instability occurred. The use of sedatives may have masked hydrophobia in this patient. Medical personnel should consider rabies as a diagnosis in any case presenting with the acute onset and rapid progression of compatible neurologic signs, regardless of whether the patient reports a history of an animal bite. Although early diagnosis cannot save the patient, it may help minimize the number of potential exposures and the need for PEP.

Unprotected People #15 Hepatitis B

Mother's death from hepatitis B moves daughter to action

In May 1998, IAC EXPRESS received an e-mail from a first-year Asian American medical student in which she shares the details of her mother's sudden death from hepatitis B. The tragedy has motivated this student to educate herself and her family and other Asian Americans about the risks of this vaccine-preventable disease.

The student's e-mail, printed with her permission, is as follows:

I recently suffered an immense loss. In the middle of January of this year, my mother experienced a sudden onset of peripheral edema and ascites. She tested negative for hepatitis B, but the doctors said that she had either liver cancer or severe cirrhosis. In the middle of February, a liver biopsy definitively diagnosed my mother as having hepatocellular carcinoma. This time, her hepatitis B serology came back positive, but her virus levels were low and nonreplicative. By the beginning of April, to the dismay of my family and all those who knew her, my mother fell into hepatorenal syndrome. She died while I was holding her days afterward, only two months after the diagnosis and one month after her intended early retirement.

Being a medical student, I could not help but feel helpless as I watched my mother slip away. What disturbed me even more was how unknowledgeable my cousins and I, all of whom are most likely infected with the same virus, were on the topic. I am writing to you today because I would like to stop feeling helpless. I would like to help educate my cousins, and other Asian Americans like us, of the risk that we face. Therefore, I would greatly appreciate it if you could inform me of the services that you provide, of the resources that you offer, and of the projects you plan. Please let me know how I can best join your effort, and how I can become actively involved with your organization. Thank you.

A First-Year Medical Student

Editorial Note: The Coalition sent this student a packet of our hepatitis B educational materials and referred her to other national organizations that are involved in hepatitis B activities in Asian Pacific Islander American communities. The Coalition's hepatitis B educational materials for providers and patients (some available in 16 languages) can be downloaded from our website at www.immunize.org.

Unprotected People #16 Tetanus

Tetanus is far more than a "rusty nail" disease

When I lost my mother to the disease of tetanus, I took it personally. I spent a year grieving about what I should have done differently so that she wouldn't have died. My thoughts were futile, but I had to reconcile myself somehow to her death.

In August 1996, my mother developed an infection in her big toe. The location was at the base of her toenail in the corner. This area was probably the site where tetanus got into her body. I learned later that a site could be as tiny as a thorn prick in the skin. Nevertheless, my mother often wore open-toed shoes, and the infected area must have become contaminated as she worked in her garden.

Tetanus thrives in compost and manure. My mother made compost from fruit and vegetable peelings, egg shells, etc. My husband and I raised farm animals and shared the resulting manure with Mom a couple of times. Hence, I feel some guilt because the manure that was to enrich her garden may have harmed her. Furthermore, she was the kind of person who used sterilized soil for her tomato seeds so they would have a disease-free start.

My mother told me that she was worried about the infected toe because it was deep purple. She said she washed it well after being in the garden, but wondered if she should get a shot. I explained that just the year before, I had cut my finger on a rusty piece of corrugated metal lodged at the end of a railroad tie. Ten years had passed since I had a tetanus shot, and I should have gone for a booster. The doctor was a half hour away, so I didn't go. Instead I looked up "tetanus" in an old 1950 medical book. The information indicated that once tetanus was contracted, symptoms would appear in 2 or 3 days to 2 or 3 weeks. I really worried during this period, was very vigilant for symptoms, but figured I probably wouldn't get tetanus. I knew I had taken a risk, and I tried to tell my mother it wasn't worth the worry I had gone through. As it turned out, she got busy and didn't go either.

Mom's infected toe healed perfectly, and she forgot about tetanus. When she began to feel poorly, she noticed a feeling in her throat. She described it as being like a sore throat, but different. She went to her neighborhood doctor whom she saw regularly and often. Her doctor did five tests. The results would be back in two days. Meanwhile, Mom went back home. That night she could barely swallow her blood pressure medicine. In the morning she called the doctor who then pushed for the test results. They were negative. The doctor questioned my mother further and told her to get an emergency appointment with a neurologist. The neurologist diagnosed the disease as tetanus and hospitalized her.

The next 10 days were a downward spiral. Mom developed double vision as the damaged nerves began to affect her voluntary muscles. At times her chest heaved in spasmodic waves as the muscles locked. The pain was worse than anything she ever experienced, even childbirth. When the pain medicines weren't adequate, the doctor paralyzed her to release her from the pain. Her kidneys failed. She suffered a heart attack and died.

The neighborhood doctor came to my mother's funeral. At communion time she stopped at our pew, held my father's hands in hers, and apologized. She said she never put 2 and 2 together until now. She never connected my mother's many gifts of garden vegetables with the potential for tetanus.

In looking back, I shudder to think of the years I went unprotected. No doctor offered me a booster for a period of 40 years. If people understood the horrific nature of the disease, many of them would ask a doctor to update them, as my family did within a month of my mother's death.

Signed,
A Loving Daughter

Item #R2057-Q (1/99)

Unprotected People #17 Pneumococcal

Two deaths in a nursing home ignite pneumococcal vaccine campaign

Editorial note: *Pneumococcal disease causes approximately 40,000 deaths, 500,000 cases of pneumonia, and 50,000 cases of bacteremia each year in the United States. A 1997 CDC survey indicated that only 45% of adults 65 years of age and older have received their recommended dose of pneumococcal vaccine (MMWR, October 2, 1998, vol. 47, no.38).*

The following article originally appeared in the Texas Department of Health's newsletter, "Accent on Health," *on March 10, 1997, and was reprinted with permission in the spring/summer 1999 issue of* NEEDLE TIPS.

According to Devora Goodnight, it wasn't just luck that only two people died in a recent outbreak of deadly pneumococcal disease where she works at the Houston County Nursing Home in Crockett. What undoubtedly saved lives when the outbreak began was a combination of the nursing home staff's recognizing the seriousness of the outbreak and their getting an immediate response from experts at the Texas Department of Health (TDH). But perhaps the most decisive single factor was the quick immunization of all potential patients with a vaccine which often is overlooked by physicians and patients alike.

After two patients died of streptococcal pneumonia infections and one other was stricken, Goodnight said, "We knew we had a situation that might cost many of our residents' lives if it got further out of hand. We had never had anything like this happen before and didn't even know what to expect if we called TDH for help. But we knew we would most likely lose more of our 'family' if we didn't."

At TDH's Infectious Disease Control and Surveillance Division, epidemiologist Beverly Ray said that Goodnight and the home's nursing director Debbie Hargrove showed "the highest standard of concern for their residents."

Ray explained that although outbreaks of pneumococcal disease caused by the *Streptococcus pneumoniae* bacteria are rare, the bacteria spread rapidly among unimmunized people whose health may already be compromised. People in good health with normal immune systems are not as likely to develop infections, but ill people, such as elderly nursing home residents with existing problems, are especially at risk of developing pneumonia after exposure to the bacteria.

According to Ray, *Streptococcus pneumoniae* causes about half a million individual cases of pneumonia, some 3,000 cases of meningitis and about seven million ear infections in the United States every year. The most susceptible people are the elderly and ill, such as those at the Crockett nursing home, infants and toddlers, people with chronic health conditions such as diabetes or emphysema, and people without spleens or with weakened immune systems. Outbreaks of the disease occur most commonly during the winter months, among nursing home patients, jail or prison inmates, and other groups who share close living quarters and often breathe the same air.

The U.S. Centers for Disease Control and Prevention recommends that all people 65 years of age or older receive one dose of pneumococcal vaccine. Those at greatest risk for serious complications from pneumococcal disease need to receive a second dose five years later. The vaccine is effective against at least 23 different strains of streptococcal bacteria and is fast acting. However, Ray said that in a recent survey of Texans 65 and older, only 42 percent said they had been vaccinated against bacterial pneumonia.

Ray said, "This vaccine is one of the most effective, fastest-acting vaccines we have for averting outbreaks among such groups as nursing home resi-

(continued on next page)

dents, yet it is unbelievably underused. We hope that physicians will offer the vaccine more often to their own patients who may be at risk, and that more patients or family members will remember to ask for the vaccine if they have not already had it."

After TDH received the Crockett nursing home's call for help on Jan. 23, Ray and a team of other epidemiology staff drove directly to Crockett to begin taking blood samples from about 90 nursing home residents and staff and obtaining permission to begin vaccinating as many of the residents as possible. Only 14 of 88 residents had previously been immunized. Vaccinations began the following morning, Jan. 24.

According to Hargrove, she and others on the nursing home staff "were amazed at how quickly TDH brought the outbreak under control."

Although two patients out of the first three diagnosed with pneumococcal disease died, the remaining victim of the outbreak survived and has recovered. The vaccines which the other residents received have begun protecting the home's residents from further infections. For a few days after the residents were vaccinated, some of their visiting friends and family members were advised to take antibiotics as an additional precaution against more pneumococcal infections, but no other cases occurred.

Goodnight said that the loss of the two residents who died from pneumococcal disease has been hard on the other residents and the staff alike. "They were part of our family. We always try to operate as one big family here, and a death is personal to all of us. We are just very, very grateful that help was there when we needed it to prevent even more tragedies," she said.

Unprotected People #18 Hepatitis B

Lack of prenatal screening for hepatitis B causes multiple tragedies for one family

The following case report of a mother who had a previous history of hepatitis B, but received no prenatal screening, serves to illustrate the importance of following the recommendation of the Advisory Committee on Immunization Practices to screen every pregnant woman during each pregnancy. Not only did this woman's baby die of fulminant hepatitis B infection, but when hepatitis B screening was done for the surviving family members, it was found that mother, father, and the other two young children were all positive for HBV.

This case report is excerpted from an Immunization Action Coalition (IAC) educational piece entitled "Universal prenatal screening for hepatitis B," *a piece that reviews neonatal transmission and screening rationale for health professionals. It was written for IAC by Deborah K. Freese, MD, pediatric gastroenterologist and member of the transplant unit at Mayo Clinic. She is also a member of the IAC Advisory Board. Written in 1993, this educational piece continues to be distributed because there are still health professionals who do not screen every pregnant woman for HBsAg during each pregnancy.*

The excerpt of Dr. Freese's article follows:

An infant with fulminant hepatitis B

The medical and economic costs of failing to screen for HBV can be illustrated on a more personal level by the case of a single infant recently cared for in the Twin Cities. This patient was the child of a middle class couple from a farming community in a neighboring state.

During her initial prenatal visit, the mother gave a history of having had hepatitis of some sort 20 years previously. She was told at that time that she had recovered from the disease and would subsequently be immune to further hepatitis infections. Despite the fact that a previous history of hepatitis would place her in the "high-risk" category, no prenatal HBV screening was done. Pregnancy and delivery were uncomplicated, and the baby did well for the first two months of life.

At that time, the parents began noting feeding difficulties, irritability, and jaundice. Evaluation revealed severe coagulopathy, markedly elevated liver tests, and hypoglycemia. The infant was eventually referred for liver transplantation with the diagnosis of fulminant hepatitis B. The infant was admitted to the intensive care unit, received very aggressive medical management, and an urgent search for donor was initiated. No suitable donor could be located, the child continued to deteriorate and died after two weeks from hepatic encephalopathy and herniation.

Hepatitis B screening was then done for the surviving family members. It was found that mother, father, and the other two young children were all positive for HBV. Mother and one child had significantly elevated liver tests and are undergoing further evaluation. It seems clear that had HBV screening been carried out, none of the children would have been infected and the death of the youngest could have been prevented.

The economic impact on the health care system from this one family alone is significant. It includes the costs of hospitalizations at two hospitals of the infant who died (approximately $100,000), the immediate costs of evaluation and possibly therapy for the surviving child with evidence of chronic hepatitis, and the long-term costs of monitoring and observation in both chronically infected children. Had successful liver transplantation been possible for the infant, the costs of that procedure and lifetime immunosuppression would have further increased the costs.

If you would like to read the complete article by Dr. Freese in camera-ready format, go to: www.immunize.org/catg.d/p2120uni.pdf

Item #R2057-S (1/99)

Unprotected People #19
Varicella (chickenpox)

How many varicella deaths will it take?

In 1998, six people in Florida died of varicella. The case reports of their deaths were published in the May 14, 1999, issue of the MMWR *as part of an article entitled "Varicella-Related Deaths Florida, 1998."*

The May 14th issue of IAC EXPRESS (#77) included these case reports. We are reprinting them here as an UNPROTECTED PEOPLE story because we believe these tragic deaths will convince those health professionals who still believe varicella is a harmless disease to begin vaccinating their susceptible patients.

Case 1: Death of a 6-year-old
On February 19, a healthy, unvaccinated 6-year-old boy developed a varicella rash, abdominal pain, malaise, and loss of appetite following exposure to a classmate with varicella. The child had asthma and intermittently had been on inhaled steroid therapy but had not received steroids within the previous month. On February 22, he was hospitalized with hemorrhagic skin lesions, tachycardia, tachypnea, and a platelet count of 89,000 (normal range: 150,000-350,000). Several hours after admission he developed pulmonary edema and respiratory insufficiency and required mechanical ventilation. He died on February 23. Tissue samples of multiple organs had a positive polymerase chain reaction for varicella zoster virus (VZV).

Case 2: Death of a 58-year-old
On March 27, a healthy, unvaccinated 58-year-old woman developed a varicella rash. She was born in Cuba and had moved to the United States in 1995. She did not have a history of or known exposure to varicella. On April 3, she was hospitalized with a 5-day history of increasing shortness of breath and productive cough and was diagnosed with varicella pneumonitis. She was treated with intravenous acyclovir and ceftriaxone, but developed adult respiratory distress syndrome (ARDS), disseminated intravascular coagulopathy, renal failure, and coma. She died on April 20.

Case 3: Death of a 29-year-old
On April 27, a healthy, unvaccinated 29-year-old man developed a varicella rash. In early April, his children had contracted varicella. On April 29, he sought care at a local emergency department for chest pain and respiratory distress. Chest radiographs showed bilateral pulmonary interstitial infiltrates. On April 30, he began coughing up blood, was intubated because of increasing respiratory insufficiency, and was treated with intravenous acyclovir and antibiotics. He developed sepsis, ARDS, and multiorgan failure, and died May 12.

Case 4: Death of a 21-year-old
On May 5, a 21-year-old unvaccinated female employee at a family child care center developed a varicella rash after exposure to a child with varicella. The employee had a history of asthma and was treated with 5 mg prednisolone per day. She was hospitalized on May 7 with varicella pneumonitis and received intravenous acyclovir on May 8, but she died the same day.

Case 5: Death of an 8-year-old
On July 11, an 8-year-old unvaccinated boy developed a maculopapular rash diagnosed clinically as varicella and confirmed by direct flourescent antibody test on July 23. He had acute lymphocytic leukemia (ALL) and had been on immunosuppressive therapy since receiving a bone marrow transplant on May 15. He had not had varicella and had no known varicella exposure. He was treated with varicella zoster immunoglobulin on July 16 and acyclovir on July 23. He died on July 25 after recurrence of leukemia with a graft-versus-host reaction complicated by disseminated varicella, cellulitis, ileus, and hypertension.

Case 6: Death of a 45-year-old
On October 3, an unvaccinated 45-year-old man with diabetes mellitus, asthma, and cirrhosis of the liver developed a varicella rash. He was born in Cuba

and had resided in the United States for 35 years. He had no history of varicella and no known exposure. He was not receiving steroids or immunosuppressive drugs. He was admitted to the hospital with varicella on October 5 and on October 6, treatment was initiated with oral acyclovir. He died on October 8; pathologic evidence from the postmortem examination revealed VZV in all major organs.

Five of the six case-patients who died because of varicella were eligible for vaccination. The sixth, a child with active ALL (case 5), was ineligible for vaccination. Under a special protocol, children with ALL who meet inclusion criteria may be vaccinated. Although one case-patient was receiving systemic steroids when she contracted varicella, the dose was not large enough to be a contraindication; varicella vaccine can be administered to adults receiving less than 20 mg prednisone per day or its equivalent, and to children receiving less than 2 mg per kg body weight per day or a total of less than 20 mg per day.

Two case-patients (2 and 6) were aged greater than 30 years and were born and raised in Cuba. The epidemiology of varicella in tropical regions differs from that in temperate regions. VZV is heat labile and may not survive and transmit well in warm climates. In the tropics, age distribution of cases and VZV seroprevalence data have indicated a higher proportion of cases occurring among adults. Clinicians should be aware of the greater susceptibility of adults to varicella when evaluating persons from tropical countries.

Shots by age two if they're important to you.

Every Child By Two

The Carter/Bumpers Campaign For Early Immunization

August 2, 1999

Honorable Dan Burton
Chairman, Committee on
Government Reform
2157 Rayburn Building
Washington, D.C., 20515

Dear Congressman Burton:

I am writing to voice my concerns about Tuesday's government reform hearing on vaccine safety. Rosalynn Carter and I, along with all our colleagues at ECBT, believe that the hearing, based on the witness list, is tilted against the National Vaccine Programs. The premise of a fair hearing is a hallmark of America, and a fair hearing requires that all sides of an issue be presented.

Although Surgeon General Satcher is scheduled to testify, we are surprised and upset that requests to testify from other nationally recognized experts and advocacy groups had been denied. Anti-immunization groups have been disseminating misleading information about vaccinations for years, while the incidence of preventable childhood diseases has dropped dramatically. Without recognized experts to dispel the myths and misleading information, public health and safety will be undermined. While the anti-vaccine groups have a constitutional right to testify, they have a moral obligation to present factual information that protects our citizens' health.

The benefits of routine immunization have been repeatedly documented. One need only remember the scourge of polio in the 1950s. We have eradicated small pox, and are steps away from the worldwide eradication of polio. Other once-common preventable diseases such as measles, pertussis and rubella are virtually unknown. In fact, immunizations have prevented more diseases and saved more lives than any other medical treatment known to man. Vaccinations are the best defense we have against preventable diseases, and public policy is essential to ensuring that everyone is immunized. Because of laws mandating vaccinations, young mothers and fathers of today have never been exposed to the ravages of preventable diseases, and therefore are susceptible to becoming complacent.

Again, I urge you to revisit your decision and allow the other side of the story to be told. I know we are all working toward the same goal – to protect public health, particularly our children's. Hopefully in the future we can work toward our mutual goal together.

Sincerely,

Betty Bumpers

Betty Bumpers
Co Founder, ECBT

Cc: Congressman Henry Waxman
Ranking Minority Member of the Committee on Government Reform

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02 August 1999

The Honorable Henry A. Waxman
Ranking Minority Member
House of Representatives, Committee on Government Reform
2204 Rayburn House Office Building
Washington, DC 20515-0529

Dear Congressman Waxman:

Pursuant to your committee hearing on Risk vs. Benefits of Vaccines, the National Foundation for Infectious Diseases (NFID) and the National Coalition for Adult Immunization (NCAI) wish to go on record as supporting the development of vaccines and the responsible use of immunizations to protect against vaccine-preventable diseases.

The National Foundation for Infectious Diseases (NFID) and the National Coalition for Adult Immunization (NCAI) recognize the importance of utilizing immunizations to protect Americans of all ages against vaccine-preventable diseases. The viruses and bacteria that cause these diseases continue to exist and cause significant rates of illness and death. The incidence of infection with these agents has drastically reduced, and this reduction is attributable to the development and utilization of vaccines.

Both the NFID and the NCAI appreciate the potential risks involved with the practice of vaccination, but feel that the benefits achieved from the appropriate utilization of safe vaccines far outweighs these risks and the greater risks of withholding vaccinations.

The NFID and NCAI believe that the practice of immunization has had and will continue to have profound and positive impacts on public health. Initiatives to increase the rate of childhood and adult immunizations have been quite successful, but opportunities to further improve immunization rates still exit. These opportunities for improvement exist mostly because of misconceptions about vaccination and discrepancies in access to vaccinations. Both the NFID and the NCAI are committed to further reducing the incidence of vaccine-preventable diseases by raising the awareness of Americans regarding these diseases and their prevention through the appropriate use of vaccines and by encouraging research into new protective measures. The common goal of the NFID and the NCAI is improving the immunization status of children, adolescents and adults to the levels specified by the U.S. Public Health Service's *Healthy People 2010*. The NFID and the NCAI serve as a source of information on immunization and immunization-related issues for consumers, professionals, and the media.

Sincerely,

William J. Martone

William J. Martone, M.D.
Senior Executive Director
National Foundation for Infectious Diseases

Peggy S. Webster

Peggy S. Webster, M.D., F.A.A.P.
Director
National Coalition for Adult Immunization

Mr. BURTON. Well, I just like to say to my colleague, I regret that we were not able to have those additional three people testify, but we had six people on our side that wanted to testify and we have to set some limits. We try to respond and we did let you pick whomever you wanted, up to three people to testify. So, I apologize for not being able to accommodate the additional three witnesses.

Mr. Shays.

Mr. WAXMAN. Just to point out, there are nine witnesses——

Mr. BURTON. Yes, I understand.

Mr. WAXMAN [continuing]. In addition to Dr. Satcher.

Mr. BURTON. We gave you more than the limit.

Mr. WAXMAN. You gave us three out of the nine.

Mr. BURTON. Yes, we gave you more than you gave us when you were in the majority. Mr. Shays.

Mr. SHAYS. I think some people got out of bed on the wrong side this morning. I don't think it was me. I welcome Dr. Weldon here and I look forward to others participating, as well.

The Subcommittee on National Security, Veterans Affairs, and International Relations, which I chair, held four hearings on the Department of Defense [DOD] mandatory force-wide anthrax immunization programs. Questions we consider today about improving the safety and ensuring the efficacy of all vaccines apply with special urgency to the anthrax vaccine. In one subcommittee hearing, a DOD physician stated an important standard: good medical care requires use of the least evasive, lowest risk therapy available. All vaccines should continuously be measured against that standard.

Immunization has been one of the most successful public health interventions in human history. It is undisputed vaccines have afforded remarkable, effective, and efficient protection against diseases that once sickened, disabled, or killed millions, particularly children. But as the number of mandatory vaccines climbs, great care must be taken, least the success begat complacency, or worse, arrogance about the extent of our knowledge about the human immune system. We know very little about the long-term cumulative effects of immunological challenges, both benign and toxic.

Genetic variance may play a role in each individual's immunological response. One size of immunity may not fit all. So, as we look for ways to protect the public health into the next century, today's discussion on ways to improve the safety and efficacy of vaccines is an important one. I look forward to hearing the testimony today from all of our witnesses, those chosen by our ranking member and our chairman. I look forward to other hearings on this, since I know that we can't attempt to cover everything in one hearing. I particularly look forward to Dr. Satcher's testimony. As Surgeon General, he has been outstanding and I appreciate his participation in hearings I had when I chaired the Human Resources Subcommittee. Welcome, Doctor.

[The prepared statement of Hon. Christopher Shays follows:]

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ONE HUNDRED SIXTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON GOVERNMENT REFORM

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Statement of Rep. Christopher Shays
August 3, 1999

The Subcommittee on National Security, Veterans Affairs and International Relations, which I chair, has held four hearings on the Department of Defense (DoD) mandatory, force-wide anthrax immunization program. Questions we consider today about improving the safety and assuring the efficacy of all vaccines apply with special urgency to the anthrax vaccine.

In one Subcommittee hearing, a DoD physician restated an important standard: good medical care requires use of the least invasive, lowest risk therapy available. All vaccines should continuously be measured against that standard.

Immunization has been one of the most successful public health interventions in human history. It is undisputed vaccines have afforded remarkably effective and efficient protection against diseases that once sickened, disabled or killed millions, particularly children.

But as the number of mandatory vaccines climbs, great care must be taken lest that success beget complacency, or worse, arrogance about the extent of our knowledge of the human immune system. We know very little about the long term, cumulative effects of immunological challenges - both benign and toxic. Genetic variants may play a role in each individual's immunological response. One size of immunity may not fit all.

So, as we look for ways to protect the public health into the next century, today's discussion on ways to improve the safety and efficacy of vaccines is an important one.

I look forward to hearing the testimony today, particularly that of our distinguished Surgeon General.

Mr. BURTON. Thank you, Mr. Shays. I just want to say you have done yeoman service with your hearings and you should be publicly acknowledged for that, and so should your staff.

Are there others, who want to make an opening statement?

Mr. DAVIS OF ILLINOIS. Just briefly, Mr. Chairman.

Mr. BURTON. Mr. Davis.

Mr. DAVIS OF ILLINOIS. Thank you, very much, Mr. Chairman. I want to thank you for holding this hearing, in particular, given the fact that I am in agreement with those, who suggest that our program of vaccination has been the greatest health achievement that we've experienced in the last two centuries. I, too, believe that it should be universal, although there are some concerns, there are some problems, there are some instances, and education must continue to be a real part of the thrust.

In addition to my own opening statement, I am also including in that statement testimony from Dr. Lawrence Frenkel, who is a physician, pediatrician, and immunologist. He's chairperson of the Committee on Infectious Disease of the Illinois Chapter of the American Academy of Pediatrics and co-chair of the Public Affairs Committee of the Greater Illinois Chapter March of Dimes and chairman of Pediatrics at the University of Illinois, College of Medicine in Rockford and has, indeed, been a health advocate for more than 30 years. So, I submit, along with my opening statement, the statement from Dr. Frenkel, and yield back the balance of my time.

Mr. BURTON. Without objection, that will be included in the record.

[The prepared statements of Hon. Danny K. Davis and Dr. Frenkel follow:]

Danny Davis

Opening Statement for the Government Reform Committee

Mr. Chairmen, I rise to speak on behalf of this nation's children, because the issue of vaccinations and our children is larger than politics. I commend Chairmen Burton for having this hearing on this important issue. This hearing gives us the opportunity to ask questions about the vaccination process for the children who do not have that opportunity: for Miranda,

Evan, Rachel, Brian, David, Katie, Tim, Catherine, and Natalie. These are all Illinois children whose vaccinations produced terribly devastating results. Children who cannot walk anymore, children who cannot play anymore, and their parent believe the vaccinations they received are the cause.

Today's USA Today features a front page story entitled "Kids in USA Get 21 Shots

Before Start of 1st Grade." This was preceded on august 1 by a Chicago Tribune story entitled "A shot in the Dark" discussing the very same topic we are addressing here today. This question is further boosted by the American Physicians and Surgeons(AAPS) call for a Moratorium on Hepatitis B vaccine for children. The experts and concerned parents have raised this issue and we, as members of

congress, have an obligation to address it. We must question whether vaccines are safe and whether they promote the health of our children.

There can be no question that the advent and implementation of vaccines have saved thousands if not millions of lives over the past 50 years. Vaccines for polio, mumps, and measles have virtually eliminated these

terrible diseases. Now it is our obligation to question whether or not newer vaccines, specifically Hepatitis B, are being tested appropriately and whether or not they are damaging more children than they are saving. We must also ask whether or not the Federal Drug Administrations Vaccine Adverse Event Reporting System (VAERS) functions so as to record all adverse reactions to vaccinations.

We know that adverse reactions take place, because we developed the National Vaccine Injury Compensation program to compensate families whose children suffer from a vaccine. This federal "No-fault" system insulates vaccine producers and doctor from liability associated with the actions and products. Whereas I understand the policy is to encourage the

development of more vaccines, we must ask whether or not people's action should be free from liability. Since 1991, families have collected over 1 billion dollars from this federal fund. Illinois Parents have written and called to express their concern over the difficult nature of the process. I hope that in the course of these proceedings and witness we able to discuss

how
~~home~~ the process affects the families involved.

The VAERS system indicates there are significant adverse reactions reported in America each year. It is our job as elected representatives to questions whether the harm outweighs the good. Hopefully, the witnesses here today will be able to provide us with important insight as to the efficacy of America's Vaccination program. I am

here to fight for the children of the Seventh Congressional District and ask the important tough questions that need to be answered. Thank you Mr. Chairman and I yield back the remainder of my time.

Part of Dennis Opening Statement

Testimony

The Honorable Chairperson Mr. Burton and Members of the House Government Reform Committee:

My name is Lawrence D. Frenkel. I am a father, physician, pediatrician, infectious diseases and immunology specialist, Chairperson of the Committee on Infectious Diseases of the Illinois Chapter of the American Academy of Pediatrics, Co-Chair of the Public Affairs Committee of the Greater Illinois Chapter, March of Dimes, Chairman of Pediatrics at the University of Illinois College of Medicine at Rockford and a child health advocate with 30 years experience caring for children and young adults with infectious diseases.

There is no grand or sinister plot to harm our children; no responsible health care provider wants any child to come to harm if that can be prevented. The original impetus for the development of the first vaccine against small pox, over two hundred years ago by Sir Edward Jenner, was the desire to protect people from death and illness. This vaccine has led to the total elimination of small pox from the face of the earth. Soon polio will be extinct, only 50 years after the nation mobilized to develop a polio vaccine with the support of the March of Dimes. Next in line is measles. These represent truly extraordinary advances for civilization and for our children world wide. Each year in the United States, hundreds of thousands of children and adults are saved from death and disability by our ever expanding armamentarium of hard won vaccines.

Time does not allow me to dwell on the benefits of this most important advance of modern civilization, however, even this human endeavor is imperfect. Sadly, vaccine preventable deaths and disease continue to occur, sometimes in children too young to be immunized, rarely in individuals for whom the vaccine was not effective and very rarely as an unfortunate adverse reaction to an immunizing agent. This latter experience motivated the recent effort to improve one of our her-to-for most reactogenic immunizing agents (pertussis) and its replacement with the safer acellular pertussis vaccine and in addition, the substitution of the inactivated polio vaccine for the live polio vaccine.

Noteworthy is the experience in other countries like Japan and Great Britain, when vaccination rates decreased in response to sensational media attention to rare adverse effects. Epidemics of vaccine preventable disease and deaths increased as fewer and fewer children were immunized, ending only when responsible parents again embraced logical public health immunization policies. Further illustration of the need for even higher levels of protective immunity in the community is our own pertussis epidemic in Rockford only two years ago with approximately 20 hospitalizations and hundreds of thousands of dollars expended, to say nothing about the suffering of the infants and the anguish of their loved ones. In California where more liberal exemptions have been enacted, there have been 14 measles and pertussis outbreaks in a little over a decade. These epidemics not only involved children whose parents did not elect to have them immunized but also children of parents who supported the appropriate immunization recommendations.

Allow me to move on to a further discussion of adverse effects of vaccines. I have already emphasized that the medical community abhors suffering or ill effects secondary to well meaning efforts, such as our lifesaving immunizations efforts. The efforts to prevent these rare events as exemplified by the new acellular pertussis vaccine and our return to the killed polio vaccine, as well as the recent alert about potential (never proven) risk from mercury-containing vaccine additives. However, we must honestly address the true incidence of these adverse effects as scientifically verified in order to make risk-benefit decisions. The vast majority of adverse effects (but sadly not all) ascribed to immunization have been scientifically and statistically proven to be unrelated. When tens of millions of people receive a particular vaccine there will unfortunately be someone who has a temporally diagnosed, sometimes rare, unrelated disease such as Juvenile Rheumatoid Arthritis, Multiple Sclerosis, or the onset of a cryptic seizure disorder. The only relationship between the vaccine and the adverse reaction is timing; they are not causally related.

People who care about children must not turn back the clock of civilized health care in this great nation. People around the United States are watching to see what our leadership does with regard to this issue in the next few weeks and months. Your votes may make the difference between life or death, health or disease for literally thousands of your citizens.

Mr. BURTON. Mrs. Morella.

Mrs. MORELLA. Thank you, Mr. Chairman. I want to thank you for holding this hearing today, to examine the role and necessary risks of vaccines and immunization. As we listen to the compelling testimony of our witnesses today, I would hope that we keep in mind the remarkable benefits society enjoys because of widespread vaccination. In fact, Mr. Chairman, vaccines and immunization programs have been so remarkably successful in eliminating or controlling many of the more common infectious diseases of childhood, that their use is often taken for granted. It's precisely because of this widespread success that the risks from vaccination, and there are risks, are causing such alarm today. However, we must not forget that vaccinations have been so successful that cases of diphtheria, whooping cough, tetanus, measles, mumps, and German measles is so unusual in the United States, that these infections and their consequences are unknown to most Americans.

To get a clear understanding of the great contributions widespread vaccination has made, we need only listen to the stories from people like Barbara Hahn. In an earlier hearing on the subject, Mrs. Hahn testified about the effects of infectious diseases on millions of American families. I'd like to just read a short excerpt from her testimony to make the point.

She said,

> I would like to tell you about my mother and all mothers like her, who suffered through the loss of a child from an infectious disease. Raising a family in the hills of Kentucky, where most people were too poor to pay for the little, if any, medical help available, my mother struggled to keep her family healthy. When one of her babies became serious ill, my mother and her parents did everything they could to try to help her. Despite their efforts, my mother watched her child, Patsy Lynne, die from whooping cough. While making arrangements for Patsy's funeral, my mother learned that another one of her children was gravely ill. Both children were buried on the same day, in the same casket, in the same grave, next to my mother's church.

Mr. Chairman, childhood diseases like whooping cough and polio have been largely eradicated. As Mrs. Hahn's testimony shows, just a generation ago, the coming of summer brought fears of epidemics of polio. And now, iron lungs can be seen only in museums and dusty hospital storerooms. This has been accomplished through the development and use of safe and effective vaccines in national immunization programs around the world. Small pox was eradicated from the planet in 1977. Polio eradication was defined as a goal for the year 2000. And remarkably, Americans were declared to be free of wild polio myelitis on September 29, 1994.

As we prepare for the 21st century, the promise of vaccines has never been greater. But, a great challenge still remains. I understand representatives of PKIDS, the Parents of Kids with Infectious Diseases, will testify about their children's continuing battle with vaccine preventable diseases. And while vaccines have virtually eradicated the childhood diseases of the last generation, other diseases, such as hepatitis B, baracella, tetanus, and meningitis, are still common and have caused serious illness or the deaths of thousands of children. It's astounding that approximately 1 million preschool American children are not adequately protected against potentially fatal diseases that can be prevented with a vaccine. Therefore, Mr. Chairman, we have to continue to work to in-

crease the awareness of the benefits of disease prevention through vaccination.

Furthermore, if the promise of vaccines is to be fully realized, vaccines must not only be effective in the prevention of disease, they have to be safe. Unfortunately, recent reviews by the Institute for Medicine have identified many gaps and limitations in current knowledge of vaccine safety. Given new technologies for the development, production, manufacture, regulation, and administration of vaccines, the vaccine safety network for the United States must be enhanced to provide appropriate evaluation of new candidates. To ensure continued public acceptance of vaccines, close monitoring of potential adverse effects and adverse reactions, adequate scientific evaluation of associates, and appropriate responses to newly identified risks of vaccines, including research in targeted development of new technologies and vaccines, are critical. So, I guess I'm saying we need to look at a balance, Mr. Chairman.

I certainly look forward to hearing the testimony from today's witnesses. I welcome them all, beginning with the distinguished Surgeon General, Dr. Satcher. Thank you, Mr. Chairman, for indulging me.

Mr. BURTON. Thank you, Mrs. Morella. Are there further opening comments? If not, Dr. Satcher, Mr. Surgeon General, would you and the people who will be testifying with you from your office, stand, so you can be sworn. Oh, you've brought a lot of people with you.

[Witnesses sworn.]

Mr. BURTON. Let the record reflect the witnesses responded in the affirmative. Dr. Satcher, we recognize you for 10 minutes for your opening statement, sir.

STATEMENT OF DAVID SATCHER, M.D., SURGEON GENERAL OF THE UNITED STATES

Dr. SATCHER. Thank you, Mr. Chairman. I am Dr. David Satcher, Assistant Secretary for Health in the Department of Health and Human Services, and Surgeon General of the United States. I thank you, Mr. Chairman and distinguished members of the committee for your invitation to testify at this important hearing on vaccines. With me today are technical experts from our department and the agencies especially involved in vaccines and immunizations activities. They are: Mr. David Benoir, Office of the General Counsel; Dr. Robert Breiman, who heads the National Vaccine Program Office; Dr. Walter Orenstein from the Centers for Disease Control, where he heads the National Immunization Program; Dr. Kathy Zoon and Dr. William Egan from the Food and Drug Administration; Mr. Thomas Balbier from the Health Resources and Services Administration; and Dr. Regina Rabenovitch from the National Institutes of Health.

As Assistant Secretary for Health and the Surgeon General, I'm called upon to use the best available science to protect and advance the Nation's health. For over 200 years now, the Public Health Service has operated with the understanding that in so much as we care for the needs of the most vulnerable among us, especially our children, we do most to protect the health of the Nation. Throughout our history, the most vulnerable have often been those attacked

by various forms of diseases. Thanks to advances in medicine and public health, vaccines have served as a way to offer protection to individuals and communities.

Vaccines represent a remarkable public health success story. They are perhaps the 20th century's most important medical interventions, having prevented millions of diseases, disabilities, pain, suffering, and death. And from a risk benefit perspective, they are considered by many to perhaps be the safest and most efficacious medical interventions of our time.

During my tenure as Director of the Centers for Disease Control and Prevention, from 1993 to 1998, we made a commitment and were successful at increasing the Nation's immunizations by the age of 2, from 55 percent to 78 percent in 1996. Determined not to allow the barriers of access, cost, lack of insurance, and others to impede us from boosting immunization rates, we went into the community, partnered with organizations, such as the National Council of LaRaza, the Congress of National Black Churches, and others, to help us overcome the barriers to immunization. Today, immunization rates are approaching 90 percent and we're working still to increase that level. But despite our success, disparities in immunization rates still exist for some racial and ethnic groups in this country. Minority children still lag behind their white counterparts, when overall vaccination rates are compared.

However, we in medicine and public health continue to be concerned that some recipients of vaccines suffer injuries, as a result of the vaccine. We recognize how important it is to acknowledge the significance of the problem of vaccine injury.

This administration has made immunizations a priority. Today, immunization coverage among children in the United States is higher than ever before for most vaccines. These high immunization coverage levels translate into record—or near record low levels of vaccine preventable diseases. So, this afternoon, I will briefly discuss issues related to the benefits of vaccines, our concerns for injuries because of vaccines, our progress through the years, what we're doing to ensure that vaccines are as safe as possible, and what we must do to continue to enhance vaccine safety.

Vaccines offer many benefits to individuals and their communities. When we vaccinate a child, for example, that child becomes protected against a series of illnesses and diseases. But not only does the vaccinated child receive protection from developing a potentially serious disease, the community also benefits when comprehensive vaccination programs are in place. Those programs provide what we call community or herd immunity, which helps to indirectly protect those individuals who cannot be vaccinated, such as those who may be too young for certain vaccinations or who have other health problems that prevent them from being immunized; yet, they're still susceptible to the disease.

For example, babies that are under 1 year of age are too young to receive the measles vaccine, but receive some protection from the vaccination of other individuals. Also protected are children and adults, who cannot be vaccinated with some vaccines for medical reasons, such as children with leukemia. So, the entire community benefits from the reduction of the spread of infectious agents, and healthier communities mean a healthier Nation.

Vaccines not only save lives and eliminate disability, pain, and suffering, they are also cost effective. Immunizations are one of the most cost effective medical and public health interventions we know.

Let me give you an overview of our experience with immunizations and treatment of vaccine preventable diseases. Today, there are far fewer visible reminders of the suffering, injuries, and premature deaths caused by diseases that can now be prevented with vaccines. By now, many Americans have heard my story. When I was 2 years old in Anniston, AL, I came down with a severe case of whooping cough, which led to pneumonia, and a family physician, who came out to the farm to visit me, predicted that I would not live out the week. I was fortunate. I survived. That year, 1943, in the United States over 190,000 children suffered from whooping cough and 3,500 died; 1995, in this country, there were 5,000 cases of whooping cough and 5 deaths. And that's not our best story. In fact, that's one of our worst stories, in terms of where we are today.

A physician entering practice today may never see a case of meningitis, due to haemophilus influenza type B. Before the introduction of effective vaccines in 1988, approximately 1 in 200 children under the age of 5 developed invasive haemophilus influenza B disease. It was the leading cause of bacterial meningitis in children under 5, accounting for about 60 percent of all such cases. Today, most residents in pediatrics will not see a child with haemophilus influenza meningitis. In fact, whereas in 1988, there were 20,000 cases, today, there are only about 100; and whereas there were almost 500 deaths a year, today, there are very few, if any. By 1998, vaccination of preschool children reduced the number of cases by more than 99 percent.

Finally, in the 1960's, many people witnessed firsthand the terrible effects of rubella, commonly known as German measles. During an epidemic between 1964 and 1965, about 20,000 infants were born with deafness, blindness, heart disease, mental retardation, and other birth defects, because rubella virus infected their pregnant mothers. Today, thanks to nearly universal use of effective vaccines, the rubella virus poses virtually no threat to the children of expecting mothers. So, we can see from our track record that vaccines offer a great many reasons for placing our trust and hope in them, in protecting the health of individuals, communities, and the Nation.

But, we are concerned about vaccine safety. As gratifying and as efficacious as the benefits of immunizations are, we still have serious concerns. Vaccines are not 100 percent safe. They have risk. A small percentage of children still suffer adverse consequences, as a result of vaccines. And as long as there is a risk of injury or illness in even one child, we should not, we will not be satisfied. Our concern for children injured because of vaccines is not without tangible expression. We've developed a compensation system to provide families with financial restitution for vaccine related injuries.

So, how are we dealing with the problem of vaccine injuries today? We're committed to vaccine safety through enhanced surveillance systems, vaccine safety research, adopting safe vaccine administration policies, and educating and providing information to parents, the health care providers, and to the general public. We

have a draft proposal for a comprehensive vaccine safety program built upon the cornerstones of surveillance, research, communication, and education. This updated proposal has been reviewed and approved by the National Vaccine Advisory Committee and is now undergoing review within the Department. We're working diligently to ensure that vaccines licensed in the United States are safe and effective as they can be, and we have one of the toughest vaccine approval systems in the world.

However, even after the extensive studies required for licensure, post marketing research and surveillance are necessary to identify safety issues, which may only be detected following vaccination of a much larger population. This is because very rare events may not even be detected and if noted, not shown to be due to a vaccine. The National Childhood Vaccine Injury Act of 1986, which Congressman Waxman authored and mentioned earlier, led to the creation of a unified national system to collect, manage, and evaluate the reports of possible adverse events. This system, which was initiated in 1990 and jointly managed by CDC and FDA, is a vaccine adverse event reporting system. And recently, the CDC has added to that the Vaccine Safety Datalink to really pursue these cases, to understand the relationship between them and vaccines.

In 1997, we had to make the very tough decision, when I was director of CDC, to switch our polio immunization strategy from primary reliance on oral polio vaccine [OPV], to an inactivated polio vaccine [IPV]. We made the switch to IPV, which never causes polio, even though OPV only very rarely caused it, 1 in 2.4 million doses. So, we estimate that we spend $3 million per injury or a case of polio from oral polio vaccine; i.e., we spend $3 million to prevent one case. And, yet, we think that's well spent. If we can save a single child, we feel that it is worth it.

A good example of how the vaccine safety monitoring system works is in alerting us to and helping address the recent concern about rotavirus vaccines and a type of obstruction, which we call intersusception. Between September 1998 and June 1999, 15 cases of intersusception following rotavirus vaccine were reported to our reporting system. The cases tended to be younger than most cases of intersusception normally occurring in the absence of vaccination. This signal led to special studies, to evaluate whether there is truly causal roles of rotavirus vaccines in intersusception. On July 16th, CDC recommended that vaccination of children scheduled to receive the rotavirus vaccine before November 1999 be postponed, until the studies are completed and findings are available.

I've adopted, as one of my priorities as Surgeon General, to move this Nation toward a more balanced community health system, which balances health promotion, disease prevention, early detection, and universal access to health care. One of the goals of that health system is to ensure that every child has the opportunity for a healthy start in life. A very definite part of that healthy start is ensuring that children are immunized against vaccine preventable diseases. And we're making great progress.

So, Mr. Chairman, in conclusion, vaccines have given us much for which we can be grateful. They've eradicated small pox. They've eliminated polio myelitis in the Americas and controlled measles, rubella, tetanus, diphtheria, haemophilus influenza type B, and

other infectious diseases. And they have saved millions of lives and avoided disease, disability, pain, and suffering, in many people.

The public has a right to and should expect safe vaccines. Although no system is perfect and no medicine or vaccine can ever be guaranteed to be 100 percent free of possible side effects or adverse events, particularly when administered to millions of people, we are still committed to improving the safety of vaccines. The Department and its constituent agencies, who are represented here today, and the scientific community and industry strive to continuous improvement in vaccine safety. As we enter the 21st century, promoting optimum health of people through the development and administration of safe and effective vaccines will continue to be a priority for our department.

Mr. Chairman and committee members, I assure you, in the interest of protecting and promoting public health, we will continue to make policy decisions and recommendations based on the best available science. Vaccines are very safe and effective. They are not perfect and will require continuing vigilance and research. Thank you for this opportunity to testify.

[The prepared statement of Dr. Satcher follows:]

Statement of

DAVID SATCHER, M.D., PH.D.

ASSISTANT SECRETARY FOR HEALTH

AND

SURGEON GENERAL

U.S. Public Health Service
Department of Health and Human Services

Before The

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON GOVERNMENT REFORM

AUGUST 3, 1999

Good afternoon. I am Dr. David Satcher, Assistant Secretary for Health, Department of Health and Human Services (HHS), and Surgeon General of the United States. I thank you, Mr. Chairman and members of the Committee, for your invitation to testify at this important hearing on vaccines. With me today are technical experts from the HHS agencies involved in vaccine and immunization activities. They are: Mr. David Benor, Office of the General Counsel; Dr. Robert Breiman, National Vaccine Program Office (NVPO); Dr. Walter Orenstein, Centers for Disease Control and Prevention (CDC); Drs. Kathryn Zoon and William Egan, Food and Drug Administration (FDA); Mr. Thomas Balbier, Health Resources and Services Administration (HRSA); and Dr. Regina Rabinovich, National Institutes of Health (NIH).

Protecting our society from debilitating and deadly diseases that can be prevented through the administration of vaccines is a cornerstone for ensuring the health and well-being of our citizens. Vaccines are highly effective in preventing death and disability, and save billions of dollars in health costs annually. We are working diligently to ensure that vaccines licensed in the United States are as safe and effective as they can be. We have a stringent regulatory process for licensing vaccines that serves as a model for all countries.

To achieve optimal prevention of dangerous infectious diseases, we must have confidence in our immunization programs. Thus, the trust of this Committee as well as parents, providers, and the general public is critical. We must be united in recognizing and overcoming our common enemy, the microbes that cause infectious diseases and threaten the health and lives of our citizens, especially the Nation's children and elderly.

This afternoon, I will briefly discuss issues related to the benefits of vaccines, the process for licensing them, what we are doing to ensure that vaccines are as safe as possible, and what we must do to continue to enhance vaccine safety.

Benefits of Vaccines

Vaccines are among the 20th century's most successful and cost-effective public health tools for

preventing disease, disability, and death. Not only do they prevent a vaccinated individual from developing a potentially serious disease, vaccines routinely recommended for children also help protect the entire community by reducing the spread of infectious agents.

Childhood immunization has been one of the earliest priorities of this Administration. Under the Childhood Immunization Initiative, a wide range of efforts such as outreach campaigns, disease monitoring and vaccine research, have been enhanced. Overall, immunization coverage among children in the United States is higher today than ever before for most vaccines. These high immunization coverage levels translate into record, or near record, low levels of vaccine-preventable diseases. For most of the vaccine-preventable diseases, there has been a 95 percent or more reduction in cases. This has occurred because States, Territories, and local governments have instituted effective immunization programs.

Today there are far fewer visible reminders of the suffering, injuries, and premature deaths caused by diseases that can now be prevented with vaccines. So that we do not forget the past, allow me to share some examples:

- Polio vaccine was licensed in the United States in 1955. During 1951 to 1954, an average of 16,316 paralytic polio cases and 1,879 deaths from polio were reported each year. As of 1991, polio caused by wild-type viruses had been eliminated from the Western Hemisphere. We have a goal that by the end of the year 2000, polio, like smallpox, will be a disease of the past worldwide.
- A physician entering practice today may never see a case of meningitis due to *Haemophilus influenzae* type b (Hib). Before the introduction of effective vaccines, in 1988, approximately one in 200 children, under the age of five, developed invasive Hib disease. Hib was the leading cause of bacterial meningitis in children under age five--accounting for about 60 percent of all cases. From 15 to 30 percent of affected children became hearing impaired and about 420 children died every year despite antibiotic therapy. In addition, Hib vaccine prevented has prevented the leading cause of acquired mental retardation in the U.S. By 1998, vaccination of pre-school children reduced the

number of Hib cases by more than 99 percent.

- In the 1960s, many people witnessed first-hand, the terrible effects of rubella, commonly known as German measles. During an epidemic between 1964 and 1965, about 20,000 infants were born with deafness, blindness, heart disease, mental retardation, and other birth defects because the rubella virus infected their pregnant mothers. Today, thanks to nearly universal use of an effective vaccine, the rubella virus poses virtually no threat to the children of expectant mothers.

The costs of caring for a child with congenital rubella syndrome are staggering, which brings me to my next point. Vaccines not only save lives, reduce pain, suffering and disability, they save money. The individual and community protection provided by vaccines help make immunization one of our most cost-effective medical and public health interventions. Most vaccines recommended are cost-saving even if only direct medical costs--and not lost lives and suffering--are considered. Our country, for example, saves $8.50 in direct medical costs for every dollar invested in diphtheria-tetanus-acellular pertussis (DTaP) vaccine. When the savings associated with work loss, death, and disability are factored in, the total savings increase to about $27 per dollar invested in DTaP vaccination. Every dollar our Nation spends on measles-mumps-rubella (MMR) vaccination generates about $13 in total savings—adding up to about $4 billion each year.

The value of vaccines also extends beyond childhood. The greatest vaccine-preventable disease burden for the U.S. population today is among adults. We estimate an average of 23,000 persons, primarily 65 and older, die from complications of influenza illness during epidemics. Over 10,000 more die from pneumococcal infections such as pneumonia annually. Many of these deaths could have been prevented by vaccination. We have safe, effective, but highly under-utilized vaccines that can help us reduce the $10 billion a year in societal costs brought about by vaccine-preventable diseases in adults.

A decision to vaccinate is a decision to help protect not only individuals, but to also protect entire communities from diseases spread by person-to-person transmission. A decision to not

vaccinate is to put the individual and community at risk. When immunization programs achieve high levels of "community" immunity—or what scientists sometimes refer to as "herd" immunity (the indirect protection of a community, including unvaccinated individuals), the likelihood that an infected person will transmit the disease to a susceptible individual is greatly reduced. Community immunity provides indirect protection to children who may be too young for certain vaccinations or have other health problems that prevent them from being immunized, yet are still susceptible to the disease. For example, children under one year old are too young to receive the measles vaccine but receive some protection from the vaccination of older individuals. Also protected are children who cannot be vaccinated with some vaccines for medical reasons—such as children with leukemia.

Vaccine Licensure

FDA's Center for Biologics Evaluation and Research (CBER) is responsible for regulating vaccines in the U.S. Current authority for the regulation of vaccines resides primarily in Section 351 of the Public Health Service Act and specific sections of the Federal Food, Drug and Cosmetic Act.

Vaccine clinical development follows the same general pathway as drugs and other biologics. A sponsor who wishes to begin clinical trials with a vaccine must submit an Investigational New Drug application (IND) to FDA. The IND describes the vaccine, its method of manufacture and quality control tests for release. Also included are information about the vaccine's safety and ability to elicit a protective immune response (immunogenicity) in animal testing as well as the proposed clinical protocol for studies in humans.

Pre-marketing (pre-licensure) vaccine clinical trials are typically done in three phases, as is the case for any drug or biologic. Initial human studies, referred to as Phase 1, are safety and immunogenicity studies performed in a small number of closely monitored subjects. Phase 2 studies are dose ranging studies and may enroll hundreds of subjects. Finally, Phase 3 trials typically enroll thousands of individuals and provide the critical documentation of effectiveness and important additional safety data required for licensing. At any stage of the clinical or animal

studies, if data raise significant concerns about either safety or effectiveness, FDA may request additional information or studies or may halt ongoing studies.

If successful, the completion of all three phases of clinical development can be followed by the submission of a Biologics License Application (BLA). To be considered, the license application must provide the multidisciplinary FDA reviewer team (medical officers, microbiologists, chemists, biostatisticians, etc.) with the efficacy and safety information necessary to make a risk/benefit assessment and recommend or oppose the approval of a vaccine. Also, during this stage, the proposed manufacturing facility undergoes a pre-approval inspection during which production of the vaccine as it is in progress is examined in detail.

Following FDA's review of a license application for a new indication, the sponsor and the FDA present their findings to FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC). This expert committee (scientists, physicians, biostatisticians, and a consumer representative) provides advice to the Agency regarding the safety and efficacy of the vaccine for the proposed indication.

Vaccine approval also requires the provision of adequate product labeling to allow health care providers to understand the vaccine's proper use, including its potential benefits and risks, in order to communicate with patients and parents and to safely deliver the vaccine to the public. Vaccines are also subject to lot release testing and protocol review to further ensure their quality.

Although extensive studies are required for licensure, post-marketing research and surveillance are necessary to identify safety issues which may only arise or be detected following vaccination of a much larger population. Rare events may not come to light before licensure, or, if noted, the evidence may not be adequate to prove that such events were due to a vaccine. The Vaccine Adverse Event Reporting System (VAERS) later in the testimony. In addition, post-marketing studies of a specific vaccine are required by FDA in order to obtain additional safety or other data. Also, after licensure, monitoring of the product and of production activities, including

periodic facility inspections, must continue as long as the manufacturer hold a license for the product.

No system is perfect and no medicine or vaccine can ever be guaranteed to be 100 percent free of possible side effects or adverse events, particularly when administered to millions of people. For these reasons, the Department, its constituent agencies (FDA, CDC, NIH, HRSA), the scientific community, and industry strive for continuous improvements in vaccine safety. Speaking for the Department and its agencies, we welcome all constructive input and criticism in this regard. While we will always seek regulatory and scientific improvements in areas where safety and effectiveness are critical to protecting the public's health as vaccines, we are gratified that the extensive prelicensing and post-marketing efforts have resulted in the United States setting the standards worldwide for development and use of safe and effective vaccines.

Vaccine Recommendations

Vaccine recommendations are derived through a careful, deliberative process involving advice and guidance from the CDC's Advisory Committee on Immunization Practices (ACIP). The ACIP is a Federally chartered, scientific advisory committee of outside experts with the goals of providing to CDC's Director and the Secretary of HHS, advice on decreasing disease through the use of vaccines and other biological products, and on improving the safety of their use.

The ACIP makes recommendations on vaccine use to CDC. If the CDC accepts the ACIP's advice, the recommendations are published in the *Morbidity and Mortality Weekly Report* (MMWR) as ACIP recommendations. As new data become available on the effectiveness of disease prevention or on adverse events, these also may be discussed and may lead to published updates or revisions of previous recommendations.

Immunization Requirements for School Entry:

State laws requiring immunization date from the early 1800s, when Massachusetts enacted a smallpox vaccination requirement for its residents. The modern era for school and licensed day

care immunization laws began with efforts to eliminate measles in the U.S. in the 1960's and 1970's.

All school and licensed day care immunization laws are State-based. There are no Federal laws mandating immunizations for school entry and day care attendance in this country. The U.S. Supreme Court, however, has affirmed the right of States to pass and enforce compulsory immunization statutes, and has upheld the constitutionality of State vaccination laws. Currently all 50 States have school immunization laws in effect although the specific vaccines, number of doses, and vaccine schedules vary by State. All States allow exemptions to immunization for medical reasons. In addition, 48 States allow religious exemptions and 15 States allow philosophical exemptions.

State-based, school-entry immunization laws establish a safety net to ensure a high level of protection from deadly diseases. Implementation and enforcement of school immunization laws have played a key role in reducing vaccine-preventable diseases in the U.S. For example, during the first 31 weeks of 1978, six States that enforced school laws reduced measles incidence by more than 90%, compared to the rest of the country.

Vaccine Safety

The public has a right to and should expect safe vaccines. While vaccines are among the safest pharmacologic interventions available, no drug or vaccine is 100 percent without risk. Even with a risk level as exceedingly low as it is for vaccines, we are working to find ways to reduce the risk even further. We are committed to vaccine safety through enhanced surveillance systems, vaccine safety research, adopting safe vaccine administration policies, and educating and providing information to parents, health care providers, and the general public.

Two recent examples reflect the emphasis we place on providing the safest vaccines possible. Beginning in 1996, to prevent pertussis in infants, we began use of a safer, newly-licensed vaccine. In recent years, we have switched our polio immunization strategy from primary reliance on oral polio vaccine, which very rarely causes polio (1 in 2.4 million doses), to

inactivated polio vaccine which never causes polio. The additional cost of full implementation of these two changes to improve the safety of our immunization schedule will be approximately $110 million, which comprises 10 percent of CDC's immunization budget.

Vaccine Adverse Event Reporting System:

The National Childhood Vaccine Injury Act of 1986 led to the creation of a unified national system to collect, manage, and evaluate the reports of possible adverse events. This system, initiated in 1990 and jointly managed by CDC and FDA is the Vaccine Adverse Event Reporting System mentioned earlier in my testimony. It is the only surveillance system that covers the entire U.S. population.

VAERS is a passive surveillance system that relies on physicians, health care providers, parents, and vaccine manufacturers to submit reports of adverse reactions that occur during a period following vaccination. To encourage reporting of any possible vaccine-induced adverse event, the criteria for reporting VAERS are non-restrictive. The system accepts and includes **any** report submitted, no matter how unlikely the possible connection with vaccination. For this reason, extreme care must be used in interpreting claims based on VAERS data. VAERS reports are helpful for suggesting adverse events—they do not however, allow us to say anything about whether a vaccine causes or caused the reported event.

VAERS receives 11,000 to 12,000 individual reports per year from vaccine manufacturers, private practitioners, State and local public health clinics, parents, and individuals who receive vaccines. Vaccine manufacturers and providers are **required** to report every potential adverse event of which they learn, regardless of the type of event. Approximately 15 percent of the reports describe events considered serious, defined as an event that is fatal, life-threatening, requires or prolongs hospitalization, results in permanent disability, or in the judgment of the physician could lead to such an outcome in the absence of medical intervention. Most of the remaining reports describe self-limited, transient events such as injection site reactions, irritability, prolonged crying, and fever. The serious events, unfortunately, are much more difficult to evaluate with regard to their causal association with vaccines. Most tend to be of a

type known to occur in the absence of vaccines, so in an individual case it is almost never possible to definitively assess the role of the vaccine.

Case reports of serious adverse events obtained through VAERS may not always represent direct consequences of vaccination. The timing, for instance, between a vaccination and a reported adverse event may simply be coincidental. In other words, there is a time-based, or temporal association, but not a causal association. By chance alone, since children receive several vaccinations in their first year of life, some children who develop symptoms of illness will do so within several days of receiving a vaccine. Reports to VAERS can provide valuable information regarding serious adverse events that **may** be associated with a vaccine and are useful for generating warning signals. It takes other types of studies to determine whether or not they are indeed due to vaccines.

Spontaneous report-based surveillance programs, such as VAERS, perform a critical function by generating signals of ***potential*** problems that may warrant further, more detailed investigation. It is especially valuable in assessing the safety of newly marketed vaccines. Careful review of reports during the initial months following licensure can provide additional assurance about the safety of a new vaccine, and uncover previously unexpected events that occur when a vaccine is used more widely than was possible during clinical trials. FDA may take information obtained from VAERS to its advisory committee (VRBPAC) for making recommendations on vaccine labeling and use.

A good example of how the vaccine safety monitoring system works is in alerting us to and helping address the recent concern about rotavirus vaccine and a type of bowel obstruction called intussusception.

Between September 1998 and June 1999, 15 cases of intussusception following rotavirus vaccine were reported to VAERS. The cases tended to be younger than most cases of intussusception normally occurring in the absence of vaccination. This signal led to special studies to evaluate whether there is a truly causal role of rotavirus vaccine in intussusception. Additional

information has been collected on the cases reported to VAERS and a multi-state study has been initiated to evaluate whether or not rotavirus vaccine is associated with intussusception. On July 16, based on preliminary suggestive but not definitive data, CDC recommended that vaccination of children scheduled to receive the rotavirus vaccine before November 1999 be postponed until the studies are completed and the findings available.

***Vaccine Safety Datalink*:**

Because of the limitations of VAERS, another systems has been developed to evaluate whether vaccines are the cause of an adverse event. Determining the association between vaccination and a potential adverse event often requires documentation that the event is more likely to occur in someone who recently has received the vaccine than in someone who has not. Because serious potential adverse events are usually rare, documenting an association between an adverse event and vaccination requires a large population of vaccinated and unvaccinated persons. In 1990, CDC established the Vaccine Safety Datalink (VSD) that links computerized vaccination, hospitalization, and medical records for members of four large managed care organizations serving about 2 percent of the U.S. population. Vaccine Safety Datalink evaluations include identifying the health outcome of interest (i.e., the potential adverse event), linking these data with vaccination records, and comparing the frequency of the health event in persons who recently were vaccinated with those who are unvaccinated or had been vaccinated at a different time. All analyses must carefully be controlled for other factors that may be associated with disease occurrence or with the likelihood of being vaccinated.

The VSD project has proven to be a very powerful research tool. It has been used to study potential associations between various vaccines and adverse events reported to VAERS. The results of many of these studies have been published in scientific, peer reviewed publications. One study evaluated the question of persistence of acute joint complaints following rubella vaccination. About 25 percent of seronegative women receiving the vaccine reported these symptoms. The study found no evidence of increased risk of new onset of chronic arthropathy or neurological conditions in women aged 15 to 59 who received the vaccines. A second study looked at the risk of hospitalization because of aseptic meningitis after MMR vaccination in one-

to-two year old children. Using data from VSD, the study found no increase in the risk of hospitalization for aseptic meningitis 8 to 14 days after MMR vaccination.

The VSD project is currently being used to examine a range of potential associations between vaccines and numerous alleged but unproven health associations including: 1) hepatitis B vaccination and risk of multiple sclerosis and other neurologic diseases; 2) timing of vaccination and risk of type-1 diabetes; and, 3) risk of seizures following vaccination.

***Enhancing Vaccine Safety Efforts*:**

The Institute of Medicine of the National Academy of Sciences has undertaken several broad reviews of vaccine safety. These reviews examined all available data specific to pediatric vaccines and drew independent conclusions on the safety of each vaccine. The IOM reviews also indicated many gaps and limitations in the current knowledge of vaccine safety. At the direction of Congress, the Secretary of HHS established a Task Force on Safer Childhood Vaccines. The Task Force examined vaccine safety issues and made recommendations to ensure development of safer childhood vaccines and improve licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, recall of reactogenic lots or batches, and research on vaccines. A comprehensive report was approved by the Secretary in January 1997.

The Task Force's recommendations are:

1. Assess and address national concerns about the risks and benefits of vaccines in order to enhance the education of the public, families, and health care professionals;
2. Strengthen the national capability to conduct research and development needed to promote the licensure of safer vaccines; and
3. Strengthen the national capability to conduct surveillance of vaccine-preventable diseases and to evaluate potential adverse events and vaccine efficacy.

The National Vaccine Program Office and its Inter-Agency Group are developing a comprehensive ***Vaccine Safety Action Plan*** based on the recommendations of the Task Force.

Progress in vaccine safety can be achieved by building upon what we are currently doing. For instance, improved surveillance and epidemiological capacity will allow improved communication and education and will help focus research and development efforts. Enhanced communication, in turn, will enhance the quality of surveillance by stimulating reporting of potential adverse events.

New research in vaccine development should soon provide us with new tools to prevent additional diseases that threaten our children and our elderly. These tools show great promise for an even healthier America and world by preventing serious diseases once thought not preventable. As the number of vaccines available for our use increases, however, an improved safety assessment program will be critical and effective risk communication will be essential for the Nation's public health.

Vaccine Injury Compensation Program

Despite all our efforts to make vaccines as safe as possible, a small number of vaccine recipients will experience serious adverse reactions. The National Vaccine Injury Compensation Program (VICP) provides a unique service to families suffering through one of the most difficult experiences imaginable. It is a system through which families can receive financial help for children injured by vaccines in the most efficient and fair manner possible. The VICP, established under the National Childhood Vaccine Injury Act of 1986, minimizes the tension associated with the traditional litigation process for resolving claims arising from injuries thought to be related to childhood immunizations. To date, more than 1,400 families have received the benefit of the Program through awards totaling in excess of $1 billion.

The Department's Advisory Commission on Childhood Vaccines (ACCV), has worked continuously to make a good program better. The members of the ACCV include parents of children thought to have been injured by vaccines, their attorneys, representatives of vaccine companies, and recognized medical experts in childhood diseases. Together this diverse body has

developed and approved a series of recommendations that form the basis for legislation recently proposed by the Secretary. This legislation includes many enhancements aimed at making the VICP even more streamlined and less adversarial for its intended beneficiaries. The proposals would double the statutory time limit for filing a claim, expand compensation to families, and simplify the process for adjudicating claims. A draft bill titled, the "Vaccine Injury Compensation Program Amendments of 1999" was sent to the Congress on June 14, and will hopefully receive expeditious and favorable consideration.

Public Information and Education

We strongly believe that parents, providers, and the general public should be fully informed about the benefits and risks of vaccination.

Vaccine Information Statements:

In addition to any disclosure that may be required by State laws, all health care providers, public and private, are required to provide parents and patients with vaccine information materials before administering particular vaccines. As required by the National Childhood Vaccine Injury Act, the Secretary is responsible for ensuring the development of vaccine information materials for all vaccines covered by the National Vaccine Injury Compensation Program. Vaccine Information Statements (VIS) are developed by CDC after notice to the public and a 60 day comment period, and in consultation with the Department's Advisory Commission on Childhood Vaccines, FDA, and health care provider and parent groups. Each Vaccine Information Statement includes a concise description of the benefits and risks associated with a vaccine. Information is included on risks that have been scientifically established as published in ACIP statements, the Institute of Medicine report on vaccine adverse events, and expert evaluation of the peer-reviewed medical literature. Alleged adverse events that have not scientifically been associated with a vaccine are not included in the VISs.

Public Information and Education:

CDC also provides additional immunization information to the public. In FY 1998 over 2 million copies of 216 separate documents were distributed to both health professionals and the general public. This distribution included general pamphlets on immunization as well as

documents that target certain populations such as senior citizens, adolescents, and persons at high risk of exposure to certain vaccine preventable diseases. CDC also has telephone hotlines in both English and Spanish which provide information on vaccines, the immunization schedule, vaccine-preventable diseases, and contact information on public and private providers by geographic areas. The hotlines receive approximately 9000 calls per month from parents and providers.

In addition, detailed immunization information is available from web sites maintained by CDC, FDA, HRSA, and the NIH. The web sites are updated on a regular basis to assure the provision of the most accurate and current information.

***Provider Education*:**

Professional training and education programs, supplemented with printed information, help keep providers up to date about current policies and recommendations. CDC conducts training on immunization through satellite training courses which are offered to health care providers throughout the United States. The target audience for these courses include physician assistants, nurse practitioners, pharmacists, medical and nursing students, epidemiologists, State and local health officials, and others who provide immunizations to and counsel patients. In 1998, CDC trained over 50,000 health professionals through nationally available satellite courses.

What Would Happen If We Stopped or Reduced Vaccination

A study published in the January 1998 issue of Lancet provides empirical evidence of what happens when successful vaccination programs are halted. The research compared countries where immunization with pertussis vaccines was disrupted to countries that maintained high coverage, including the United States. The findings were clear and consistent. Pertussis incidence was 10 to 100 times lower in countries where high vaccination coverage was maintained relative to those countries where unsubstantiated vaccine safety claims temporarily halted use of the vaccines. Australia, Ireland, Japan, the United Kingdom, Italy, the Russian Federation, and the former West Germany Republic all experienced pertussis outbreaks following the suspension of successful pertussis vaccination programs. Each country also found it necessary to reinstate their pertussis immunization recommendations.

We know that vaccines have dramatically reduced the number of people who get infectious diseases. Without vaccines, epidemics of vaccine-preventable diseases return, resulting in increased and unnecessary illness, disability, and death. History shows that in times of high vaccine coverage and very low incidence of vaccine-preventable diseases, it is common and very easy to shift attention away from the real benefits of vaccines to potential vaccine risks. We should use our past experience with the 1989-1991 measles resurgence which resulted in 55,000 cases of measles and 11,000 hospitalizations—along with experiences in other countries—to remind ourselves of the need to maintain our diligence and perspective when it comes to vaccines.

Conclusion

Vaccination is one of the greatest public health achievements in the United States during the 20th century. Immunizations have eradicated smallpox; eliminated poliomyelitis in the Americas; and controlled measles, rubella, tetanus, diphtheria, *Haemophilus influenzae* type b, and other infectious diseases. There are tremendous accomplishments but more remains to be done.

As we enter the 21st century, promoting optimal health of people through the administration of safe and effective vaccines will continue to be a priority for the Department. Mr. Chairman and Committee members, I assure you, in the interest of protecting and promoting public health , we will continue to make policy decisions and recommendations based on the best scientific evidence.

Thank you for the opportunity to testify before this Committee.

Mr. BURTON. Thank you, Dr. Satcher. We have to go and vote. It will take about 10 minutes.

[Recess.]

Mr. BURTON. Would everyone please take their seats. We have other Members who will be drifting back in. We had two votes on the floor of the House. I apologize for the delay, but this is a very hectic week. In order to make sure that we keep the hearing moving, I will go ahead and start the first round of questioning. I'm sure Mr. Waxman will be back here shortly.

Dr. Satcher, first of all, I would like to preface my questions by saying we think the Department of Health and the National Institutes of Health, the National Cancer Institute, and the Food and Drug Administration do a great deal of very, very good work. I don't think anybody on this committee or probably in the entire country believes that vaccinations should be done away with. We all believe that vaccinations have provided a quality of life and health in this country that is unparalleled in the annals of world history.

However, there have been some disturbing things that we have been told over the past couple of years. I, myself, have experienced some things that have been of concern to me. My granddaughter, whom I told you about before the hearing, when she was very, very young—she's 5 years old now and doing very well, I might add—she got a hepatitis B shot and within 12 hours, she was in the hospital and not breathing. It was a direct result of a reaction to the hepatitis B shot. She came out of it and the doctors did a good job, but that was of great concern to us.

My grandson—I only have two grandchildren—my grandson got a DPT shot, and he's now been adjudged to be somewhat autistic. We've talked to other people who have had similar problems.

So, what we want to find out, if we can, if not today, at some point in the future, whether or not these are problems that emanate from these shots, because there are a number of cases like that across the country. We're going to hear from some witnesses today who will talk about that.

So, let me start off with hepatitis B cases. Can you tell us what percentage of hepatitis cases are not from sexual transmission or from blood or needle exchange properties? What percentage is caused by either needle exchanges or blood transmissions or from sexual transmission?

Dr. SATCHER. You want to know what percentage are not from one of those causes?

Mr. BURTON. Yes.

Dr. SATCHER. OK. Well, let me ask Dr. Orenstein to respond.

Dr. ORENSTEIN. Thank you, very much. About 25 to 30 percent of cases have no identified risk factors that are reported.

Mr. BURTON. About 25 to 30 percent have no identified risk factors, that's correct?

Dr. ORENSTEIN. Yes.

Mr. BURTON. When I talk to some other physicians, who are in the Congress, and they thought the percentage was much lower than that. But, is that a scientific fact?

Dr. ORENSTEIN. Those are data collected from both Sentinel Surveillance System, is the main area that information comes from.

These are people, who are interviewed and do not admit to any risk factors. And you will hear about cases—or have seen cases in prior hearings that have had no identified risk factors.

Mr. BURTON. How many children under the age of 5 have been infected with hepatitis B from things other than needle exchanges, blood products, or from sexual transmission?

Dr. ORENSTEIN. I don't have the data broken down by under 5. But under 9, the CDC estimates that about 19,000 infections with hepatitis B virus occur——

Mr. BURTON. What percentage would that be, Doctor?

Dr. ORENSTEIN. Overall, it would be, in the absence of vaccination, about 350,000 infections. So, I'd have to do the math, but it's about——

Mr. BURTON. So, 350,000 infections about. And how many did you say from under the age of 9?

Dr. ORENSTEIN. Under the age of 9, with no known risk factors, there are about 19,000.

Mr. BURTON. So, 20,000 out of—so, it's about one-twentieth?

Dr. SATCHER. For that age group, it would be much higher than that.

Dr. ORENSTEIN. For that age group, it would be——

Mr. BURTON. No, but I mean overall cases.

Dr. ORENSTEIN [continuing]. Higher. But for all cases, it would be, I guess, 6 percent, isn't it—about 6 percent.

Mr. BURTON. OK. But under the age of 5, it would be much, much less than that?

Dr. ORENSTEIN. According to some of our data on serology, the incidence occurs between—often between age 2 and age 5. And so, it's not clear that there is like a continuous level increase up through age 9.

Mr. BURTON. If you keep statistical data, for the record, I'd like to have you submit, the number of cases and the percentage of hepatitis B cases under the age of 5. When do we require children to get the hepatitis B shot, at what age?

Dr. ORENSTEIN. It depends on the State, because it——

Mr. BURTON. Well, most States.

Dr. ORENSTEIN. Most States would be school entry, age 5 to 6.

Mr. BURTON. I think it's very significant, because like I said, my granddaughter had to get it at a very, very young age and there were very severe side effects. I'm sure other parents have that same problem.

Dr. SATCHER. Well, I think the question here is when is it recommended——

Mr. BURTON. Right.

Dr. SATCHER [continuing]. As opposed to when is it required.

Mr. BURTON. It's recommended at what age?

Dr. SATCHER. Well, now—at birth for most children. As you know now, we've at least relaxed that for children of mothers, who have not shown any evidence of exposure. But the requirement relates to day care or school entry.

Mr. BURTON. That's usually 5 to 6 years old?

Dr. SATCHER. Right.

Mr. BURTON. We talked a while ago about the filing deadline of August 6th for hepatitis claims to the National Vaccine Injury

Compensation Program. As I understand it, that is statutorily set for August 6th, which is about 3 days from now; is that correct?

Dr. SATCHER. Well, I will ask the person who heads that program, to respond.

Mr. BALBIER. Mr. Chairman, you are correct. August 6th is the deadline for filing claims that are——

Mr. BURTON. Well, there are a number of people, I'm sure, across the country that were unaware of that. I was wondering, would you work with us to try to get that extended for, say, 3 or 4 months, so that people across the country, who may be paying attention to what we're talking about today, would have a chance to file a claim, if they need to?

Mr. BALBIER. It would require legislation to extend the deadline. I would point out that that did happen once before in the history of the program for claims arising prior to 1988.

Mr. BURTON. Well, what method has been employed to make the public aware of that?

Mr. BALBIER. We have several ways of doing that. We have vaccine information statements that are provided routinely. Every time a child is immunized, it provides information on the Vaccine Injury Compensation Program, including our 800 number and our website, where they can get more information.

Mr. BURTON. Well, unfortunately, we had a problem in our family and I didn't know about it and I'm chairman of this committee. So, I know that it must not have been as far reaching or as effective as it could have been. So, I wish we would work together to try to get an extension and try to inform the public, because I'm sure there are a lot of people who would like to at least make that kind of a claim.

Mrs. MINK. Would the chairman yield?

Mr. BURTON. I'd be happy to yield to my colleague.

Mrs. MINK. I wanted to inquire why we have a statutory deadline? Why did Congress set a deadline?

Mr. BALBIER. The deadline that we're going to reach at the end of this week is the deadline for filing claims that occurred for the 8 years prior to the coverage of the hepatitis B vaccination. Hepatitis B vaccination was covered under the National Vaccine Injury Compensation Program on August 6, 1997, when the excise tax went into effect to cover that vaccine. At that time, the vaccine was covered for any injury that was thought to be related to the vaccine, and people had 2 years to file a claim, for any vaccine administered during the 8 years prior to 1997, and they had 2 years to do so. So, we are now reaching the August 6, 1999 deadline for filing those 8 year retroactive claims. So, it's only for those claims that occurred prior to the coverage of hepatitis B vaccine under the compensation program.

Mrs. MINK. So, subsequent to 1988, there are no statutory deadlines. Is that what I'm to understand?

Mr. BALBIER. There are deadlines of 3 years for filing an injury claim from the onset of injury and 2 years from the date of death, if a death is thought to be related to the vaccine, or 4 years from the onset of the injury that led to the death from an injury thought to be——

Dr. SATCHER. We wish to point out, Mr. Chairman, that the Secretary has submitted proposed legislation that would extend some of those times.

Mr. BURTON. Well, I would like to work with you and the Secretary, then, to get that extension passed through the Congress, because, like I said, I'm not sure the American people have really been well informed about that.

Dr. SATCHER. I believe it would extend it to 6 years, right?

Mr. BALBIER. That's correct.

Mr. BURTON. Oh, to 6 years?

Mr. BALBIER. It would double the statute of limitations to 6 years for injury requirements.

Mr. BURTON. That would be even better.

Mr. BALBIER. We have already proposed legislation to do that, and we would like very much to see that happen.

Mr. BURTON. We'll work on that. Would you make sure we do that?

The other things that I wanted to ask you about, do you keep records on people's concerns about the side effects of certain vaccines, like hepatitis B and the DTP shot?

Mr. BALBIER. With the compensation program, itself?

Mr. BURTON. Not necessarily the compensation, but where people are making claims that their child or have been making inquiries about their child being affected, they believe, by the shot.

Mr. BALBIER. We have several ways of tracking that. We have what we call a passive surveillance system, called the Vaccine Adverse Event Reporting System, whereby any provider of the vaccine can report any injury thought to be related to vaccine.

Mr. BURTON. Wait a minute, any provider of the vaccine? You're talking about the pharmaceutical company?

Mr. BALBIER. No, the administrator of the vaccine. That's one way.

Mr. BURTON. Which would be the doctor?

Dr. SATCHER. But, it also could be—it's not limited to the doctor.

Mr. BALBIER. Right. In fact, one of the advantages of the system that was developed, the Vaccine Adverse Event Reporting System, is that it allows anybody to report. The law also requires that physicians give out vaccine information statements to parents before their child is immunized. And on that statement, it gives the parent the number that they can report a case. And that was put in purposely, because some parents were concerned, in the 1980's, that their doctors weren't reporting cases. So, we offer the opportunity for parents to report, as well.

Mr. BURTON. Could we get the statistical data on at least two of those: hepatitis B and the DTP shot?

Dr. SATCHER. There's another point that I think we should probably make and that is the reporting system is one thing. And as you know, there are about 12,000 incidents reported a year. Recently, CDC has initiated what is called the vaccine survey data link. So, we are actually aggressively studying the relationship between the vaccine and adverse events, in about 2 percent of the population?

Dr. ORENSTEIN. It covers about 2 percent of the U.S. population of children. And it allows us to look at when a given illness occurs,

how often it's occurring without vaccination, so that we can compare the two.

Mr. BURTON. If you could provide that information, we would really appreciate it.

Now, regarding anthrax and the anthrax vaccine, we have been told by the General Accounting Office [GAO], in two separate hearings that my colleague, Mr. Shays, held as chairman of that subcommittee——

Mr. SHAYS. Four hearings.

Mr. BURTON. Four hearings, that for 20 years, the person, who was producing this, really wasn't checked thoroughly, as far as the quality control at their facility, I believe it was in Michigan. And when they found out about it, they went up there and checked, and they found that it was way below par and that the serum that was being used, and is still being used, might be, in many cases, tainted. Now, we've had 300,000 people vaccinated in the military with this serum and I just don't understand how we could allow that to happen, if there's some question about the cleanliness of the product, whether or not it might cause side effects simply because it might be tainted and why that product was not inspected more thoroughly over that 20-year period and why the producer of that product is still producing it, to the best of my knowledge.

Dr. SATCHER. I'm going to ask Dr. Kathy Zoon, who is head of the Center for Biologic Evaluation and Research at FDA, to respond. You know that the anthrax program is a DOD program, but your question is still relevant.

Mr. BURTON. I understand. But, I understand that they're talking about expanding the anthrax vaccination program to children. And that troubles me a great deal, because we have had a number of service people, who are not only getting out of the service, but have had severe side effects.

Dr. SATCHER. We have not made that recommendation and that kind of recommendation would come through the Advisory Committee on Immunization Practices.

Mr. BURTON. Well, maybe it was just for military children; I don't know. But, that's what I've been told.

Dr. ZOON. Thank you, Mr. Chairman. I would like to, one, say that vaccine safety to the FDA is extremely important and with any vaccine, including anthrax, there are four levels, in which we oversee the safety. One is through the review of the data that comes in during the development of a vaccine and then data that comes into the agency, as part of the licensure procedure. That is the beginning of the vaccine and the surveillance that FDA does. Subsequently to that, we do inspections of facilities that produce vaccines. And we, also, are involved in release of lot material and review of protocols for lot release before any product can be distributed. And finally, that we are involved with surveillance, which includes the VAER system and work with the CDC very closely on followup.

With respect to your question regarding the facility producing anthrax vaccine, there have been many inspections of that particular facility over the years. On each inspection, not every part of the facility may be inspected completely at each time. However, many of the records are inspected on each of the inspections. And,

in fact, there have been multiple FDA inspectors in the course of the past 10 years in the facility at which you're speaking. So, there has been followup. In addition, FDA reviews all the lot release protocols for this. And right now, the company is not manufacturing and distributing vaccines.

Mr. BURTON. Thank you. I'll followup on that later. Mr. Waxman.

Mr. WAXMAN. Dr. Satcher, you're the head of the Public Health Service, and that Public Health Service in the United States, as I recall, was set up in the last part of the 18th century, 1798. I also recall the reason that we have the Public Health Service in the United States was because of the yellow fever epidemic, which was transmitted by merchant sailors who had wiped out 10 percent of the population of Philadelphia. As a result, we set up the Public Health Service. Isn't that right?

Dr. SATCHER. Yes, an act of Congress, because at that time, as you know, Congress was located in Philadelphia. President John Adams signed the act of Congress in 1798, giving rise to what we then called the Marine Hospital Service to take care of merchant seamen. But, you're absolutely right, it was in 1793 that this yellow fever outbreak hit Philadelphia and it was felt to have been related to merchant seamen, who were going in and out of the country. It was a devastating experience. As you said, it wiped out over 10 percent of the population; 50 percent of the population of Philadelphia fled because of that epidemic.

We were back there last year, in fact, to begin the 200th anniversary celebration of the Public Health Service, because, later, the Marine Hospital Service became the Public Health Service. So, we went back there in July to begin our celebration. And we retraced the trail of the yellow fever epidemic and it was really quite an experience. But, it was this outbreak that gave rise to the Marine Hospital Service, which would later on become the Public Health Service.

Mr. WAXMAN. I think we shouldn't forget history.

Dr. SATCHER. I agree.

Mr. WAXMAN. And I worry sometimes that the successes that the immunization program has brought to this country and to the world might be a victim of the—the program might be a victim of its own success, when people forget about these dreaded diseases——

Dr. SATCHER. Right.

Mr. WAXMAN [continuing]. That still occur. Right now, as a matter of fact, in certain parts of the world, mainly Russia, according to press accounts, there are over 2,000 reported cases of diphtheria since January 1 of this year. Can you explain how existence of a disease in a foreign country, such as diphtheria in Russia, can threaten unvaccinated children in the United States?

Dr. SATCHER. Let me give another example, measles. Virtually all of the cases of measles that we have seen in recent years have been imported. They've come in from other countries and they've led to, in some cases, outbreaks in this country, when they got into a population that was not vaccinated. The risk to the population of people, who take exemptions for vaccinations, the risk of measles is 35 times what it is in the rest of the population and you know less than 1 percent of the population takes advantage of religious

or philosophical exemptions. We're talking 0.64 percent. But even with that small number, there's a 35 time full risk of measles. And most of the measles comes from other countries.

Mr. WAXMAN. So, in the United States, some people don't get vaccinated?

Dr. SATCHER. They take exemption because of religious reasons there are 48 States that allow for religious exemptions, every State except Mississippi and West Virginia.

Mr. WAXMAN. Now, as I understand the chairman's statement, I don't want to attach any policy to it because he has to speak for himself, but it sounds like he and others are saying maybe we ought to leave a choice to everybody, whether they want their kids to be immunized or not. I don't know if that—let me not attribute it to him. Would that make sense as a policy for public health, if we just let people make that choice for themselves?

Dr. SATCHER. I think by definition in public health, we're concerned about the health of the individual; but, we're also concerned about the health of the community, the population. And we make rules to protect the community. In fact, you can't even protect the health of the individual, unless there is a community approach to things like immunization. So, it is true that when we make decisions and recommendations about immunization, we're concerned about the population. That's very basic to public health.

Mr. WAXMAN. What if I say it's my child and I'm willing to take the chance because I heard that there are some adverse reactions. I heard about a congressional hearing that seemed to put a spotlight on those adverse reactions and I don't want to take a chance for my child. My child might be at risk, but am I putting other children at risk?

Dr. SATCHER. Well, no question about it. I mean, when a child is not immunized—and many States, as I said, allow exceptions—exemptions for religious, and then 15 States, I believe, allow philosophical exemptions. But, we know from much of our experience, and certainly Dr. Orenstein can give more details about outbreaks that have occurred in population for religious reason and others that took exception—I respect people's religion if they decide to take an exemption. But, clearly, if States did not have any rules about what it takes to get into school, many more children would be affected by infectious disease outbreaks.

Mr. WAXMAN. Now that means we've got to be sure that these vaccines are as safe as possible. What mechanisms are in place to assure the vaccines are safe?

Dr. SATCHER. Well, there are quite a few of them, and I'll just give an overview. We have a very tight surveillance system. And I believe the most important thing, of course, is what Dr. Zoon said. We take new vaccines through at least four phases. I mean after the animal studies, there's the phase one study, looking at safety in a small number of individuals. Then there's the phase two studies, which look at dose ranges for vaccines. Phase three studies, like the one that they're beginning now in Thailand for HIV vaccine, really implements the vaccines in a larger population of people, who are at great risk for an infectious disease like HIV. And it evaluates what happens, in terms of safety and efficacy. And only after you've been through that does FDA then approve imple-

mentation of that program. And even after that, there's a so-called post marketing phase, in which you really look at what happens when you make this vaccine available to a broader population.

Mr. WAXMAN. That's the Vaccine Adverse Event Reporting System?

Dr. SATCHER. That's right.

Mr. WAXMAN. That's the post-marketing surveillance?

Dr. SATCHER. Post-marketing surveillance is the Vaccine Adverse Event Reporting System, and, in some cases, even some more detail followup. As I mentioned, the Vaccine Safety Datalink, which is primarily with managed care programs, but involves more than 2 percent of the population, looks at these events and sees to what extent they relate to the vaccine.

Mr. WAXMAN. Mr. Chairman, I appreciate getting a little extra time because I want to ask some questions about the Vaccine Compensation Program, which I am proud to have authored, and I also have a conflict because I'm supposed to be at a conference on another piece of legislation. It has nothing to do with anything we're discussing today.

The Vaccine Compensation System was set up to try to make sure that people didn't have to go to court and go through all the expense of litigation in order to be compensated when they had an adverse reaction from vaccines. And I think it's well worthwhile, Mr. Chairman, for us to use our oversight authority to be sure that program is working.

Now, the administration is proposing that there be a lifting of the time limits for people to come in with their claims. Could you tell us about that?

Dr. SATCHER. We have—and I'm going to ask—where is——

Mr. BALBIER. I'm right here.

Dr. SATCHER [continuing]. In terms of how the litigation process has worked and how well it's worked. But, I think what we're concerned about is making it as easy as possible for people to file claims and to report adverse events. So, the Secretary made some proposals—legislative proposals that would make that process much easier than it is now. And I, also, want to say that when in doubt, we try to give the benefit of the doubt to the petitioner.

Mr. WAXMAN. I sure hope so.

Dr. SATCHER. We do. Without question, we do it in this program.

Mr. WAXMAN. Well, we're going to hear testimony contrary to that and I'm concerned about it, because I think we ought to give the benefit of the doubt.

Dr. SATCHER. I think we can demonstrate that. I can give some specific examples, where the Advisory Committee on Childhood Vaccines, made up, in addition to experts, parents of children, who have suffered events, are members of that committee. And there have been times when that committee has used its authority to override other committees, to make sure that we give the benefit of the doubt to the petitioner.

Mr. WAXMAN. I want to get more detail on that and I want to get more for the record. The administration is going to propose some legislation. And if Congress is going to deal with legislation, I think we can recognize the fact that there is a lot of money in that vaccine fund at the present time. Mr. Chairman, maybe one

area where we can work together is to make sure that if there are excess funds, we devote those excess moneys for more vaccine safety research and surveillance.

I don't know if you're in a position to comment on that, because the administration would have to take its position. But do you think that might make some sense?

Dr. SATCHER. Well, obviously, Congress is going to have to make that decision. I believe there is about $1.4 billion in that trust fund now and there have been various proposals suggested. One proposal would reduce the excise tax from 75 cents to 25 cents. Another proposal would be to use money from that fund to fund safety research. And, you know, obviously, I would—I favor vaccine safety research, because I think, as I said in my testimony, we should do everything we can to make vaccines as safe as possible. But, using the trust fund for that purpose is something the Congress must decide.

Mr. WAXMAN. Yes. Now, you get these reports about adverse reactions. What do you do with them? Do you have any examples of where you've gotten the information and have been able to do something to make vaccines safer?

Dr. SATCHER. Tom, I believe that you——

Mr. WAXMAN. Rotavirus is one issue that I've heard about. Can you tell us——

Dr. SATCHER. Oh, yes, no, that's the one, OK.

Dr. ORENSTEIN. I think there are a number of things to evaluate the reports and to take action when action is indicated and to do further research when signals are generated that there may be a problem with vaccine safety. Vaccine safety is absolutely critical to the immunization program.

Rotavirus is probably a very good example, because it's a recent example, in which a signal was generated about potential intestinal blockage in children younger than the usual age at which the blockage would have occurred in the absence of vaccine. Because of that, we did two things. It was such a strong signal, and combined with other data we had, that we recommended a postponement to vaccination, at least until November, so we could clarify whether, indeed, rotavirus is causing intestinal obstruction or not. And we are in the process of undertaking a major national study to evaluate that.

There are other signals that have been suggested in the Vaccine Adverse Event Reporting System, such as the relationship of Guillian-Barré Syndrome, a paralytic illness with influenza vaccine. We undertook research to look at that, which suggested that about once in a million doses of influenza vaccine, there could be a problem. There is continuous monitoring. The FDA looks at death reports. It looks at clinical reports. There are meetings regularly with FDA and CDC in order to try to take a comprehensive look at vaccine safety.

Mr. WAXMAN. Let me say if in rare cases there is an adverse reaction, we ought to compensate the victim as best we can for that adverse reaction. But I don't want this country to become lax in the area of vaccinating our kids, because I don't want these diseases to come back and I don't want people looking at a hearing like this

and thinking, oh my gosh, more people are hurt than helped when the child's immunized.

Because that isn't any cost benefit evaluation—we always hear we ought to have cost benefit evaluation—but the benefits outweigh the costs enormously to have our children immunized. Do you agree with that?

Dr. SATCHER. Well, a good example is just the followup on what Dr. Orenstein just said about the one in a million risk of Guillian-Barré Syndrome for influenza. The risk of hospitalization from getting the disease influenza ranges from 200 to 1,000 times that. That's the risk of not just having influenza but having to be hospitalized with influenza. It's 1,000 times greater than the risk of getting Guillian-Barré Syndrome.

Mr. BURTON. Thank you again, and let me just apologize to you for trying to impute some views. I don't know what your views are on the subject so I should not have asked the question in that way.

Mr. SHAYS. Thank you.

Mr. BURTON. But I appreciated the witnesses answering the question.

Mr. SHAYS. Thank you, Dr. Satcher, and your staff for being here. We are not looking at the issue of vaccines for children right now, but my subcommittee is looking at the issue of whether we should have a mandatory program for our military personnel to protect against various biological agents; one is anthrax. But there are many others, and there are questions of different types of anthrax and which you should be protected from. I'm going to focus more on that, and I'm just going to accept as a fact that besides just teaching general cleanliness, which has probably done a world of difference to society, vaccines have been second only to that in terms of their benefit to society.

And so I don't know if this would be Dr. Zoon or anyone else, but I will ask you and you can defer. How long might it take to review and approve a new recombinant vaccine against anthrax? How long would it take, or should it take?

Dr. ZOON. If a biologic license application came in and it was evaluated that a new recombinant anthrax vaccine would presumably be a priority for the FDA, which would probably mean we would review the application within 6 months.

Mr. SHAYS. But overall, from start to the end, review an application, so much more, would have to go in before they could make that application.

Dr. ZOON. Yes.

Mr. SHAYS. What's the sense of the total—it would just take you 6 months, or it would take the Government 6 months, but in addition——

Dr. ZOON. I think you're asking about the development time?

Mr. SHAYS. Right.

Dr. ZOON. Is that correct?

Mr. SHAYS. Yes, ma'am.

Dr. ZOON. Yes. It varies for a product how long it can take under development. And presumably, once you've discovered it through the time it has all the pre-clinical information, manufacturing information, and clinical information can vary in the timeframe. Gen-

erally, the shortest timeframe to collect all that information is 2 years, and sometimes it can take much longer.

Mr. SHAYS. What kind of data would FDA require to demonstrate efficacy of a new anthrax vaccine against aerosol challenges in humans?

Dr. ZOON. At this point in time, there are a number of different opportunities and models that we would look at for both pre-clinical data and data in humans. Because of the seriousness and the ethics involved with doing a challenge study with anthrax, clearly that would not be possible. Also, the incidence of anthrax in the United States is very, very low and therefore a natural history could not be done. What could be, what we would have to look at would be several things, and this is not all-inclusive, but just to give you some sense is, we'd look at pre-clinical data, animal model data, looking at challenge data in good animal models. We'd also look at safety data in humans and we'd look at immunogenicity data in humans as a start.

Mr. SHAYS. Which leads to the question, what is the status of the FDA regulations on correlating the data on animal immune response to the likely response in humans?

Dr. ZOON. My understanding, there is a proposed regulation that has been drafted. I am not certain as to the status of it right now.

Mr. SHAYS. And finally, of the most widely discussed biological warfare agents, one is smallpox, another is anthrax, another is the plague. Now there's botulism, glanders and others. How many do we have vaccines against?

Dr. ZOON. Currently there is a licensed smallpox vaccine, of which there is limited quantity. There's one licensed anthrax vaccine.

I thought they—I'd have to get back to you on the rest, sir, because I'm not 100 percent sure.

Mr. SHAYS. But clearly one of the challenges we have is developing vaccines. The military is talking about ultimately vaccinating for a good number of perceived potential attacks against our military. The challenge that we are going to have, it seems to me, is developing a vaccine that we think will do the job given the challenge of how you test it. And it will be interesting to see how you all weigh in on this, because that's the direction our military's going in and it raises gigantic questions. Thank you.

Mr. BURTON. If the gentleman would yield. I think a lot of people who are paying attention to this discussion right now might not understand what kind of questions you're asking, in layman's terms. So I'd just like to clarify a couple of things. As I understand it right now, the anthrax vaccine has been proven effective to a degree against the kind of anthrax that is communicated through the skin and through touching. As far as anthrax being communicated through an aerosol or through a missile that would explode and spray anthrax into the atmosphere where people would breathe it, it has not been proven effective in that. As a matter of fact there was one test, as I understand it, or one case where they had given people the anthrax vaccine in a farm environment, where five people died who inhaled the anthrax bacteria. The thing that a lot of people in the military would like to know is, does the anthrax vaccine work against an aerosol or an aerosol-type dispensing of this,

this dread disease? And along with that, if it doesn't—because the most likely way that an enemy would try to attack the U.S. military operation would be through an aerosol-spread bacteria—why are we using this vaccine? If it's not effective against that, and that's the most likely way that an enemy would attack us with it, why are we using that vaccine and mandating it right now?

Dr. SATCHER. I don't think we're going to try to answer that because—I think it's a very good question, but I think——

Mr. BURTON. It needs to be answered because 300,000 of our troops have been vaccinated, and right now, according to what I've been able to understand, it isn't going to protect them if an aerosol attack with anthrax ensues.

Dr. SATCHER. I just mentioned the question of why because the Department of Defense obviously has risk information that we don't have in terms of terrorism. We can answer the other question you raised. But if you say, why, the Department of Defense made the decision; they certainly have security information that we don't have about the risk that we're facing. And they make decisions based on that. We can answer the question about the relative risk.

Dr. ZOON. Yes, Mr. Chairman——

Mr. BURTON. Would the gentleman yield? Just to clarify the information being provided. If you could, and National Security, Veteran's Affairs, and International Relations Subcommittee would love the answer to the question that you said you would get back to us on. I'm going to have my staff followup on that, so it would be helpful. You may answer, then I'll yield to Mr. Davis. Thank you, Mr. Davis.

Dr. ZOON. Thank you, Mr. Chairman. There is, while be it limited data looking at the ability of the current anthrax, licensed anthrax vaccine to be protective of inhalation anthrax, you are very right, sir, that the primary incidence of the disease in the mills where the study was done on the original anthrax was cutaneous, or skin. However, there were five cases of inhalation anthrax. And when the data was looked at, four of these five cases were fatal cases. When the data was looked at this single-blinded control study, it was discovered that of those deaths from inhalation anthrax, two were in the placebo group and three were in the unvaccinated group, and zero were in the vaccinated group.

Mr. BURTON. So you have none that were vaccinated, that you can tell one way or the other about the aerosol.

Dr. ZOON. Well, in fact, those people that were vaccinated did not have any cases of inhalation anthrax.

Mr. BURTON. So using deductive reasoning, you say it was effective against that?

Dr. ZOON. Within that limited data base, for that study, we have that information, which would suggest some protection against inhalation anthrax. Subsequently, studies were done in a primate model looking at protection challenge studies that were done by Dr. Ivens. And this was a study where they used a spore challenge in rhesus monkeys. And it was shown to protect against the aerosol challenge.

Mr. BURTON. Mr. Davis.

Mr. DAVIS. Thank you very much, Mr. Chairman. Dr. Satcher, let me thank you for your testimony, and also the advances that I

think we're making in public health under your leadership and with the assistance of your team. I agree that the greatest weapon we have, the greatest defense that we have against childhood diseases are vaccinations. According to Evan, Rachel, Brian, David, Katie, Tim, Catherine and Natalie, these are all children who live in Illinois, whose vaccinations produced terribly devastating results for them. They are children who cannot walk, children who cannot play, and they're children whose parents believe that their conditions were caused by their vaccinations. In addition to that, there is a group in my community headed by a woman named Barbara Mallarky, who is the spokesperson for the Illinois Coalition for Vaccine Awareness and a health activist who lives in my community. I see her quite frequently. She believes that strong anecdotal evidence suggests that children are being adversely affected by vaccinations, especially hepatitis B. My question is, what can we tell the parents of these children, and what can I tell Ms. Mallarky and her group?

Dr. SATCHER. Thank you, Congressman Davis. And I appreciate your background in public health, too, so I know I don't have to tell you how we go about making decisions and the struggles that we go through. There are a few issues involved here. And the first one, of course, is that there are adverse events that occur from vaccines. They are very rare. They don't compare with the benefits, but—they are very rare, but they are very significant for the people who are affected. That's the first thing, and we are determined to reduce adverse events to as near zero as possible. The other thing, of course, is that it is sometimes difficult for us to determine when an event occurs temporally related to vaccines, that the vaccine caused the event. And the only way we can determine that to the best of our ability is to investigate. That's why we have a system that allows those kinds of investigations to take place. People can petition, and in many cases it has been found—I believe there have been 1,400 families who have received a little over $1 billion from the system, because they filed complaints about injuries that occurred. I don't believe it is possible to compensate people adequately for the kind of thing that we're talking about. But there is a system set up to investigate and to determine the likelihood that an adverse event was due to the vaccine. And if it is determined that it was, we have a system to attempt to provide some compensation. So the system, I think, is there. The most important system is the one in which we are working night and day to continue to improve safety.

Mr. DAVIS. So I can assure them that the Public Health Service is doing everything in its power to continue with the research, to investigate, to try and reduce as near to zero as we can, these situations that may occur.

The other question that, that I'd like to ask—we have the injury compensation program, which is publicly funded. Are there any liabilities for the manufacturers of the vaccinations that we use?

Mr. BALBIER. If a petitioner under the program chooses to reject an award or is unsuccessful in obtaining an award, that individual may then sue the manufacturer. So the program is not an absolute protection of the manufacturers by any means.

Mr. DAVIS. So it is the first line of defense for the consumer. Then if people are not satisfied, they can go beyond that in terms of seeking redress.

Dr. SATCHER. That is correct. But there is a very important point here, and I don't know if we've made it yet. Part of the value of this program—sort of a no-fault, where the Government takes responsibility—is that we have been concerned and are concerned that manufacturers are willing to continue to take the risk to develop vaccines. We have been successful in developing effective vaccines because there is a program like this available in which we share the risk of vaccines.

Mr. BENOR. Absolutely.

Dr. SATCHER. I think one of the major benefits of this program is that manufacturers are encouraged to continue to do research. And as Dr. Zoon described, it's an odious process of bringing a vaccine to market.

Mr. DAVIS. So you're really saying that we are co-partners in a way, in trying to make sure that we have available to us the, the medicines or the pharmaceuticals that are needed to address some of the problems. Well, I appreciate that. And let me, Mr. Chairman, thank you, and also just say that, I have studied the public health system for a long time and I can tell you it is so refreshing to see that we are moving toward a public health modality in terms of really trying to move beyond just the individual protections, to the point of protecting our communities, our cities, our States, and indeed our Nation. I thank you very much.

Mr. BURTON. Before I yield to my colleague, let me just say that we should be concerned about the public health and public welfare. But our country was set up in such a way as to try to maximize the protection of the individual as well. And that's why, one of the reasons we're having this hearing today, because we want to make absolutely sure that people are getting as much information as possible about these vaccines and the possible side affects. Now I don't want to prolong this because I want to yield to my colleague. But my granddaughter had a hepatitis B shot, and within 12 hours, she was in intensive care; she couldn't breathe. One of my daughter's best friends is in the audience, and her child had a hepatitis B shot and died. Now that's 2 people that I know personally. Now this may just be a coincidence, but if those kinds of side-effects occur, then we need to know why. We need to be able to inform people across this country of the risk. Maybe we're giving too many shots in too short a period of time. Maybe, unlike Japan, we're not checking the immune systems of children before we give the shots. Do we check the number of the antibodies? Do we check these really thoroughly before we give our children shots, or do we just indiscriminately give them shots? Twenty-one shots before they're 6 years old. Can their little immune systems stand that much onslaught? Those are the questions that need to be answered. But I know that in my family, I've got an autistic grandchild—out of two grandchildren, one's autistic, the other almost died from the hepatitis B shot, and one of her best friend's child did die from a hepatitis B shot. Now you can call that coincidence if you want to. I kind of think it's more than coincidence. That's why we're having this hearing—not that we don't want to vaccinate, but we need to

have an informed population to make sure that parents, while conforming to the rules of society to make sure that the whole population is safe, protects their family and their children as well.

Dr. SATCHER. Chairman Burton, let me just say I agree with you. I think this is a very important hearing. I can't think of any hearing that could be more important. So there's no question in my mind about the importance of this hearing and the importance of this issue.

Mr. BURTON. I look forward to working with you, Doctor.

Dr. SATCHER. We want safe vaccines.

Mr. BURTON. I think you're a sincere fellow, and from what I can tell, you've done a good job. Of course, I'm a layman; I'm not a doctor. [Laughter.]

Mr. MICA. Thank you, Mr. Chairman, Dr. Satcher. I have a couple of questions. In January I took over a subcommittee that deals with the oversight of HHS and was immediately deluged by people contacting our subcommittee about the need for oversight of some of the vaccine programs, particularly hepatitis B. We did some studies and investigation, and we conducted a hearing on May 18. I'm pleased that you, and the administration, shortly thereafter have taken some actions. You told us today that you have several actions which you are recommending. One is lifting of the time limits; two, I heard about dollars for research—two items that were raised at our hearing. Could you tell me about the specifics of lifting the time limits, what this involves? And then, we now have $1.3 billion in the fund. Are we talking about taking money out of that for additional research purposes?

Dr. SATCHER. To respond to your last question, we don't have the authority to do that. Any use of those funds other than——

Mr. MICA. Oh, I know. But you're recommending to Congress that we change the law to give you the authority, but to what degree?

Dr. SATCHER. Well, I'm not sure we have made that specific legislative recommendation.

Mr. MICA. You don't have a specific legislative proposal.

Dr. SATCHER. No, we don't.

Mr. MICA. When can we expect that?

Dr. SATCHER. I hate to try to make predictions—because it's been discussed between the administration and Congress.

Mr. MICA. Can we get a recommendation from you, say by September since we're well into the 106th session? We're going to do a hearing on the compensation fund because it's been brought to light that there were problems, and this is the first time that I've heard of the administration's proposal in this regard. Maybe sometime in September, could we get that?

Dr. SATCHER. Let me say there exists now a set of legislative recommendations from Secretary Shalala to Congress about how to improve this system to improve the benefits to people who are adversely affected by vaccines. Those are in place now. I don't want to say exactly when the administration will submit other proposals because I don't know.

Mr. MICA. Well, maybe we can work with you.

Dr. SATCHER. Yes.

Mr. MICA. One of the things that also came out in the hearing is the frustration with the compensation and that the average length of time to go through the process is 2 years. That's average length, and many of these take more time. Do you know if you have any recommendation about how to deal with speeding up that process for compensation?

Dr. SATCHER. I'm going to ask the attorney but—let me just say, there are times when we compare this system to the regular tort system. As you know, it's been much more efficient, but still we're not satisfied with it—but it's much more efficient than the——

Mr. MICA. Then that would be one area too we'd like to—if we don't have a recommendation. I have a press account that says, that relates to a surprise announcement. It says, a surprise announcement late yesterday. And this was a change in policy relating to mandatory vaccination of children with hepatitis B vaccine. It says, the surprise announcement came late yesterday afternoon, just 7 weeks after a May 18th hearing on the safety of hepatitis B vaccine. The vaccine policies in the U.S. House—our subcommittee conducted—brought out problems with that. And I guess the announcement related to eliminating mercury content in hepatitis B vaccine. It was a joint announcement by the Public Health Service, your folks, and the Academy of Pediatrics. OK. Our hearing was May 18th. When did you have the first information that there might have been a problem relating to the mercury content? Was that after our May 18th hearing and before your announcement, or before our hearing?

Dr. SATCHER. I can speak to that from the Public Health Service. I was involved in that announcement with the American Academy of Pediatrics, and the announcement was to give pediatricians and parents more flexibility in terms of implementing the hepatitis B vaccine.

Mr. MICA. What I'm interested in, I want to know when you had the information. When did you know——

Dr. SATCHER. I'm going to get to—Dr. Zoon——

Mr. MICA. And was that in your possession before the hearing that we held, or did they come to you after the hearing that we held?

Dr. SATCHER. It was after the hearing that you held.

Mr. MICA. It was.

Dr. SATCHER. In fact, it came to my attention, it came, I believe, less than a week before we made the decision. We—and this included the American Academy of Pediatrics. Now there have been some studies in other countries about thimerasol and its effect. But in terms of FDA looking and getting reports from manufacturers in this country, and the information coming to us, it was a few days or weeks before—Dr. Zoon, do you want to comment?

Mr. MICA. Would you supply the committee and the subcommittee with any communications you had, all communications you had, relating to this particular matter, say, in the last year? Would that be possible?

Dr. ZOON. Yes. Certainly we can provide you—would you like me to give you some background, sir, or would you just like it for the record?

Mr. MICA. I'd just, I'd like to have the information for the record.

Dr. SATCHER. We can say more about that if you'd like.

Mr. MICA. The last thing—and my time is about up. You are the Surgeon General, the Chief Health Officer of the United States, and I noticed an article that was included here. I don't know if you gave it to us or if it was provided in our packet. But you talk quite a bit about some health issues, particularly smoking, excess, not eating enough vegetables, and not exercising. I chair the Criminal Justice, Drug Policy, and Human Resources Subcommittee, and our concern is, of 14,000 young people and others die every year in drug related deaths.

Dr. SATCHER. Would you like for me to read the Surgeon General's prescription?

Mr. MICA. No. But I just——

Dr. SATCHER. It, includes advice against the use of drugs.

Mr. MICA. Yes, but again, I noticed this. I think you threw away your pipe to set an example.

Dr. SATCHER. That's a good article.

Mr. MICA. My concern is, having survived one of your predecessors, the infamous Jocelyn Elders, that she sent the wrong message out on drugs. And that, to me, is our biggest social and societal problem, with 2 million Americans behind bars, 70 percent of them because of drug-related offenses, and with skyrocketing teen addiction rates and usage rates. Since this administration has taken office—again, people have to look up to folks. And you, as the Chief Health Officer, I would hope, would give us every bit of support relating to hard narcotics—heroin, cocaine, and the methamphetamine addiction that we're facing. I count on you for that.

Dr. SATCHER. Yes, you can. But I would also like to just say that I believe that the program that General McCaffrey is running, dealing with the use of illicit drugs, is the most aggressive in the history of this country, and we're seeing results.

Mr. MICA. That's only as a result of the predecessor to Mr. Shays' subcommittee, Mr. Hatcher, who came forward to lead the subcommittee and restore the funds and——

Dr. SATCHER. I will be willing to give credit to as many people as possible.

Mr. MICA. Thank you.

Dr. SATCHER. I'm just happy to see that the program is working.

Mr. MICA. But we need you; you're our chief health spokesperson.

Mr. BURTON. The gentleman's time has expired. Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman and Dr. Satcher. It's a pleasure to meet you. As a new Member of Congress, and someone who comes from a State legislature where we have had to make decisions about mandatory vaccination programs, I've been a supporter of those because I think, as we look around at the chief reasons that we've been able to extend life expectancy and improve the general health of our population, that one of the chief public health strategies has been these vaccination programs for polio and rubella and smallpox, et cetera. But I am concerned because under the strong leadership of my subcommittee chairman, Mr. Shays, I have been hearing a lot about the anthrax vaccine. And one of the things that came up is that there was very little research done on the different reactions that women may have to vaccines, that

there's a different kind of immune system. And I'm wondering if there are gender-difference studies that are required, and if you're aware of this?

Dr. SATCHER. Let's ask Dr. Zoon from FDA.

Dr. ZOON. The original anthrax vaccine, which is the licensed vaccine we have today, was licensed back in 1970. And at that time there were not guidance documents available in general on inclusion of different populations. Subsequent to that though, there are guidances now that the FDA issues in drug development on the inclusion of different populations, of which women are a significant population. So I think that I cannot give you the breakdown of male and female that were in the original trial, and in fact, we had tried to go back and find some of those data, and they're not as easy to find in terms of the way they were recorded, based on the participants in those studies. But I think I would like to assure that right now, the information we do gather on vaccines do include different populations.

Ms. SCHAKOWSKY. Well, let me ask you then about another population, which is hyper-reactors. That came up also in the anthrax discussions. And it may refer back to what the chairman was asking, that there are individuals whose bodies do produce adequate immune response with a lower dosage, for whom a higher dosage may pose a real problem. Is there any way to identify these individuals and provide alternative vaccination schedules or lower doses, et cetera, so that in the future we may be able to avoid some of these adverse reactions?

Dr. ZOON. In vaccine and other product development that is done today, there are—as Dr. Satcher alluded to in phase II studies of clinical development, these are generally dose ranging studies, where they look at the immune response, immunogenicity, as well as safety. I would have to go back to look at those original data, and I'm not sure that all that data would be available from the old studies, because those were done in the 1950's.

Ms. SCHAKOWSKY. Well, it seems to me that might be a direction that we need to go in.

Dr. SATCHER. Let me just say that's a very important question, and it is a very important subject of research. We need to be able to better predict how individuals will react to a vaccine much better than we can now. Now in the other medications too, I think you're right—Chairman Burton's example sounded like an anaphylactic-type reaction. I wouldn't know, unless I had the records, but that's what it sounded like. A very dangerous reaction; they can occur with any medication. I've seen them occur with the dye used for renal tests, and people can go into anaphylactic reaction soon after being exposed. We need better ways to predict who will respond in different ways to vaccines and different medications than we have now. That research has to continue.

Ms. SCHAKOWSKY. One other line of questions—let me just ask them, and then you can respond. The VAERS system, which is really a rather passive system of reporting adverse reactions—there were a lot of reasons again, in hearing the anthrax debate and testimony, to doubt the system, not the least of which was, it seemed some people from the Department of Defense were discouraged, some of the people in the Armed Services were discouraged

from making those reports. But in a broader sense, how satisfied do you feel that we're getting an adequate representation? Some have projected maybe we only hear about 1 in 10 adverse reactions. And I wonder if you have thought about ways that we can improve the VAERS system so it's more useful to us in making these important decisions.

Dr. SATCHER. Dr. Orenstein of CDC is here.

Dr. ORENSTEIN. Thank you very much. The VAERS system is really our warning system for problems. It generally can be very helpful, particularly at finding serious problems. The reporting efficiency of VAERS, which is what you're getting at, is how often are events reported. This varies with the severity of the reports. We find, for example, with regard to vaccine-associated polio that about 70 percent or so of the cases that are known get reported to VAERS. With regard to other serious events like seizures, we generally see about 25 to 40 percent of what we would expect to be reported. When we deal with more mild events, or events that require, let's say, a laboratory test to document an abnormality, the reporting efficiency goes down substantially. But it's very difficult with any passive system to get a feel for how much is out there and whether it's causing something, because many of the illnesses that occur after vaccination also occur in the absence of vaccination. For example, in 1990, there were over 5,000 deaths from Sudden Infant Death Syndrome—children who died from Sudden Infant Death Syndrome, children who were well, most of them, and then were found as crib deaths, or may have had some mild illness beforehand. We would expect when we vaccinate large numbers of children—and we're talking about a birth cohort of 4 million children—that you're going to get deaths after vaccination. The real issue is, is the clinical syndrome different, or is it occurring more frequently than expected? And that's when we use our Vaccine Safety Datalink. The Vaccine Safety Datalink is a project where we fund independent researchers in 4 large managed-care organizations, in the Western United States, who have access to all of the medical records, so they can determine the expected incidence in the absence of vaccination to compare with the incidence in the presence of vaccination. We need to do more with VAERS. And I think that we are not satisfied with where VAERS is. Each year we send out a letter to 200,000 individuals to encourage reporting to VAERS. We've put in our standards for pediatric immunization practices that we want reported to VAERS, serious events even if you don't think that it's related to vaccination. We've done a lot; we need to do more. And I think that what you're pointing out is some of the weaknesses to VAERS.

Mr. BURTON. The gentlelady's time's expired.

Mr. WELDON. Thank you, Mr. Chairman. I want to thank you for extending an invitation to me, and I want to thank the ranking member for withdrawing his objection.

[The prepared statement of Hon. Dave Weldon follows:]

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Opening Statement of Rep. Dave Weldon

Committee on Government Reform

I appreciate Chairman Burton calling this very important hearing. As a physician I am very grateful for his invitation to join the committee today to discuss this important public health issue.

As a physician, I understand the importance of vaccination in providing our children protection from the ravages of diseases that are foreign to many of us here in this room today. Certainly, all of us in this room can agree that vaccinations our children receive are preferable to leaving our children exposed to the diseases themselves.

In recent years, however, there has been an increase in public concern about the safety of some vaccines. Indeed some parents are refusing to have their children vaccinated because of their concerns about side effects associated with some vaccines. The Congress has a responsibility to ensure that our vaccines are as safe as they can possibly be. I believe that this hearing today will help us explore the safety of vaccines and help us emphasize to the public that vaccine safety is a priority with the Congress.

It is very appropriate and timely that the Committee would hold this hearing today.

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Mr. WELDON. I certainly want to thank you, Mr. Surgeon General, for your testimony. I know some of the people who are joining you there have been in my office to talk about these issues. And I want the record to reflect that I am a strong supporter of vaccination; that I vaccinated my patients according to CDC recommendations when I was practicing. But I'd like the record also to reflect that there is an increasingly growing level of public concern about the safety of our vaccines, and therefore I think it's extremely important that this issue be aired before the Congress. And if the light of scrutiny makes a determination that the system is safe, then we have the ability to broadcast that information to the public. And as well, if there are areas that need to be investigated further, we have the ability to appropriate the funds necessary to make sure the appropriate studies are done. I'd just like to start off with a couple of questions I have about the hepatitis B vaccine, the decision to recommend that for all newborns. My understanding of the transmission of hepatitis B is obviously it can be done through blood-borne contamination, through transfusions or infected needles, but as well through the route of sexual transmission. And indeed it's the sexually transmitted route that's deemed to be the most rapidly increasing segment of that problem. Am I correct in my understanding of this disease?

Dr. ORENSTEIN. The known modes of transmission are the ones that you have mentioned. Clearly, there has been much greater recognition of transmission among heterosexuals because, with regard to multiple sex partners. And that has accounted for a substantial proportion of hepatitis B cases. On the other hand, there are cases that we are not getting any, any history of any of these known risk factors for transmission. We presume in some way that they've been exposed, to either blood on abraded skin, a bite, or some other means. But there are these 25 to 30 percent of cases in which, at least, there is no admitted risk factor for transmission.

Mr. WELDON. How did hepatitis B compare to some of the other diseases where decisions were made to inoculate the whole population in terms of its incidence, as compared to polio, pertussis—I realize hepatitis B is a very serious illness and it costs a tremendous amount of money. But did the cost benefit analysis of this disease include the consideration that it's obviously different? The point I really am curious about is, being that a major mode of transmission is sexual transmission, we have never proposed inoculating the whole population for a sexually transmitted disease, am I correct?

Dr. ORENSTEIN. I'm not aware of anything where we've recommended the whole population be vaccinated for a sexually transmitted disease. But clearly this has more—sexual transmission is very important and I don't want to minimize that, but it's not the sole way of transmitting it.

Mr. WELDON. Do you know what percentage is through sexual transmission, or could you speculate?

Dr. ORENSTEIN. I could get that data for you, for the record—a substantial proportion.

Dr. SATCHER. Let me just say one other thing. The process by which we decide to initiate an immunization program for any given agent is a very interesting and open process, as you probably know.

The Advisory Committee on Immunization Practices is widely publicized. It includes experts from clinical practice, research——

Mr. WELDON. I assume the American Academy of Pediatrics as well.

Dr. SATCHER. Yes. Very important representation from AAP and the American Academy of Family Physicians. But it's a very good question. They debated extensively before recommending.

Mr. WELDON. I'm running out of time. The context of my concern is, it's three more shots, and one of the complaints is, it's getting to be a lot of shots. I think we have to address those issues.

Dr. SATCHER. Right.

Mr. WELDON. I have a couple of other questions that maybe you can, you may just need to supply for the record. One is, if you can supply for the record the studies that are currently being done through CDC and NIH on vaccine-related side effects. I know there's—and as I said, some of you have come in the office and talked to me and there's a lot going on. But I think it would be important for us to have that for the record. And the other question I had was, is a legislative fix going to be needed if you're going to use the vaccination compensation fund to fund research studies? Because I know there's some discussion of that. And is that allowed under current law?

Dr. SATCHER. My understanding is that it would require an act——

Mr. WELDON. An act of Congress.

Mr. BENOR. Yes, I can confirm that.

Dr. ORENSTEIN. Can I answer your other question that we never answered, and that is to put hepatitis B in perspective with some of the other vaccine-preventable diseases? We estimate that about 4,000 to 5,000 persons die each year from hepatitis B related liver cancer and hepatitis B related cirrhosis. If we compare that to measles in the pre-vaccine era, there were about 400 to 500 deaths from measles. If we compare it with haemophilus influenza type B, which is a severe cause of meningitis, we estimated that it was about 400 to 500 deaths. So hepatitis B, when you look at the long-term consequences, was one of the most severe of the vaccine-preventable diseases.

Dr. SATCHER. If you have time, Dr. Regina Rabinovich from NIH can respond to your other question about research.

Mr. BURTON. We'll let her answer and then we'll go to Mr. Cummings.

Dr. RABINOVICH. Your question, I believe, related to the research that's ongoing looking at vaccine-adverse events. And I think that I'd have to emphasize that looking at all aspects of vaccine safety begin with evaluation of pre-clinical data prior to going to, and deciding that there's enough safety data to go into your first phase I study in humans. The NIH conducts a broad program of clinical research in the number of different candidate vaccines, and for every study, safety is integral to that evaluation. And that is particularly true of the phase I studies, where it it's the first time that it goes into humans, as well as the phase III trials where you can really get more information in larger numbers of the target population.

Mr. BURTON. Thank you. The gentleman's time has expired. Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. I want to thank all of you for being here. In Baltimore we have probably one of the most effective immunization programs in the country. It is patterned after, as I understand it, the method of getting people vaccinated in Third World countries. I don't know if any of you are familiar with it?

Dr. SATCHER. Yes.

Mr. CUMMINGS. You, Dr. Satcher?

Dr. SATCHER. Yes.

Mr. CUMMINGS. Is that done other places also?

Dr. SATCHER. Well, let me just say in terms of Third World countries, we've made a lot of progress in recent years working with the World Health Organization. And among other things, coming up with schedules, but also implementing national immunization days. I was in India on December 7, 1996, when we immunized 120 million children in 1 day against polio. We've used strategies like that, which we don't have to use in this country because of ongoing programs. But in those countries because of where they were, we had to. And that's why we're very close to eradicating polio. I know CDC has funded Baltimore directly. It's one of those cities we funded directly, and not through the States, to develop exemplary immunization programs. And I agree, that program there has included a variety of strategies to get children immunized that have been very effective.

Mr. CUMMINGS. It's my understanding the hepatitis B is a blood-borne disease. How do children transmit it? Young children?

Dr. ORENSTEIN. You're absolutely correct. It is a blood-borne disease. It is in the blood; it can be in other body fluids. It's in a low amount in saliva. The presumption for childhood transmission is, one, there is transmission from mother to affected baby if the mother is a chronic carrier. Aside from that, we think it may be perhaps from sharing washcloths with abraded skin; bites that might occur that would break the skin; children with rashes who might be exposed to someone bleeding. It's not really clear how it's happening; we just know it is happening in young children. And about 10 percent of the infections overall are occurring by 9 years of age, about 6 percent of those with no known risk factors.

Mr. CUMMINGS. Say that last sentence again.

Dr. ORENSTEIN. We estimate that about 6 percent of all of the infections that occur with hepatitis B annually would occur without a vaccination program, occur with children with no known risk factors. That includes, that's primarily in Caucasian and African American children.

Mr. CUMMINGS. So a universal vaccination for infants against hepatitis B is very important, is that correct?

Dr. ORENSTEIN. Universal vaccination of infants for hepatitis B is important to protect them both from infection in early childhood as well as from infection later in life. The risk of infections are different when you get them. If you get infected as an infant, one, you're likely to have no symptoms at all. You're likely to never know you were infected. And you have a 90 percent chance of becoming a chronic carrier. And about a quarter of those go on to de-

velop either liver cancer or cirrhosis of the liver 20 to 40 years or so afterwards, and they may never know how they got it. So we vaccinate them because the risk of the consequences of hepatitis B is much more severe, the younger you are. Contrast that with an adult. An adult who gets infected with hepatitis B, they have only a 6 to 10 percent chance of becoming a chronic carrier. About more than one-third of all chronic carriers in the United States are believed to be from childhood infections.

Mr. CUMMINGS. Dr.—I'm sorry, I forgot your name. Next to——

Dr. SATCHER. Dr. Rabinovich.

Mr. CUMMINGS. Yes—you were shaking your head. Did you have something?

Dr. RABINOVICH. No, I agree that those figures indicate that hepatitis B is an important disease to prevent and that children are at particular risk.

Mr. CUMMINGS. Have there been any published peer review studies that show a link between hepatitis B vaccine and conditions such as multiple sclerosis and SIDS?

Dr. ORENSTEIN. There have been case reports that have suggested that this is a possibility, and that's why we are doing more comprehensive research. The people who are developing these illnesses after vaccination have very, very severe illnesses; there's no question that these are terrible tragedies. The problem is that there are people who develop these same kinds of tragedies, these same kinds of illnesses in the absence of vaccination. And that's why we're engaged, we and others are engaged in substantial research to try and see whether the vaccine increases the risk over what would be expected.

Dr. SATCHER. It's important to point out, as Dr. Orenstein said, "and others," because it's not just the Government. The Institute of Medicine has been one of the major players in looking at these relationships between adverse events and vaccines. And a lot of the information has been reviewed thoroughly by the Institute of Medicine, as well as the Advisory Committee that we relate to. So it's not just those of us within government looking at this. Congress often relies upon the Institute of Medicine and other agencies—the National Academy of Sciences, which the Institute of Medicine is a part of—for independent reviews of issues like this. And we have a lot of reviews from the Institute of Medicine.

Mr. CUMMINGS. My time has run out. Thank you.

Mr. BURTON. Thank you, Mr. Cummings. Mrs. Biggert.

Mrs. BIGGERT. Thank you for having this hearing. Many of those who have been concerned regarding mandatory vaccinations would like to see the States and/or the Federal Government do more in the area of advised consent. I would just like to know from the panel how you would define "advised consent?"

Dr. SATCHER. You mean informed consent.

Mrs. BIGGERT. Well, it's called "advised consent," but it would be "informed consent," whether parents should make up their mind whether to have such a vaccination.

Dr. SATCHER. Oh, yes. I'm sorry. So you're talking about a parent having the choice and obviously having the information to make that choice.

Mrs. BIGGERT. Right.

Dr. SATCHER. Well, I think as we said earlier, the whole issue of immunizations are looked upon both from the standpoint of benefits to the individual, but also benefits to the community. And as you know, the requirement for immunizations are at the State level. But 48 States allow religious exemptions; 15 States allow philosophical exemptions. In all of those States, less than 1 percent of parents decide not to have their children immunized when they have those exemptions. So decisions are being made—but religious and philosophical exemptions are a very small percentage. But States have a responsibility to protect children in schools. And therefore, the requirements for immunization, in the absence of religious or philosophical exemptions, are based on the desire to protect the entire community, not just the individual.

Mrs. BIGGERT. What I'm asking is, what action has CDC taken to improve the accuracy of information relating to the adverse impacts of a vaccination? Is that given to, to parents, or——

Dr. SATCHER. Yes.

Mrs. BIGGERT [continuing]. Do you have an information campaign really targeted both to doctors and to prospective patients?

Dr. ORENSTEIN. CDC believes very strongly in the need to provide information to parents. We've done a lot. I think we need to do more. I think it's very clear that the information isn't always getting out. We helped develop a vaccine information statement that is required, actually by law, to be given to children for vaccination, if they receive a vaccine covered by the injury compensation program, which contains information on the risks of disease, the complications from disease, known risks, scientifically accepted risks from vaccines. It tells them about the compensation program; it tells them how to report adverse events; who might be at risk for these complications where it is known. And we distribute them to the States for distribution to all vaccine providers. In addition, we have developed websites where people can get more information. We have hotlines, which are listed in these information statements, where people can get more information. And we also put in each of these information statements, for the parent who wants more, one, to ask their doctor or nurse, and also even refer them to—some parents maybe want to see the package insert, which will contain more detailed information. I think we do a lot and are continuing to do more, and we will need to do more because we know of instances where this is not being done.

Mrs. BIGGERT. I would imagine that some of these reactions would be something in common, like coughing or rashes or something that might start out that way. But how is it determined that these could be tied to the vaccination? Is there a problem making that connection? Are doctors given enough information?

Dr. ORENSTEIN. I think we provide information as well as others—the American Academy of Pediatrics, the American Academy of Family Physicians—about vaccines, both risks and benefits. I think there are issues, we encourage reporting of serious adverse events, regardless of whether the physician thinks they are vaccine-related or not. I realize there are still physicians who only report adverse events if they think they are related to vaccines. We are trying in multiple venues, and we will continue to try, to get all serious adverse events reported. What's difficult with many of

the adverse events that are reported is that, while they are, can be very serious and very problematic, many of them are also occurring in the absence of vaccination. And when that occurs, and the clinical syndrome is not unique, then we need to do special studies. And that's why we have a system we call our Vaccine Safety Datalink, which works with four managed care organizations in the Western United States and independent researchers, to look at what the expected incidence of this illness would be in the absence of vaccination, to compare with the incidence in the presence of vaccination. And if it's higher after vaccination, that will be strong evidence that vaccine is actually causing it.

Mrs. BIGGERT. I know there was a school in Illinois at one time where there was a measles outbreak. And it was a school for religious purposes, and nobody was vaccinated. Well, the school was shut down for a while until everybody recovered, and I think some of them probably had vaccinations. But is there a plan, if that happens, that addresses that problem in such a school?

Dr. ORENSTEIN. I think that each State would decide how best to deal with that situation. Although we may recommend mandatory immunization because we've seen how effective it is, how it's implemented is a State decision. So in terms of dealing with an outbreak in a college, for example, where there are large numbers of people who are unvaccinated and who can infect the community, that's usually worked out on a case-by-case basis, and there may be actual plans as to whether the States would quarantine the school so that the children didn't go and spread it into many communities, or whether they just tried to make voluntary efforts to vaccination, or other kinds of efforts to vaccinate.

Mrs. BIGGERT. Thank you. Thank you, Mr. Chairman.

Mr. BURTON. Gentlelady, thank you very much. Let me—I want to apologize to all the other panelists who are here because I know it's been a long day. It's extremely important though that we get through a few more questions and then we'll get to our next panel. I apologize once again for everyone getting saddle sores.

First of all, why are individuals not tested when a series of three or five vaccines is given to determine their antibody levels, since this level would indicate that they may already be protected? Along with that, I understand, as I said before, in Japan they check the antibody levels to make sure a person's immune system is not depressed before they give them some of these shots. And they wait, or they wait until they're a little bit older. I just wonder why we don't look into that as well?

Dr. SATCHER. Well, I guess it gets back to risk and benefits, because a lot of the deaths that we have seen from these infectious diseases occur very early in children, 1 and 2 years of age. So——

Mr. BURTON. Well Japan, I think, has a very, very good record in this regard. I think they have as good a record or even a better record as far as deaths or diseases caused in infants from these diseases. In fact, I've ordered the studies they have done and they are going to be sending those to us. But the fact of the matter is, they're as good or at least as good or better. And they check the immune system first, before they start administering some of these vaccines. I just wonder why we don't look at that. The cost benefit ratio, is that what you're saying?

Dr. ORENSTEIN. I'm not aware of what's done in Japan. I know Japan had two deaths after pertussis-containing vaccines in the 1970's. They stopped their pertussis vaccination and then had 41 deaths in an epidemic of pertussis afterwards. I do not know what they test for, but I do know that for some of these diseases, there aren't antibody tests. We don't know, for example, what——

Mr. BURTON. Where there are, why don't we?

Dr. ORENSTEIN. In many of them it may be maternal antibody. Maybe another antibody passed from the mother to the child. And by the time we would find out that they were susceptible, they may have already become infected. From any of this, it becomes a very difficult thing to do in the setting of a public clinic——

Mr. BURTON. Are you indicating to me that there are not antibody tests that can be performed prior to giving these children these shots? Because they get 21 by the time they're 6 years old.

Dr. ORENSTEIN. There are antibody tests that could be performed in some children for some diseases, but as a matter of trying to assure vaccination and assure protection from vaccine-preventable diseases, it would be very difficult to do that for large number of children.

Mr. BURTON. But I understand that they do that in Japan. I wonder why?

Dr. SATCHER. But these are some areas where we're still doing research in terms of how much can we know about the individual's immunogenicity.

Mr. BURTON. Well, if you have any information, please submit it to us for the record. We have heard from individuals who have had remarkable healing after vaccines events through the use of homeopathic remedies. Has our Government or is our Government doing any research into that area?

Dr. SATCHER. As you know, Congress has established the National Center for Complementary and Alternative Medicine Center at NIH, so we are doing more research in the different approaches to clinical care.

Mr. BURTON. Their budget's very——

Dr. SATCHER. It's very early. It's very early.

Mr. BURTON. Their budget's very small. Would you recommend that we increase that a little bit?

Dr. SATCHER. Well, you know, we have certainly recommended that you increase the budget of NIH overall.

Mr. BURTON. Well I know, but when you do that, I'd kind of like for you to shove a little bit into the alternative thing.

Dr. SATCHER. And I think that will certainly happen.

Mr. BURTON. Would you do that?

Dr. SATCHER. Yes.

Mr. BURTON. Thank you. How do you explain the huge jump in autism and developmental delays?

Dr. SATCHER. Again, I'm taking the prerogative here on some of the questions, but many studies have been done looking at the relationship between autism and vaccines, and there have not been any conclusive studies showing that vaccines cause autism. That's still——

Mr. BURTON. There is a large increase.

Dr. SATCHER. Yes, and we're still studying it. But to date, we cannot demonstrate the causal relationship, but we continue to look at the issue.

Mr. BURTON. Well, if you have any additional information on that, we'd like for you to——

Dr. SATCHER. We certainly will. We will update you on what we have.

Mr. BURTON. Mr. Waxman, do you have any questions before we break?

Mr. WAXMAN. Yes, sir. Thank you very much, Mr. Chairman. We know that when we immunize a child, we're trying to protect that child from certain diseases. But we're also protecting children who cannot be immunized, for example, children who have leukemia who can't be vaccinated. Isn't it true that some children who are vaccinated do not respond to the vaccine and develop an immunity to the disease?

Dr. SATCHER. Definitely. But the other point you made is so important—in response to Congresswoman Biggert's point about the school, the real question is, in addition to the children in that school who got measles, we don't know how many other people were exposed to measles because of that, who themselves might not have even been subject to vaccination because of an immune problem, or leukemia, or what have you. So when a group of people become infected by an infectious disease like measles, a lot of other people are exposed.

Mr. WAXMAN. Isn't it the case that there will always be a small percentage of children who will not be immune to these vaccine-preventable diseases, so a parent who chooses not to have his or her child vaccinated is therefore putting these other children who cannot be vaccinated or do not respond to vaccines at a greater risk of——

Dr. SATCHER. Yes, I think that's the basis on which States have made the kind of decisions that they've made in terms of requiring immunizations.

Mr. WAXMAN. I wasn't here for a lot of the questions on anthrax, and I know one of our subcommittees has held hearings and I haven't been a part of those hearings. But, what is your role on the anthrax vaccine compared to the Department of Defense?

Dr. SATCHER. Yes, I pointed out that the decision to immunize the troops was a decision made by the Department of Defense, and in some cases using information that's really security information that we don't have access to. I think what we can talk about is the vaccine and the studies that have been done to show both its safety and efficacy. And the FDA has been involved in those studies. It is on that basis that we can say, the vaccine is safe, and it's also effective.

Mr. WAXMAN. And you haven't made a recommendation that everyone be immunized for anthrax, have you?

Dr. SATCHER. No, we haven't.

Mr. WAXMAN. So that's not even an issue at the moment.

Dr. SATCHER. No, we don't anticipate making it. But obviously, as you know, in the area of bioterrorism, it just depends on what happens in the future in terms of what the real risks are.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

Mr. BURTON. Thank you. You've been very patient, this panel, and so have been all of the rest of the people who are going to be testifying. We have to go vote. We will be back as quickly as possible. I think we only have one vote on the floor. As soon as we return, we'll have the next panel. Mr. Surgeon General, thank you very much for being here. We really appreciate it. We stand in recess.

[Recess.]

Mr. SHAYS [presiding]. Ms. Nelson, Ms. Spaith, and Ms. Cole.

I'm not succeeding in my coup. We have two we are still waiting for. Can we swear them in privately?

Here is what we are going to do. We are going to ask you to stand, and then we will—we are calling our witnesses to come forward on panel two.

Would you raise your right hands, please.

[Witnesses sworn.]

Mr. SHAYS. We will note for the record all our witnesses were sworn in except Ms. Spaith, and we will start with Tonya and Gerald Nelson. We will invite you to give your testimony.

What we are going to do is we are going to turn the clock on for 5 minutes, and then we will roll over if we have to and welcome your testimony. And please feel relaxed. It is wonderful to have you here, you should feel very comfortable being here.

Ms. NELSON. Thank you.

Mr. SHAYS. Thank you for being here.

Are you both going to give testimony, or one of you?

Ms. NELSON. I will give mine, and then he will continue.

Mr. SHAYS. OK. Ms. Nelson, why don't you start.

STATEMENTS OF TONYA AND GERALD NELSON, INDIANAPOLIS, IN; RICK ROLLENS, GRANITE BAY, CA; CAROLA ZITZMANN, VOICE OF THE RETARDED; ANTONIA C. SPAITH, FALLS CHURCH, VA; REBECCA COLE, PKIDS, CHAPEL HILL, NC; AND KEITH BERGEN VAN ZANDT, M.D., PKIDS, WINSTON-SALEM, NC

Ms. NELSON. Thank you.

Thank you Mr. Chairman and members of the committee. I am grateful to be here today to share with you our story regarding vaccines.

I am the mother of four children. Abigail was my third. Abigail was born at 11:27 p.m., on March 22, 1994. She was a very healthy baby. We stayed 2 days in the hospital. Prior to our release from the hospital, she was given the hepatitis B vaccine.

Mr. SHAYS. Ms. Nelson, I am going to ask you to put that microphone a little closer to you. That is the problem. It needs to be down. That is all right. We have to remind ourselves that, too. And you don't have to rush. You can speak more slowly.

Ms. NELSON. I asked questions about the injection and was given a booklet to read that stated to expect no side effects except soreness in the area of the injection.

We came home after receiving the vaccine. She was very cranky and her cry was very disturbing. It was more of a scream than crying. She began to spit up a lot.

I called the doctor and was told to give her some water between feedings and to call back in a week. I did as the doctor suggested, but I began to get scared because her stool became loose and greenish-yellow. So I called back in a week and was told that was normal and to keep an eye on her and call if I needed to.

The second week was worse. Her cry was just as bad and stool seemed loose. She became cold to the touch and shivered a lot. I called the doctor again. She told me to put her in her infant hat and to check her temperature four times a day and to call back the following week.

I did this. Her temperature stayed at 96 degrees. Then her third week she began to turn purple in her hands and feet and around her lips. I called the doctor and was told to watch her breathing and they would see the baby the next week for her 1-month checkup and to keep her wrapped tightly in blankets.

I was becoming scared. I asked him to get her in before her checkup and was told they had no appointments. I hung up from that call and called my son's old doctor. She told me that she could not help without seeing the child, and since Abby was on Medicaid and she was not a Medicaid provider, she was restricted from seeing Abby. I offered to pay cash, but she said she could not take the money from a Medicaid patient. At this point Abby is still crying and vomiting and having loose stools and very cold.

The night before she died she screamed for 6 hours straight, plus she had a lot of bowel movements. She finally fell asleep at 11:30 p.m. We woke up to find her dead at 6 a.m.

I placed my 9–1–1 call and started CPR. The firemen and paramedics showed up. They pronounced her dead shortly after they arrived. The coroner said it would be 2 weeks before the cause of death could be determined.

About 2 months later we received a telephone call from Dr. Thomas Gill of the Marion County Coroner's Office. He told us the cause of death was the hepatitis B virus, which she could only have gotten from the vaccine. He told me that he would get the death certificate out to me soon.

Sixteen weeks later we received the death certificate in the mail, and the cause of death was natural causes, otherwise known as SIDS, Sudden Infant Death Syndrome.

I was shocked to say the least. I called the coroner's office and spoke to a Dr. Manders, the coroner of Marion County, and was told that Dr. Gill had been asked to resign.

Dr. Manders stated he had signed the death certificate. I asked how he could sign the death certificate if he did not perform the autopsy. He told me that he had done so since Dr. Gill was no longer there. We had not been able to determine how he came to the cause of death, since he did not perform the autopsy, and that Dr. Gill told us something very, very different. He told me that if I had questions to call a Dr. Pless, a pathologist at Indiana University.

I did call and made an appointment to speak to Dr. Pless. He was a man without compassion, and the most cold-hearted I have ever met. He told me to stop trying to place the blame on my child's death and to go on with my life. He also stated that if the

vaccine did kill my daughter, it was saving more lives than it was taking.

I contacted a lawyer and he said to get all the information together and to call him back. I contacted the Infectious Disease Center at Riley Children's Hospital and spoke to a registered nurse. She was very helpful. She told me the vaccine has been known to take infants' lives and also to make them very sick. She could not help me other than that. She was scared she would lose her job. She also told me that the infant does not develop its own immune system till 3 to 4 months of age. I confirmed this with other doctors, who said they are very uncomfortable giving the injection at such an early age.

I tried to contact the Center for Disease Control and Prevention and the vaccine company. I left messages that were never returned.

To retain my own emotional well-being and to care for my two older children I had to take a break from this, thinking I had plenty of time to pursue this with the Government. I had to return to work because we were already behind the 8-ball financially. Having to pay for a funeral and headstone for Abby only made that worse.

I was not the only member of the family who needed to heal from this trauma. My husband Gerald will share his experiences shortly. My older child needed counseling we could not afford, and the school told us she was young enough, she would soon forget.

Finally I was able to call the attorney back and was told that it was too late. He said I only had 2 years to get compensated for our loss unless she had lived. Then I would have had 7 years.

We had a lot of bills and misfortunes due to this one vaccine. We had lost the most important things in our lives, and nobody cared. They were too busy or too afraid of losing their jobs or paying too much malpractice insurance.

I also know that my child was not a priority of getting an appointment with the doctor because she was on Medicaid. The doctors do not get enough compensation to encourage them to make Medicaid patients a priority.

Since we were in such financial distress already, I tried to get State funding for her funeral, and was told it would take a few weeks to get approved for this, and that I would have to fill out paperwork. I didn't feel that I could hold off for weeks to bury my child while paperwork was being filled out and reviewed.

I gave up hope and contacted Beth Clay on the committee staff. This has been like an open wound that has been trying to heal for 5 years but has not. I feel like coming and telling our story will be worth it if I can help save just one child's life. I hope through my own experience I will be able to help other parents also.

Of course none of this will make up for the loss we encountered 5 years ago. By testifying today my husband and I may finally be able to bring closure to our grieving. So far we have been so busy trying to survive that we have not done so. Our Abby would have been in school now learning to read and writing songs. Instead we have a baby book that has never been filled out.

Mr. NELSON. Tonya and I are like many other Americans, ordinary Americans, hard-working, struggling to survive. Tonya came into our marriage with two beautiful children, Sabrina and Kegan,

whom I love dearly. Abby was a beautiful and healthy child. She was my first child. I was the proudest of fathers.

This tragedy compounded with other family losses really tore me apart emotionally. I ended up losing my job. We have struggled to recover from this tragedy and to further understand how it is appropriate for babies whose immune systems are not even fully developed are being vaccinated. We also want to see more information be provided to parents prior to vaccination and that they be informed that there are medical and religious exemptions.

Physicians also have to be educated about these exemptions and be comfortable giving them. We were told that the worst that would happen to our little Abby was that she would have a sore leg. That was certainly not accurate information.

By coming today we hope that the Government will move forward with more research in the safety of vaccines in infants and the combination of vaccines. We also want medical freedom to be a consideration in finding the balance between public health and each individual's health and safety.

Thank you, Mr. Chairman and members of the committee for this opportunity for us to testify.

Mr. BURTON [presiding]. Mr. Shays, you had something you wanted to say?

Mr. SHAYS. Mr. Chairman, I first wanted to say to both Mr. and Mrs. Nelson that it is, one, very important that you are here. Second, that there is not a person in this room who doesn't find it outrageous that you would have encountered such resistance, one, to look at your child, and, two, that you weren't given the kind of sympathy that any grieving mother and father deserve. I am just glad to know about your case and see how I can be helpful to you. I do appreciate you being here, and since I did swear you in, I want to say that.

Mr. Chairman, we do need to swear in Ms. Spaith. You might want to do that right now.

Mr. BURTON. I will be happy to do that.

Before I do that, Mrs. Nelson and Mr. Nelson are friends of my daughter, and of course I told you earlier about my granddaughter having a problem with the hepatitis B vaccine. I want to also express my concern about what you folks went through. I have instructed my assistant here, Beth, to help you make a claim, which I think is justified, against the Government for this problem. And I hope—you have to do that by August 6, so we have got only 3 days, and we will assist you in doing that so that you can be at least partially compensated for that horrible thing.

Ms. NELSON. Thank you.

[The prepared statement of Mr. and Mrs. Nelson follows:]

Testimony

Of

Tonya and Gerald Nelson
Indianapolis, Indiana

Before
The
Government Reform Committee
Hearing of August 3, 1999

Vaccines: Finding the Balance
Between Public Safety and Personal Choice

2157 Rayburn House Office Building
Washington, D.C.

Tonya

Thank you Mr. Chairman and members of the Committee, I am grateful to be here today to share with you our story regarding vaccines. I am the mother of four children. Abigail was my third. Abigail was born 11:27 p.m.on March 22, 1994. She was a very healthy baby. We stayed two days in the hospital. Prior to our release from the hospital, we was given the Hepatitis B vaccine. I asked questions about the injection and was given a booklet to read that stated to expect no side effects except soreness in the area of injection.

We came home after receiving the vaccine. She was very cranky her cry was very disturbing more of a scream than crying. She began to spit up a lot. I called the doctor and was told to give her some water between feedings and to call back in a week. I did as the doctor suggested. But I began to get scared because her stool became loose and greenish yellow so I called back in a week and was told that was normal and to keep an eye on her and call if I needed to.

The second week was worse her cry was just as bad and stools still loose. She became cold to touch and she shivered a lot. I called the doctor again she told me to put her infant hat on her and check temperature four times a day and to call back the next week. I did this. Her temperature stayed at 96 degrees. Then her third week she began to turn purple in her hands and feet and around her lips. I called the doctor and was told to watch her breathing and they would see the baby next week for her one-month check up and to keep her wrapped in blankets tightly.

I was becoming scared I asked them to get her in before her check up and was told they had no appointments. I hung up from that call and called my son's old doctor. She told me that she could not help without seeing the child and since Abby was on Medicaid and she was not a Medicaid provider, she was restricted from seeing Abby. I offered to pay cash, but she said she could not take money from a Medicaid patient.

At this point, Abby is still crying and vomiting and having loose stools and very cold. The night before she died she screamed for six hours straight plus she had a lot of bowel movements. She finally fell asleep around 11:30 pm.

I woke up to find her dead at 6 am. I placed my 911 call and started CPR the fireman and paramedics showed up. They pronounced her deadly shortly after they arrived.

That afternoon we were picking out her coffin instead of a crib. We had to choose an outfit to bury her in instead of picking one out to have her one-month pictures taken. The coroner said it would be two weeks before a cause of death could be determined. The coroner and police treated me like I had committed a crime, taking pictures of her old bottles and formula. They questioned me over and over. It was not the kind of situation a mother should be in when her child has just died.

About two months later, we received a telephone call from a Dr. Thomas Gill, of the Marion County Coroner's Office. He told us the cause of death was the Hepatitis B virus – which she could only have gotten form the vaccine. He told me that he would get the death certificate out to me very soon.

Sixteen weeks later, we received the death certificate in the mail and the cause of death was "natural causes" otherwise known as "SIDS" (Sudden Infant Death Sudden). I was shocked to say the least. I called the Coroner's Office and spoke to Dr. Manders, the Coroner of Marion County and was told that Dr. Gill had been asked to resign.

Dr. Manders stated that he had signed the death certificate. I asked how he could sign the death certificate if he did not perform the autopsy. He told me that he had done so since Dr. Gill was no longer there. We have not been able to determine how he came to the cause of death since he did not perform the autopsy and that Dr. Gill told us something very very different. He told me that if I had questions, to call a Dr. Pless, a pathologist at Indiana University. I did call and made an appointment to speak to Dr. Pless. He was a man with out compassion. The most cold-hearted I have ever met. He told me to stop

trying to place the blame of my child's death on someone and go on with my life. He also stated that if the vaccine did kill my daughter that it was saving more live than it was taking.

I contacted a lawyer and he said to get all my information together and call him back. I contacted the Infectious Disease center at Riley Children's Hospital and spoke to a Registered Nurse. She was very helpful she told me that the vaccine has been known to take infants lives and also to make them very sick. She could not help me other than that she was scared she would loose her job. She also told me that the infant does not develop it's own immune system until it is 3-4 months of age. I confirmed this with other doctors who said they are very uncomfortable giving the injections at such an early age.

I then called my son's old doctor again and she told me she could not help me because malpractice insurance is too expensive as it is. I tried to contact the Centers for Disease Control and Prevention (CDC) and the vaccine company. I left messages that were never returned.

To retain my own emotional well-being, and to care for my two older children, I had to take a break from this, thinking that I had plenty of time to pursue this with the Government. Our family was still grieving the loss of Gerald's parents, then my Abby died, a not too much later a nephew died. I had to return to work because we were already behind the eight ball financially, and having to pay for a funeral and headstone for Abby only made that worse.

I was not the only member of the family who needed to heal from this trauma. My husband, Gerald will share with you his experiences shortly. My older children needed counseling that we could not afford and the school told us that she was young enough that she would soon forget. To compound all of this, my second child went blind in his right eye and I was trying to get disability for him to help with medical bills. That request was declined. I can not say that the state was a big help at all.

Finally, I was able to call the attorney back and was told that I was too late. He said I only had two years to get compensated for our loss unless she had lived. Then I would have had seven years.

We have had a lot of bills and misfortune due to this one vaccine. I had lost the most important thing in my life and nobody cared. They were too busy or too afraid of loosing their jobs or paying too much malpractice insurance. I also know that my child was not a priority at getting an appointment with the doctor because she was on Medicaid. The doctors do not get enough compensation to encourage them to make Medicaid patients a priority.

Since we were in such financial distress already, I tried to get state funding for her funeral and was told it would take a few weeks to get an approval for this and that I would have to fill out papers. I didn't feel that I could hold off for weeks to bury my child while paperwork was being filled out and reviewed.

I gave up hope until I contacted Beth Clay on the Committee staff. This has been like an open wound that has been trying to heal for five years, but has not. I feel like coming and telling our story will be worth it if I can help save just one child's life. I hope that through my own experience, I will be able to help other parents also.

Of course none of this will make up for the loss we encountered five years ago. By testifying today, my husband and I may finally be able to bring closure to our grieving. So far, we have been so busy just trying to survive that we have not done so. My Abby would be in school now, learning to read and write, and sing songs. Instead, we have a baby book that never got filled out.

Gerald

Tonya and I are like many other ordinary Americans – a hard working struggling to survive. Tonya came to our marriage with two beautiful children – Sabrina and Kegan. Abby was born beautiful and healthy – she was my first child. I was the proudest of Papa's. This tragedy compounded with other recent family losses really tore me apart emotionally. I ended up loosing my job. We have struggled to recover from this tragedy and to further understand how it is appropriate for babies whose immune systems are not fully developed are being vaccinated. We also want to see more information be provided to parents prior to vaccination and that they be informed that there are medical and religious exemptions. Physicians also have to be educated about these exemptions and be comfortable giving them. We were told that the worst that could happen is that our little Abby might have a sore arm – that was certainly not accurate information. By coming today, we hope that the Government will move forward with more research in the safety of vaccines in infants and in the combination of vaccines. We also want medical freedom to be a consideration in finding the balance between public health and each individual's health and safety. I would also add that the Committee staff spoke with the Coroner's office yesterday and that Abby's toxicology report showed that she had Hepatitis B.

Thank you Mr. Chairman and members of the Committee for this opportunity to testify.

Mr. BURTON. Ms. Spaith, would you stand, please?

[Witness sworn.]

Mr. BURTON. Mr. Rollens, you are next.

Mr. ROLLENS. Mr. Chairman and members, my name is Rick Rollens. I currently reside in Granite Bay, CA, which is located 30 miles east of Sacramento, with my wife of 23 years, Janna, and my two sons, Matthew, 13, and Russell, 8.

Thank you for inviting me today to testify. For me this is somewhat of a homecoming, for in 1973 I had the privilege of serving on the Washington staff of former Representative Jerome Waldie of California.

Following my service in the House, I embarked upon a 23-year career of public service with the California State Senate. Working through the ranks, I was elected by the Members of the Senate to serve as their Secretary of the Senate, until I chose to resign my position in 1996 in order to dedicate myself to the pursuit of effective treatments and a cure for my beloved son, Russell.

I am here today to share with you the story of my son's case of vaccine-induced autism and to report on the growing autism epidemic in California and the pandemic of autism throughout this country. Russell began his life as a normal, healthy, and robust child, meeting all his age-appropriate milestones. At 7 months old, within 72 hours after receiving his third DPT and first hep B vaccination, Russell developed a high fever and shrieked with a high, wailing scream for days. After these vaccinations, he started losing eye contact, smiling less, losing interest in people, developed constant croup, and was chronically sick. At 7 months old, Russell's life had begun to change along with the lives of all who know and love him.

Within days after his first MMR vaccination, at 18 months, Russell began his final journey into the abyss of what my wife and I now know is autism, losing most of his remaining skills, developing severe sleep irregularities, chronic gastrointestinal problems, and expressing constant pain exhibited by harrowing days of endless crying. Russell was officially diagnosed at 2½ years old with autism.

After many months of medical investigation of Russell's condition, including state-of-the-art brain scans, immunological and neurological and genetic workups, we consulted a noted pediatric neurologist who thoroughly examined Russell and reviewed all of Russell's medical history. He advised us that in part Russell's brain dysfunction had very likely occurred as a result of some form of encephalitis resulting in bilateral damage to the temporal lobes of his brain.

Based on the facts that we have absolutely no family history of autism or any other type of brain disorder in our family, that he was born a normal, healthy child, that there exists a strong temporal relationship between the timing of the DPT vaccination he received at 7 months old and the onset of his autistic condition, his classic DPT vaccine reactions, coupled with the 18-month-old hit from the MMR and subsequent deterioration of his condition, as well as the scientific evidence that one of the many serious adverse effects of DPT vaccine is encephalitis and brain damage, I believe that Russell is a victim of vaccine-induced autism.

My story is far from unique. Mr. Chairman and members, next week when you return home to your district, talk to your constituents, many of whom are among the growing number of parents who have children with autism. I can assure you that you will hear firsthand accounts from those parents about their normally developing children and the introduction and reaction to a vaccine or multiple vaccines, the timing of their children's regression and vaccination, and the onset of a multitude of other medical conditions and complications that accompany this acquired autistic condition.

The first rule of medicine is to listen to the patient. A child born today in California will have received his first vaccination between 6 to 8 hours old. By the time that child is 6 months old, he will have received 15 doses of vaccines, and by the age of 5 years old, 33 doses of vaccines.

Vaccines contain numerous active agents such as live viruses, killed bacteria, and toxic chemicals, including aluminum, mercury, and formaldehyde. Where are the safety studies on the short- or long-term effects of the interaction of these numerous multiple vaccines and their agents on the developing brain and immune systems of our children? Where is the science?

Many safety studies of individual vaccines only include a few days of followup periods for reactions, but the CDC tells parents and the news media that the onset of autism after vaccination could only be "an unrelated chance occurrence." Dr. Satcher, show me the studies. Show me the science. Is it appropriate to continue to entrust the CDC and the indemnified vaccine manufacturers with the responsibility of guaranteeing parents of this country that these vaccines do not cause autism or other serious brain disorders when these same groups are the most aggressive promoters of vaccine use?

The situation can easily be likened to charging the tobacco industry to undertake independent scientific studies to find out if there is any relationship between lung cancer and smoking. The science on the safety of vaccines and their relationship to the development of autism is not there. Not there because the pleas of parents have been ignored. I suffered the ultimate betrayal of trust by blindly allowing my child to be injected with a multitude of vaccines, trusting my Government had made sure that my child would not become autistic after his vaccinations.

Responding to the outcry of parents such as myself, professionals, and educators over the concern of the rapidly increasing number of children with autism and autism spectrum disorders, the California legislature and two Governors of different political parties have responded within the past 12 months by requiring a study on whether autism was increasing in the State, and after finding that there was a huge unexpected increase, appropriated several million dollars for independent research as well as an independent followup study into the real factors causing the increase.

Under the leadership of State Senator, now U.S. Representative Mike Thompson, last year the legislature required the Department of Developmental Services to report on the increase of autism from 1987 through 1998. The report was released earlier this year, and documents a very conservative 273-percent increase in the number of children with autism entering the developmental services sys-

tem, 1,685 new children last year alone, when incidence projections for that population would have predicted between 105 and 263 new children. The report led the Los Angeles Times to declare that the State has an epidemic of autistic children. An epidemic of autistic children? Isn't that an oxymoron? We all know there is no such thing as a genetic disease epidemic. So clearly other factors are involved.

According to the department, this year from January 6 to July 7, 1,027 new children with autism were added to the system, which means that California alone on average is adding 6 new autistic children a day, 7 days a week, 1 new child every 4 hours. Besides the unmeasurable human costs on the child and the family, the thousands of autistic children already in our system, along with these 1,027 new children, are according to the Department of Developmental Services going to cost the taxpayers of California and the country a minimum of $2 million each for the lifetime of their care.

Surely any intelligent, thoughtful person with a straight face could not suggest that this huge increase in one of the most easily recognizable of all childhood disorders is all due to genetics, better recognition, or to minor changes in the diagnostic criteria that occurred 10 years after the massive increase in autism had already begun over two decades ago.

Earlier this year the local and national news media extensively covered the story of the observations by parents in Brick Township, NJ, that there were a lot of kids with autism in their community. In fact, the CDC publicly announced that they had discovered a cluster of autism in Brick. What the CDC found was that the prevalence of autism in Brick was 1 in 150 children; 1 in 150 children represents a prevalence rate 12 times higher than the published prevalence rate. My family and I live in a community approximately 3,000 miles away from Brick Township, a community that is almost in every way as different from Brick as two communities in America can be. Where we live, our children are served by a single public elementary school district. The prevalence of autism in our elementary school district is 1 in 132 children.

Mr. Chairman and members, Brick Township, NJ, and Granite Bay, CA, are not clusters of autism, but snapshots of what is occurring everywhere. Numerous parent organizations around the world, including the Autism Research Institute, the National Vaccine Information Center, Families for Early Autism Treatment, Autoimmunity Research Project, Cure Autism Now, and Allergy-Induced Autism are all constantly hearing from scores of parents reporting vaccine-related autism. You will find these children throughout the neighborhoods of your own districts.

Vaccine policy has always been a cost-benefit proposition. I am here to tell you today that the once numerically rare sacrificial lambs that society has been willing to tolerate for the good of the whole could now very likely before our eyes be turning into herds of casualties of the most precious resource we have, our children and our grandchildren. We must act quickly by investing in good,

independent research and science to pursue the truth about the link between vaccines and autism. If we don't discover all the causes, we will never find a cure.

Thank you for your time.

[The prepared statement of Mr. Rollens follows:]

Testimony of Rick Rollens
Before The
House Committee on Government Reform

August 3, 1999

Mr. Chairman and Members:

My name is Rick Rollens. I currently reside in Granite Bay, California which is located 30 miles east of Sacramento with my wife of 23 years, Janna, and my two sons, Matthew,13, and Russell, 8. Thank you for inviting me to testify.

For me, this is somewhat of a homecoming. In 1973 I had the privilege of serving on the Washington staff of former Representative Jerome Waldie of California. Following my service in the House, I embarked upon a 23-year career of public service with the California State Senate. Working through the ranks, I was elected by the Members of the State Senate to serve as the Secretary of the Senate until I chose to resign my position in 1996 in order to dedicate myself to the pursuit of effective treatments and a cure for my beloved son, Russell. I am here today to share with you the story of my son's case of vaccine induced autism and to report on the growing autism epidemic in California, and the pandemic of autism sweeping across this country.

Russell began his life as a normal, healthy, and robust child, meeting all his age appropriate milestones. At seven months old, within 72 hours after receiving his third DPT and first HIB vaccinations, Russell developed a high fever and shrieked with a high wailing scream for days. After these vaccinations, he started losing eye contact, smiling less, losing interest in people and had constant croup and was chronically sick. At seven months old, Russell's life had begun to change along with the lives of all who know and love him. Within days after his first MMR vaccination at 18 months, Russell began his final journey into the abyss of what my wife and I now know as autism – losing most of his remaining skills, developing severe sleep irregularities, chronic gastrointestinal problems, and expressing constant pain exhibited by harrowing days of endless crying. Russell was officially diagnosed at two and a half years old with autism.

After many months of medical investigation of Russell's condition, including state-of-the-art brain scans, immunological, neurological and genetic work-ups, we consulted a noted pediatric neurologist who thoroughly examined Russell and reviewed all of Russell's medical history. He advised us that, in part, Russell's brain dysfunction had very likely occurred as a result of some form of encephalitis resulting in bilateral damage to the temporal lobes of his brain. Based on the fact that we have no autism or brain disorders in our family, the fact that he was a normal, healthy child, along with the strong temporal relationship between the timing of the DPT vaccination he received at seven months, his classic DPT vaccine reactions and the subsequent deterioration of his health, as well as the scientific evidence that one of the many serious adverse effects of DPT vaccine is encephalitis and brain damage.... I believe that Russell is a victim of vaccine-induced autism and that the MMR vaccination only made things worse.

My story is not unique. If you talk to your constituents, you will find many who are among the growing number of parents who have children with autism. I can assure you that you will hear first hand accounts from these parents of normally developing children, the introduction and reaction to a vaccine or multiple vaccines, the timing of their children's regression and vaccination, and the onset of a multitude of other medical conditions and complications that accompany this acquired autistic condition.

A child born today in California will have received his first vaccination between six to eight HOURS old. By the time that child is 6 months old he will have received 15 doses of vaccines and by the age of 5 years old, 33 doses of vaccines. Additionally in California, it is likely this child before age 18 months soon will be receiving chicken pox and hepatitis A vaccines as well.

Vaccines contain numerous active agents such as live viruses, killed bacteria and toxic chemicals including aluminum, mercury and formaldehyde. Where are the safety studies on the short or long term effects of the interaction of numerous multiple vaccinations on the developing brain and immune systems of our children? Where is the science? Many safety studies of individual vaccines only include a few days follow-up period for reactions but the CDC tells parents and the media that the onset of autism after vaccination could only be an "unrelated chance occurrence." Show me the science. Is it appropriate to continue to entrust the CDC and the indemnified vaccine manufacturers with the responsibility of guaranteeing parents of this country that these vaccines do NOT cause autism when these same groups are the most aggressive promoters of vaccine use?

The situation can be likened to charging the tobacco industry to undertake independent scientific study to find out if there is any relationship between lung cancer and smoking. The science on the safety of vaccines and their relationship to the development of autism is not there. Not there because the pleas of parents have been ignored. I suffered the ultimate betrayal of trust by blindly allowing my child to be injected with a multitude of vaccines...trusting my government had made sure that my child would <u>not</u> become autistic after his vaccinations.

Responding to the outcry of parents, professionals, and educators over the concern of the increasing number of children with autism and autism spectrum disorders, the California Legislature and two Governors of different political parties responded within the pat 12 months by funding a study on whether autism was increasing in the State and, after finding there was a huge unexpected increase, appropriating several million dollars for independent research into <u>all</u> possible causes. Under the leadership of former State Senator, now U.S. Representative Mike Thompson, last year the Legislature required the Department of Developmental Services to report on the increase of autism in California from 1987-1998. The report was released earlier this year and documents a 273% increase in the number of new children with autism entering the developmental services system.

The release of the Report led the Los Angeles Times to declare that the state has an epidemic of autistic children. There is no such thing as a genetic disease epidemic so, clearly, other factors are involved.

During the first six months of this year, 1,027 new children professionally diagnosed with autism were added to the system which means that California is now adding on average six new autistic children a day seven days a week .....or ONE NEW CHILD EVERY FOUR HOURS! As with the thousands of autistic children already in our system, these 1,027 new children are, according to the Department, going to cost the taxpayers of California and the country a minimum of $2 million each for their lifetime of care.

Surely any intelligent, thoughtful person cannot with a straight face suggest that this huge increase in one of the most recognizable of all childhood disorders is all due to genetics or to subtle changes in the diagnostic criteria that occurred 10 years AFTER the massive increase in autism had already begun two decades ago.

Earlier this year, the national and local media extensively covered the story of the observations by parents in Brick Township, New Jersey that there were a lot of kids with autism in their community. In fact, the CDC publicly announced that they had discovered a cluster of autism in Brick. What the CDC found was that the prevalence of autism in Brick was 1 in 150 children. 1 in 150 represents a prevalence rate 12 times higher than the published prevalence rate for autism.

My family and I reside in a community approximately three thousand miles from Brick Township, a community that is ALMOST in every way as different from Brick as two communities in America can be. Where we live, our children are served by a single public elementary school district. The prevalence of autism in our elementary school district is 1 in 132 children.

Mr. Chairman and Members, Brick Township New Jersey and Granite Bay California are not clusters of autism but snapshots of what is occurring nationwide. Numerous parent organizations around the world, including the Autism Research Institute, the National Vaccine Information Center, Families for Early Autism Treatment (F.E.A.T.) , Autoimmunity Research Project, Cure Autism Now and Allergy Induced Autism are all hearing from scores of parents reporting vaccine-related autism. If you look, *you will find these children* in your districts.

Vaccine policy has always been a cost-benefit proposition. I am here to tell you that the numerically rare sacrificial lambs that society has been willing to tolerate for the good of the whole could now, very likely before our eyes, be turning into a herd of casualties of the most precious resource we have - our children and grandchildren. We must act quickly by investing in good, independent research and science to pursue the truth about vaccines and autism. For if we don't find all the causes, we will never find a cure.

Thank you.

NA/FRIDAY, APRIL 16, 1999 A3

Los Angeles Times
April 16, 1999

State Reports an Epidemic of Autistic Children

■ Health: Researchers say reasons for 'epidemic' are unclear. Some of the increase may be due to better reporting.

By THOMAS H. MAUGH II
TIMES MEDICAL WRITER

The number of autistic children in California has exploded during the last decade, according to a new state survey released Thursday.

The survey, conducted by the state Department of Developmental Services, concludes that there were 11,995 autistic children enrolled in the department's 21 regional programs in 1998, a 210% increase compared with the 3,864 enrolled in 1987.

During the same period, enrollment of children with other disorders, such as cerebral palsy and epilepsy, has increased at a rate consistent with the state's population growth—about 30% to 40%.

"Autism is increasing at an alarming rate," said psychologist Ron Huff, who wrote the study. "That raises a lot of questions" that have few answers yet, he said.

"We're in the middle of an autism epidemic," says Dr. Bernard Rimland of the Autism Research Institute in San Diego.

The chief question is how much of the increase reflects actual growth in the disorder as opposed to more common diagnosis and greater awareness. Researchers believe both may be playing a part.

"I was never taught anything about it" in medical school, said Dr. Pauline Filipek of UC Irvine. "I heard the 'A word' twice in seven years of postgraduate education, and never in medical school."

But even with increased awareness, "A lot of us feel that there is an increase in the actual prevalence," she added, "but we don't really have the data to show that."

One answer that researchers do have is that California is probably not unique. "There is absolutely no doubt the numbers are going up nationwide, even worldwide," said Dr. Eric London of the National Alliance for Autism Research. Between 1975 and 1985 studies showed the worldwide rate of autism to be about 4 cases per 10,000. Between 1985 and 1995, the numbers tripled to 12 per 10,000. But researchers believe that the actual rate may be much higher, on the order of one in 500 children.

Autism is a severe developmental disorder in which children seem isolated from the world around them. There are a broad spectrum of symptoms, but it is marked by poor language skills and an inability to handle social relations. No cure exists, but many problems can be alleviated with intensive behavioral therapy. Some parents have reported marked improvement in children treated with certain drugs, including secretin or Prozac, but clinical trials have not yet confirmed those claims.

The new report's numbers may actually understate the number of autistic children in the state, Filipek said. Some autistic children are incorrectly given other diagnoses, such as attention deficit hyperactivity disorder.

Particular attention has been paid to reported clusters of autism cases. Last year, for example, parents in Brick Township, N.J., became alarmed when they observed an unusual number of autism cases in their blue-collar community of 71,000. Among an estimated 6,000 children between the ages of three and ten, parents identified 53 cases of autism—an incidence of just over four cases for every 500 children.

Many parents attribute the cases to a nearby landfill, but epidemiologists from the federal Centers for Disease

Please see AUTISM, A14

Los Angeles Times
4-16-99

AUTISM: Study

Continued from A3

Control and Prevention have been unable so far to identify any unusual pollutants in the air or water of the area.

But Rimland, for one, says he is not sure the number of autism cases in Brick Township are actually elevated above the norm. "I think this is just a cross-section of what would be found if you looked carefully anywhere in America," he said.

Rick Rollins, a former secretary of the California state Assembly who was instrumental in creating the new autism research center at UC Davis points to his own community of Granite Bay, a wealthy suburb of Sacramento.

Of the 2,930 children enrolled in grades K-6 in the Eureka Union School District that serves Granite Bay, he said, 22 are autistic, a rate comparable to that found in Brick Township. There is no industry in Granite Bay and the area is "environmentaly pristine," and "geographically as different from Brick as you can get," Rollins said.

Beyond increased awareness, experts have proposed many possible causes for the apparent increase in autism. Some have speculated the syndrome is induced by infectious agents or by an allergic reaction to foods, such as proteins in milk. Others blame an allergic reaction to vaccines. Indeed, several parents of autistic children in Great Britain are suing the maker of the mumps-measles-rubella vaccine, claiming it triggered the disease.

But Kathleen Stratton, a vaccine specialist at the Institute of Medicine, a quasi-governmental think tank in Washington, D.C., believes that connection to be unlikely. "Childhood vaccine safety is very contentious, very emotional," she said, but any link between the vaccine and autism "has not been proved by any means."

Government officials are pushing for more research funds for the disease. "What is generally considered a rare condition is increasing faster here than other developmental disabilities," said state Sen. John Burton, the Senate majority leader. "We need to find out why."

Developmental Disorders Increase

The number of children and adolescents enrolled in programs run by the State Department of Developmental Services has grown sharply over the past decade, while the number with other developmental disorders has increased in tandem with increases in the population, according to a new state report.

Disorder	1987	1998	% Change
Autism	3,864	11,995	210%
Cerebral Palsy	19,972	28,529	43
Epilepsy	22,683	29,645	31
Mental Retardation	72,987	108,563	49
Total	80,469	136,183	69

Source: California Department of Developmental Services

LYNN MEERSMAN / Los Angeles Times

The Department of Developmental Services provides a variety of services to parents of children with developmental delays.

News Release

Senator John Burton

President Pro Tempore

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FOR RELEASE:
April 15, 1999
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BURTON, CHESBRO CALL FOR STUDY IN WAKE OF NEW REPORT ON INCREASE IN AUTISM CASES

SACRAMENTO—Senate President pro Tem John Burton (D-San Francisco) and Senator Wesley Chesbro (D-Arcata), Chair of the Senate Select Committee on Developmental Disabilities and Mental Health, said today a new state report raises troubling questions about why California's developmental services system is experiencing a large and unexpected increase in the number of children with autism.

"In the past 10 years, California has had a 273% increase in the number of children with autism who enter the developmental services system – 1,685 new cases last year alone," Burton said. "What is generally considered a rare condition is increasing faster here than other developmental disabilities. We need to find out why."

"The number of new children with autism greatly exceeds the numbers you'd expect from traditional incidence rates," Chesbro said. "The findings and conclusions of this report show we need to take action now to figure out where this increase is coming from, what the causes of autism are and what we as a state can do."

The Department of Developmental Services report. "Changes in the Population of Persons with Autism and Pervasive Developmental Disorders in California's Developmental Services System: 1987-1998" was released to the Legislature this morning. While it confirms the increased incidence. the report does not examine factors leading to the increase. The report was required as a result of legislation developed after parents, human services professionals and educators expressed concern that they were seeing a dramatic increase in children with autism.

(more)

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(Burton / Chesbro cont.)

In addition to special legislative hearings on the issue, Burton and Chesbro called for funding an independent epidemiological study to help identify the causes of autism and the factors leading to California's increase in autism cases. The Senators suggested that the U.C. Davis Medical Investigation of Neurological Disorders Institute (M.I.N.D.) would be the appropriate organization to perform the research.

"Autism exacts a tremendous cost on children, on families and the developmental disabilities system," Burton said. "The system is getting seven new kids with autism seven days a week. Is this because of families coming to California for services? A change in diagnostic practices? Something environmental? We need to get to the bottom of this and we need to do it right," Chesbro added.

For copies of the report contact Paul Verke at the California Department of Developmental Services (916) 654-1820. The report will also be up on the Department's web site www.dds.ca.gov The contact for the M.I.N.D. Institute is Carole Gan (916) 734-9047.

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June 17, 1999

LOS ANGELES TIMES

State Allocates $4 Million for a Heartfelt Special Interest

By DAN MORAIN
TIMES STAFF WRITER

SACRAMENTO—Line item 6440-122 of California's new budget scarcely attracts notice.

It is, after all, a [illegible] $4 million in an $82-billion spending plan. But it has significance for Rick Rollens and his wife Janna.

It's Rollens' handiwork, and that of a few other parents who share the same special interest—finding the causes of and cure for autism, which afflicts their children.

Rollens spent 23 years as a legislative staffer, rose to become secretary of the Senate and now works for Kahl/Pownell Advocates, among the richest lobbying firms in town. It represents blue-chip clients including big oil, timber companies, HMOs and the like.

With that background, Rollens was able to make his pitch to the most powerful lawmaker in town, Senate President Pro Tem John Burton. There already was $2 million in the budget for Line Item 6440-122; the San Francisco Democrat added $2 million more.

Burton and Sen. Wesley Chesbro (D-Arcata) pushed for another line item of $1 million, for study of the causes of autism, which is on the rise.

California's budget pays for big things like prisons, public schools and health care. But it also pays for small things, and much of what gets funded happens because lobbyists push for it. Most of the time, their clients have a financial stake in the outcome.

Line item 6440-122 has nothing to do with the moneyed interests Kahl/Pownell represents. For Burton and other lawmakers who support the funding, there are no campaign donations at stake.

The goal is far loftier: to discover the causes of developmental disabilities, including autism, and develop effective treatments.

"If we find there is an environmental cause, we can put an end to the misery," Rollens said.

If Gov. Gray Davis leaves the money in place—which appears likely—the dollars would go to a new center at UC Davis called the Medical Investigation of Neurodevelopmental Disorders (M.I.N.D. Institute, for short).

The fledgling institute would use the new money to research the causes of autism, a nerve development disorder that leaves children isolated from the world around them. The center studies other disorders as well, among them Tourette's syndrome, cerebral palsy and learning disabilities such as attention deficit disorder.

The idea for such an institute was born two years ago, when two other fathers, both with autistic children and both friends of the Rollens', decided to approach UC Davis about it.

"They kept telling us we couldn't do it," said Chuck Gardner, a general contractor, whose son, Chas, 7, is autistic. Gardner's response: "Sounds to me that the problem is money. What's the figure?"

The academics answered $5 million.

"If you've got a child with autism, that's not much money," Gardner said.

Another father of an autistic child, Dr. Louis Vismara, knew Angelo Tsakopoulos, a Sacramento developer and a large donor to Democrats, and called him. Tsakopoulos gave $500,000 and called Steve Beneto, a trucking company owner. Beneto, a large donor to Republicans, gave $500,000. Beneto has a 40-year-old son who is autistic.

"It's not going to benefit him," Beneto said. "I'm doing it for the future."

Within six months, the parents had raised $1.5 million, which the university matched. Then Rollens turned to the Legislature.

Diane Watson, then a Democratic state senator from Los Angeles, introduced a bill last year that created the M.I.N.D. institute and provided the first state money, $2 million. Former Gov. Pete Wilson supported it.

"They were very persistent," said Dr. Thomas Anders, acting director of the M.I.N.D. Institute. "It's the parents who are forcing scientists to look at new approaches."

Some parents believe that there is a correlation among immunizations and various childhood diseases and autism. Anders wants to fund research into the question. "It needs to be explored and either laid to rest or put out there and recognized," Anders said.

He also wants to expand research into autism beyond the brain, and look into reasons why many autistic children suffer gastrointestinal problems and sleep disorders.

Rollens figures that he will come back next year for more money. His reasoning is the sort that sways legislators. The state cost of caring for a severely disabled person is about $2 million over the individual's lifetime. If a cure can be found or such disabilities can be prevented, "the investment of a few million dollars is well spent."

Janna Rollens hopes the institute has a short life. "I want to see them go out of business. I want them to find a cure, and move on to other things."

California has spent modest sums for similar causes in the past. In 1988, the infant son of a legislative aide, Barry Brokaw, died of sudden infant death syndrome. Then-Sen. Dan Boatwright responded by carrying legislation to provide money to increase research into SIDS and awareness of it.

The legacy of Brokaw's baby, Kevin, continues. The state will spend $668,000 next year on SIDS awareness and training for police and others who deal with parents of children who die of SIDS.

Such efforts draw "something positive from a tragedy, so others won't have to go through it," said Brokaw, now a lobbyist.

Parents blame MMR for children's autism

San Jose Mercury News 6/22/99

Despite CDC's no-link statement, more study needed

MY recent columns about a suspected link between the measles, mumps, rubella vaccine and a sharp increase in autism (which many researchers, parents and educators now are freely calling an epidemic) elicited a huge response. Most of the letters and calls came, predictably, from parents of autistic children.

Q Thank you for your recent stories on autism and vaccinations. We need to look at immunization and recognize that some children have fragile immune systems. I agree that vaccines have alleviated much suffering in the world. However, if they need to be administered in a different manner we need to know this and develop better screening tools to determine who is at risk.

Parenting an autistic child is painful. I can't begin to imagine how hard it is for my son. Just like polio, no child should have to live with such a horribly painful disease.

A 273 percent increase in California is a big number. If we saw that with measles, mumps or rubella you can bet we would be looking deep to find its source. These children deserve the same.

Jodi Conti
Morgan Hill

A Dr. Jane El-Dahr, a pediatric immunologist at Tulane University Medical Center in New Orleans, poses an interesting question. She wonders whether the number of children who once suffered severe reactions to the measles virus is consistent with the sharp increase in autism being reported throughout the United State and other industrialized nations.

"Are these the same kids who once would have gotten the disease and died? Are we now selecting out those same two per 1,000 children who would once have died or suffered encephalitis from measles? Are we just causing a low-grade encephalitis, instead of rapid, acute death? Two per 1000: Doesn't that sound like the numbers we're coming up with for autism? It's in the ballpark."

Q I can't trace my daughter's autism to a single event, but I believe intuitively that it is risky to be bombarding young systems with all the immunizations that we give to infants and toddlers. I don't know what the trigger was for Lisa, but I would love to be able to "redo" her baby years with the information and life lessons I now have.

Judie
e-mail

A Who was it who called "if" the saddest word in the English language?

Q How do I voice a complaint with my health department? I believe that the shot might be partly responsible for my son's autism. He also had normal intelligence with speech, only to lose it all at 18 months after his MMR shot, which shortly followed the roseola fever.

Christine Sgro
New Jersey

A Concerns should be addressed not only to your state health department, but also to the Centers for Disease Control and Prevention in Atlanta, which will be happy to send you a prepared statement to the effect that there is no relationship between the vaccine and autism. I quote: "To date, there is no convincing evidence that any vaccine can cause autism or any kind of behavioral disorder. . . . Typically, symptoms of autism are first noted by parents as their child begins to have difficulty with delays in speaking after age 1. MMR is first given to children at 12 to 15 months of age. Therefore, autism cases with an apparent onset within a few weeks after vaccination may simply be an expected but unrelated chance occurrence."

It's a logical argument — and one that could be applied just as forcefully toward the suggestion that the vaccine be postponed, or at least separated into three live vaccines, as suggested by Dr. Andrew Wakefield, the British gastroenterologist whose research has spurred so much of the controversy on this subject.

Q I am the mother of a 14-month-old son who is due for his first MMR next month. After reading your first column, I called my pediatrician and was amazed at how she responded to my questions about the vaccine. She basically dodged the question and finally answered that as a parent I do not have a choice but to vaccinate with a combination vaccine. I need to look further. Can you help me? Do you know of any health-care providers that administer the vaccine separately or any contacts that would lead me closer to finding out?

Ana Regalo

A To the best of my knowledge, separation of the MMR into its three components is unavailable in this country. If I'm wrong, let me know.

Q My 3½-year-old daughter has vaccine-induced autism. At 15 months she had her scheduled MMR shot and from that point on, Jennifer slowly stopped feeding herself, never rode a swing again and stopped calling our names.

Our child is not capable of communicating, and my family struggles every day to reverse the damage done by these vaccines.

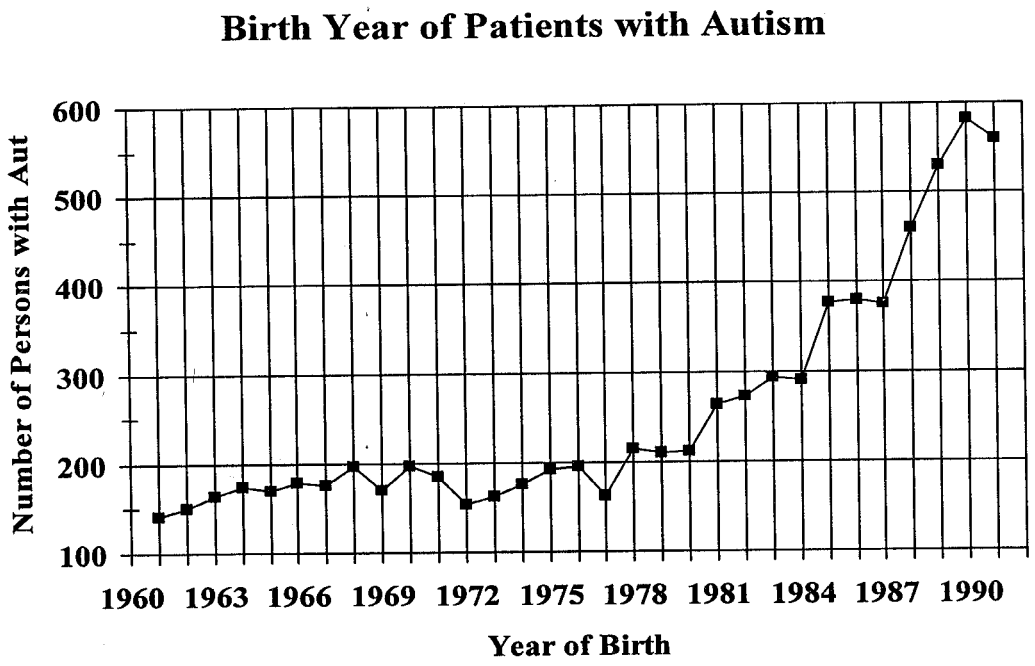
I hear that you have an autism cluster in your state. So does New Jersey. I prefer to label it an autism epidemic and . . . I strongly believe that the vaccine program is playing a damaging role in this. Unfortunately, our government research is concentrating on genetic causes, and no long-term research has been done on the current vaccine program. What angers me most is that this situation will not change any time soon, that many children will pay the price and that our government, medical establishment and pharmaceutical companies are aware of it all — but will deny and try to cover up for as long as they can. Simply, it all comes down to greed.

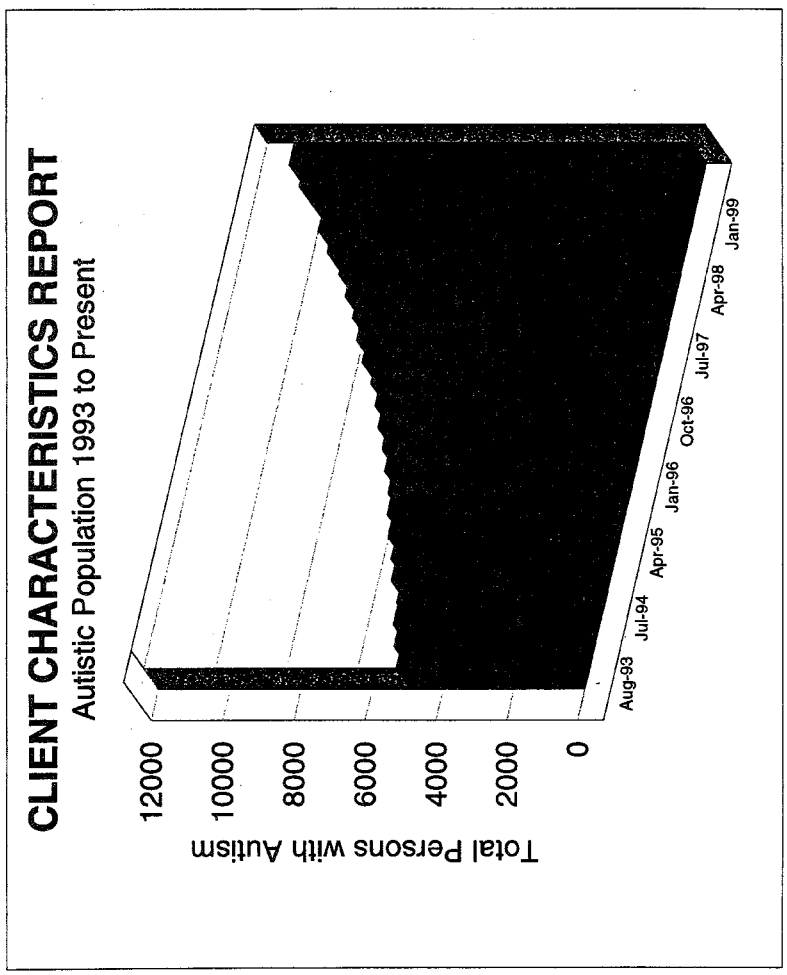
Joseph Pelosi
New Jersey

A Is it greed, or is it the conviction that vaccines save lives? We've been standing in line, awaiting our vaccines, for many decades. The time has clearly come for further study and questioning.

Contact Sara Solovitch at solo@cruzio.com or (408) 920-5863. The fax number is (408) 271-3786.

Is Incidence Increasing?




CLIENT CHARACTERISTICS REPORT
Autistic Population 1993 to Present
Total Persons with Autism
12000
10000
8000
6000
4000
2000
0
Aug-93
Jul-94
Apr-95
Jan-96
Oct-96
Jul-97
Apr-98
Jan-99

Department of Developmental Services

Changes in the Population of Persons with Autism and Pervasive Developmental Disorders in California's Developmental Services System: 1987 through 1998

A Report to the Legislature
March 1, 1999

Department of Developmental Services
1600 Ninth Street, Room 240
Sacramento, CA 95814

California Health and Human Services Agency • State of California

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EXECUTIVE SUMMARY

A. Purpose

Budget bill language (AB 1656, Chapter 324, statutes 1998) requires the Department of Developmental Services report to the Legislature on the incidence of autism and pervasive developmental disorders and compare the number of persons with autism to the other developmental disabilities as defined by Lanterman Developmental Disabilities Act (Division 4.5, commencing with section 4500, of the Welfare and Institutions Code). The report contains findings and conclusions that are based on an analysis of data provided by the regional centers to the Department for the period 1987 through 1998.

B. Description of Autism

Autism is a profound and poorly understood developmental disorder that severely impairs a person's abilities, particularly in the areas of language and social relations. Autistic children typically are normal in appearance and physically well developed. Their disabilities in communication and comprehension range from profound to mild. Historically, about 75 percent of persons with autism are classified as mentally retarded. Their most distinctive feature, however - which helps distinguish them from those solely mentally retarded - is that they seem isolated from the world around them.

Autism is manifest uniquely and heterogeneously in a given individual as a collection of symptoms which are rarely the same from one individual to another. Two children with the same diagnosis, intellectual ability and family resources are more likely to be recognized more for their differences than their similarities. Variation in the degree of impact on the individual is well documented and subtypes of the disorder have been identified. The professional community continues to work to clarify the confusion and controversy concerning the nature, causes, methods of diagnosis, and treatment of autism. As research has uncovered subtle differences in the onset and development of symptoms, different types of autism have been described. The current Diagnostic and Statistical Manual Fourth Edition (DSM IV), published in 1994, identifies five different disorders referred to collectively as the pervasive developmental disorders (PDDs).

C. Incidence of Autism

The most cited incidence statistic is that autism occurs in 4.5 of every 10,000 live births. This is based on large-scale surveys conducted in the United States and England. In addition, the estimate of children having autistic-like behaviors, i.e., when other disorders under the PDD umbrella are included, the incidence rate may go as high as 15 to 20 of every 10,000 live births. In this report the incidence of autism is not measured. The unit of measure reported here is the rate of occurrence of persons with autism or other PDDs in the regional center and developmental center system during a specified period of time. The main question addressed in this report is whether the number of regional center eligible persons with a diagnosis of autism has increased in comparison to the other Lanterman Act developmental disabilities: Cerebral Palsy, Epilepsy and Mental Retardation.

D. Findings

The findings and recommendations presented in the report are derived from analysis of demographic and Client Development Evaluation Record (CDER) data compiled at each of the 21 regional centers and forwarded electronically to the Department. Data covering a period of eleven years, beginning in January 1987 and continuing through December 1998, show that the number of persons with autism grew markedly faster than the number of persons with other developmental disabilities. Significantly greater numbers of persons with autism are entering the regional center system. In just the past year, there were 1, 685 persons with autism taken into the system. The number of persons entering the system far exceeds the expected number determined by traditional incidence rates. Estimates suggest that, compared to the other disabilities, net growth in the number of persons with autism is on average about 3 percent greater each year. Because the current trend has continued for the past several years, it suggests that relatively faster growth in the number of eligible persons with autism will continue. Compared to characteristics of 11 years ago, the present population of persons with autism are younger, have a greater chance of exhibiting no or milder forms of mental retardation, are more likely to live at home, and are more likely to receive an earlier diagnosis.

E. Conclusions

This report was not an investigation of incidence, but was rather an official counting and reporting of the numbers of persons with autism and other developmental disabilities served by the regional center system over time. This report does not include any data on those persons in California who are not part of the Developmental Services system. The Department's CDER data provide evidence that support the following two general statements: (1) the number of persons entering the system with autism has increased dramatically over the past 11 years relative to the other three developmental disabilities, and (2) the accelerated rate appears to be sustaining an upward trend into future years. In light of the information presented in this report, it is reasonable to assume that the population of persons with autism will continue to rise faster, relative to the other developmental disabilities. A valid ascertainment of the incidence of autism and other PDDs could not be made. However, the persistent and apparently stable increase in intake rates of persons with autism is justification for further and accelerated scientific study. Unfortunately, the quality and type of information examined in this report were not suitable for measuring incidence in the population of persons with autism. Ascertaining the incidence for autism and the other PDDs will require carefully controlled research. Furthermore, it is far beyond the capability of this Department to undertake such studies. Independent study of the factors that have contributed to the increase in the population of persons with autism needs to be conducted by academic institutions and medical researchers with the experience and knowledge necessary to conduct such research.

I. Introduction

This report constitutes the response of the Department of Developmental Services to legislative directives contained in the 1998-99 Budget Act for Item 4300-101-0001, provision 9. The specific requirements are that:

> The State Department of Developmental Services shall survey all regional centers and secure data from the data base of the department to ascertain the incidence of autism and pervasive developmental disorders in California. The department shall compile the number of persons who entered the regional center system during the period between January 1, 1988, to January 1, 1998, inclusive, with the diagnosis of autism and pervasive developmental disorders. The survey shall include a comparison during the period between January 1, 1988, to January 1, 1998, inclusive, of the numbers of persons with each of the other disabilities as defined by the Lanterman Developmental Disabilities Services Act (Division 4.5 (commencing with Section 4500) of the Welfare and Institutions Code) and those diagnosed with autism and pervasive developmental disorders. The department shall report its findings to the Legislature by March 1, 1999.

In 1969, landmark legislation, AB 225 (Lanterman) Chapter 1594, was signed into law by governor Ronald Reagan; this later became known as the "Lanterman Developmental Disabilities Services Act"(California Welfare & Institutions Code, Section 4500-4519). Under the Lanterman legislation, "The State of California accepts a responsibility for persons with developmental disabilities and an obligation to them which it must discharge." This bill mandated that a network of regional centers be created throughout the State. In addition, it also mandated the regional centers to serve not only persons with mental retardation but also cerebral palsy, epilepsy, autism and other neurological conditions closely related to mental retardation.

Regional centers function as a service hub, coordinating, linking and funding services and supports in their local communities for all eligible consumers and their families. The California Legislature has established that developmentally disabled residents and their families are entitled to government (state and federal) funded services. Regional centers have an obligation to ensure that essential services are provided through generically funded public agencies or, in the absence of generic agencies, through regional center funding. Services offered by regional centers include outreach and case-finding, assessment and diagnosis, individualized planning and service coordination, information and referral, and brokering of services and supports from a network of community service providers. Additional services include advocacy, crisis intervention and resource development. There are 21 regional centers from San Diego to Eureka that serve each of the 58 counties in California. The total community population including high risk infants is more than 150,000. Approximately 3,930 persons reside in the five developmental centers.

II. An overview of Autism

A. Background

It has been more than 50 years since Dr. Leo Kanner, a psychiatrist at Johns Hopkins University, wrote the first paper applying the term "early childhood autism" to a group of 11 children who were self-absorbed and who had severe social, communication, and behavioral problems. In the 55 years since autism was identified, a great many developments in diagnostic and treatment methodology have occurred. In the past 20 years there has been an explosion in scientific research in autism. More than 10,000 articles with autism as the subject appear in the scientific literature. The clinical definition of autism and other pervasive developmental disorders has evolved with highly specific behavioral descriptions that cover each age and developmental spectrum. The diagnostic criteria that define autism are written to ensure that behavioral symptoms must be observed as distinctly deviant relative to the individual's developmental level or mental age. These refinements in the diagnostic criteria increase the chance of an earlier and accurate diagnosis. See Appendix B. for the early history of autism.

Additionally, sophisticated teaching and early intervention programs have been developed that offer realistic hope for long-term developmental growth in children with autism. All of these advancements have supported the desire of parents, professionals and advocates for timely and high quality services.

B. Characteristics of Persons with Autism

Autism is a profound, and poorly understood developmental disorder that severely impairs a person's abilities, particularly in the areas of language and social relations. In many cases the disorder is evident during the first 30 months of life. Autistic children typically are normal in appearance and physically well developed. Their disabilities in communication and comprehension range from profound to mild.

There is no single adjective that can be used to describe every person with autism because the disorder is manifest in many different forms. For example, some individuals are antisocial, some are asocial, and others are partially social. Some are aggressive toward themselves and/or aggressive toward others. Approximately half have little or no language. Perhaps 25 percent repeat (echo) words and/or phrases, and another 25 percent may be capable of acquiring nearly normal language skills. Since there are no medical tests at this time to determine whether a person has autism, the diagnosis of autism is given when an individual displays six of 12 characteristic behaviors that match the criteria in the Diagnostic and Statistical Manual, Fourth Edition (DSM IV), published by the American Psychiatric Association. Persons who present autistic behaviors but fail to qualify for six or more of the criteria can be diagnosed with PDD,NOS (Pervasive Developmental Disorder, Not Otherwise Specified).

Persons with autism, compared to other disabled persons of commensurate ability, are more difficult to teach. Comparatively, persons with autism have significantly greater problems acquiring and using language and relating socially. They are rarely able to work productively in

the mainstream of employment. Historically about 75 percent of persons with autism are classified as mentally retarded. Their most distinctive feature, however - which helps distinguish them from those solely mentally retarded - is that they seem isolated from the world around them, i.e., they sometimes appear detached, aloof, or in a dreamlike world. Many individuals oftern appear only vaguely aware of others in their environment, including family members. Another characteristic that differentiates autism from persons with a primary diagnosis of mental retardation is the much greater likelihood that the autistic person will display strange postures, mannerisms, habits, and compulsions. Ritualistic behavior, hand-flapping, unusual food preferences, absence of establishing eye contact, apparent insensitivity to pain, and self-injurious behaviors are sometimes seen in persons with autism. Appropriate play with other children or toys is uncommon. There is often a great interest in inanimate objects, especially mechanical devices and appliances.

III. Recent Developments in the Field and PDD

A. The Broader Definition of Autism

Autism has multiple causes and is manifest uniquely and heterogeneously in a given individual as a collection of symptoms which are rarely the same from one individual to another. Two children with the same diagnosis, intellectual ability and family resources are more likely to be recognized more for their differences than their similarities. Variation in the degree of impact on the individual is well documented and subtypes of the disorder have been identified. The professional community continues to work to clarify the confusion and controversy concerning the nature, causes, methods of diagnosis, and treatment of autism. As research has uncovered subtle differences in the onset and development of symptoms, different types of autism have been described. In recent years an effort has been made to reclassify autism as one type of pervasive developmental disorder (PDD). The term "autistic spectrum disorder" is frequently employed to acknowledge the diversity and severity of autism. As different types of autism have been identified through scientific research, the criteria for diagnosing these other types overlap with the definition of autism and tend to make autism more difficult to diagnose. In 1968, the American Psychiatric Association's definition of autism referred to a single disorder, not a syndrome of behavioral and medical effects as it is now known to be. The third edition of the Diagnostic and Statistical Manual, published in 1980, introduced the term "pervasive developmental disorders." The current Diagnostic and Statistical Manual Fourth Edition (DSM IV), published in 1994, identifies five different disorders referred to collectively as the pervasive developmental disorders.
Those disorders include five separate diagnoses:

- Autistic Disorder, (299.00)
- Pervasive Developmental Disorder, NOS (not otherwise specified), (299.80)
- Asperger's Disorder, (299.80)
- Rett's Disorder, (299.80)
- Childhood Disintegrative Disorder, (299.10)

See Appendix A. for the specific diagnostic criteria for each of these conditions.

B. Description of the Other PDD Disorders

The following is a brief description of the other four pervasive developmental disorders:

1. **Pervasive Developmental Disorder, NOS** (PDD,NOS) is diagnosed when autistic symptoms are present but the full criteria for autistic disorder are not met. Therefore, persons diagnosed with PDD,NOS present with autistic symptoms, but typically are not as involved with the social and communication deficits as persons who meet the full criteria for autism. Generally, they are higher functioning and more responsive to treatment. PDD,NOS, along with Asperger's disorder, is thought by some researchers to be as common as autism.

2. **Asperger's Disorder** was first described by a German doctor, Hans Asperger, in 1944 (one year after Leo Kanner's first paper on autism). In his paper, Dr. Asperger discussed individuals who exhibited many idiosyncratic, odd-like behaviors. Unlike children with autism, children diagnosed with Asperger's disorder develop lucid speech before age four years and their grammar and vocabularies are usually adequate for normal conversation. Their speech is sometimes stilted and their repetitive voice tends to be flat and emotionless; their conversations revolve around themselves. Asperger's disorder is characterized by concrete and literal thinking. Persons with Asperger's disorder are usually obsessed with complex topics, weather, music, astronomy history, etc. Intellectual ability for most is in the normal to above normal range in verbal ability and in the below average range on tasks of visual-perceptual organization. Sometimes it is assumed that the individual who has autism and average mental ability has Asperger's disorder. However, it appears that there may be several forms of high-functioning autism, of which Asperger's disorder is only one form.

3. **Rett's Disorder** is a degenerative disorder which affects only females and usually develops between six months and 18 months of age. Some of their characteristic behaviors may include the following: loss of speech, repetitive hand-wringing, body rocking, and social withdrawal. Those individuals suffering from this disorder may be severely to profoundly mentally retarded. This disorder, along with childhood disintegrative disorder, is extremely rare.

4. **Childhood Disintegrative Disorder** (CDD) is included among the PDDs because these children apparently develop normally for two or more years before suffering a distinct regression in their abilities. Affected children lose previously acquired functional skills in expressive or receptive language, social skills or adaptive behavior including bowel or bladder control, play, or motor skills. Individuals with this disorder are rarer than persons with autism or one of the other PDDs; they exhibit the social, communicative and behavioral deficits observed in autism including loss of desire for social contact, diminished eye contact, and loss of nonverbal communication.

As research into autism continues, the diagnostic criteria published in DSM IV are continuing to be modified to reflect what is known about the different types of autism. As research has revealed the essential qualities of the disorder, clearer criteria allow more accurate diagnosis.

IV. Rates of Occurrence of Autism

A. Incidence Defined

Scientific measurement of the incidence of autism requires a carefully controlled study that captures the number of newly diagnosed persons with autism during a specified period of time and in a location with specified boundaries. The study would also have to identify the entire population of persons at risk, i.e., the number of new born infants in a specified location. To ensure the accuracy of the study, a large number of confounding variables would have to be controlled. Some of the variables that would have to be carefully controlled are accuracy of the diagnosis of autism, determining and counting the at-risk population, consistency of data collection across a large geographic area, subject finding, etc.

The most cited incidence statistic is that autism occurs in 4.5 of every 10,000 live births. This is based on large-scale surveys conducted in the United States and England. In addition, the estimate of children having autistic-like behaviors, i.e., when other disorders under the PDD umbrella are included, the incidence rate is 15 to 20 of every 10,000 live births. The scientific literature reports that autism is three times more likely to affect males than females. The gender difference is not unique to autism since many developmental disabilities have a greater male-to-female ratio.

B. Approach Used In This Study

In this report the incidence of autism is not measured. The unit of measure reported here is the rate of occurrence of persons with autism or other PDDs in the regional center and developmental center system during a specified period of time. The number of persons with autism, or other disability, varies daily by a small percentage because persons are leaving the system and newly eligible persons are entering. Because the number of persons in the system varies, data presented in this report were taken at the end of the year for years 1987 and 1998. The values of variables sampled at these two different times are compared to determine what significant changes may have occurred. The main question addressed in this report is whether the number of regional center eligible persons with a diagnosis of autism has increased compared to the other developmental disabilities, i.e., Cerebral Palsy (CP), Epilepsy (EP) and Mental Retardation (MR).

The findings and recommendations presented in the report are derived from analysis of demographic and Client Development Evaluation Record (CDER) data compiled at each of the 21 regional centers and forwarded electronically to the Department. The CDER file contains

consumer diagnostic and evaluation information recorded at the regional center or developmental center when a consumer is given a client development evaluation. This report focuses on the rate of intakes of persons with autism and other developmental disabilities into the regional center system over an 11-year period.

Autism is recorded on the CDER with one of three different codes - Level 1, Level 2 and Level 9. For the purposes of this study, a fourth code (Level 4) was created to capture four other types of PDD, including PDD,NOS, Asperger's Disorder, Rett's Disorder and Childhood Disintegrative Disorder. These PDD codes are recorded in the Mental Disorders section of the CDER. The four levels of classification used to search the Department's data files are listed accordingly:

- Level 1 - Autism, full syndrome
- Level 2 - Autism, residual state
- Level 4 - Composed of DSM IV, PDD codes 299.1, 299.80 and 299.88
- Level 9 - Autism suspected, not diagnosed

For the purposes of this report, data are reported using all four levels unless otherwise noted.

C. Early Start Program

Additionally, the Department provides early intervention services to infants and toddlers under three years of age who may be at risk or have significant developmental delay. In 1992, the Department began entering demographic data for children considered at-risk in the age range birth to three into a different database. Data describing these children are reported on the Early Start Profile. These data were not counted in this report as the majority of these children are not yet diagnosed with a developmental disability such as autism but are receiving services because of atypical development or language delay. As of January 6, 1999, there were 15,083 children receiving services through the Early Start program. The data reported here were taken from the total number of CDERs on the electronic file at the end of 1987 and 1998. The Department estimates that 95 percent of all active cases, including persons in the developmental centers, have a completed CDER on file. At the end of 1987 there were 80,389 CDERs on file. At the end of 1998, there were 129,169 CDERs on file.

V. Findings

A. Summary of the 1987 and 1998 Populations

Table 1 shows the number and percent change in the number of persons with autism and other PDDs counted from all four levels of CDER classification in the 11 years between 1987 and 1998. The population of persons with autism increased from 4.85 to 9.37 percent of the total

state wide client population. At the end of 1998 there were 12,780 persons, of all ages, with autism listed on the CDER. Autism as a percent of the total client population nearly doubled.

Table 1 - Number of Persons with Autism in 1987 and 1998

	1987	1998
Total Client Population	80,483	136,383
Persons with Autism (Levels 1, 2 & 4)	3,902	12,780
Percent of Total Client Population	4.85 %	9.37 %

Table 2 presents the total number and percent change between 1987 and 1998 for persons with autism, cerebral palsy, epilepsy and mental retardation. To maintain equivalency in the way each diagnostic condition is counted, only CDER classification Levels 1 and 2 for persons with autism are used in this table. Because some individuals have two or more of the four eligible conditions at the same time, all possible combinations of eligible conditions were used and a separate count was obtained for each condition or combination of conditions. For example, if an individual has cerebral palsy, epilepsy and mental retardation, that person would be counted three separate times, once for each separate condition to get the total for each separate condition.

Table 2 shows that the percent occurrence of persons with autism increased dramatically in comparison to the other conditions for the 11 years between 1987 and 1998. The rate of the increase is more than four times as great as the other diagnostic categories.

Table 2 - Percent Increase in Diagnostic Populations from 1987 to 1998

	1987	1998	Percent Change
Autism (All Combinations)	3,864	11,995	210.43%
Cerebral Palsy (All Combinations)	19,972	28,529	42.84%
Epilepsy (All Combinations)	22683	29,645	30.69%
Mental Retardation (All Combinations)	72,987	108,563	48.74%
Whole Population	80,483	136,383	69.46%

As one example of the increase in the number of persons with autism, between 12/31/97 and 12/31/98, there was a net increase of 1,685 persons with autism into the system. The population of persons with autism increased 16.3 percent in one year, not including persons with other PDD diagnoses. By the end of 1998, there were 785 persons in the system with a diagnosis of one of the (Level 4) PDD diagnoses, i.e., Asperger's, PDD,NOS or Rett's disorder.

Table 3 shows the percent change in occurrence of the other PDDs in comparison to autism. There was a 273 percent increase in the number of persons with autism between 1987 and 1998 and nearly a 2000 percent increase in the PDD categories. Table 3 also shows that as of December 31, 1998, there were 1,635 individuals coded on the CDER as "autism suspected, not diagnosed."

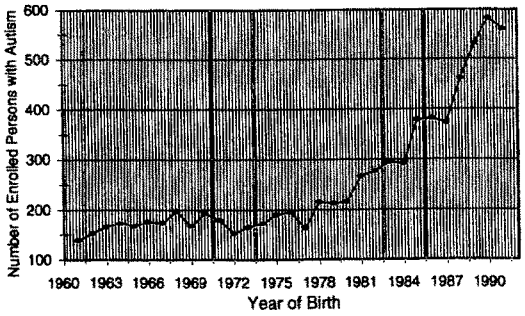
Table 3 - Autism and the Other PDDs Compared

	1987	1998	Percent Change
Autism (CDER Levels 1 & 2)	2,778	10,360	272.93%
Other PDD Types (CDER Level 4)	38	785	1,965.79 %
Autism Suspected, Not Diagnosed (CDER Level 9)	1,086	1,635	50.55 %

B. Changes in Population Rates of Intake

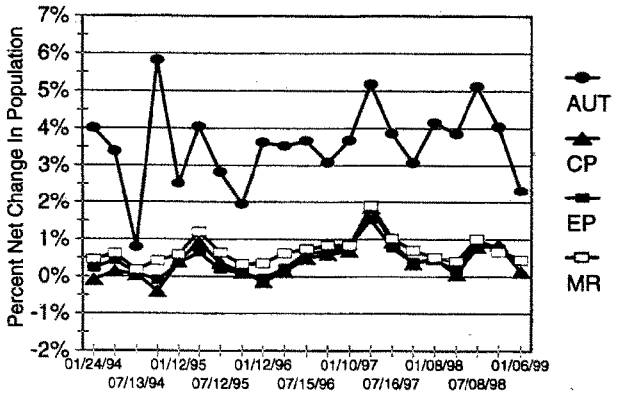
One method of recognizing if there is a change in the number of persons entering the system is to plot changes in the number of persons in the system across a number of years in order to identify trends and significant changes in the numbers. Figure 1 plots the 1991 population of persons (7,915) with autism by year of birth. Data points in Figure 1 do not show how many persons entered the system in a given year, but how many already in the system were born in a given year.

Figure 1 - Distribution of Birth Dates of Regional Center Eligible Persons with Autism



Beginning in August 1993, the Department began to publish quarterly summary reports of the number and characteristics of persons in the entire service delivery system. Figure 2 shows the quarterly net percent change in the number of persons with autism reported in the Statewide Client Characteristics summary compared to persons with CP, EP and MR. Comparison data run from August 1993 to January 1999. Figure 2 suggests that persons with autism were entering the system at a significantly faster pace than the other three eligible conditions at the beginning of 1994, or before 1994.

Figure 2 - Net Percent Change In Eligible Condition From August 1993 to January 1999



C. Changes in Autism Population Characteristics

The DSM IV reports that the male-to-female ratio among persons with autism is "four to five times higher in males than in females." CDER data support this claim. Males represent 79.9 percent of the population of persons with autism compared to 20.1 percent for females. In 1987, the percent of males was 74.6 versus 25.4 percent for females. There has been a 5.3 percent increase in the proportion of males in 11 years.

Age distribution of the population of persons with autism is shown in Figure 3. By the end of 1998, nearly half of the population of persons with autism consisted of children between birth and nine years of age. What is more important, during the 11-year period between 1987 and 1998, the median age of the population of persons with autism drops from 15 years to nine years. Clearly, more and younger children are entering the system.

Figure 3 - Age Distribution for Autistic Population in 1987 and 1998

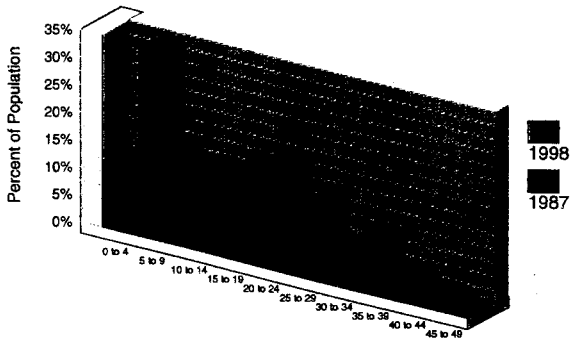


Figure 4 shows age at the time of intake into the regional center. Figure 4 shows that persons with autism who are four years or younger account for the greatest increase in new intakes. By the end of 1998, more than half (55 percent) of all persons with autism were made eligible before their fourth birthday. By comparison, only about one third (34.6 percent) of the 1987 population were enrolled by age four. In 1987, 30.1 percent of the intakes were in the 10 to 19 year age range compared to 17 percent in 1998. A one year comparison between 1997 and 1998 shows that the greatest relative increase in new intakes was in the birth to four year group (See Figure 4).

Figure 4 - Age At Intake Into Regional Center

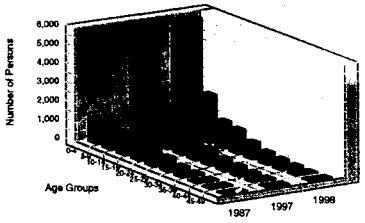
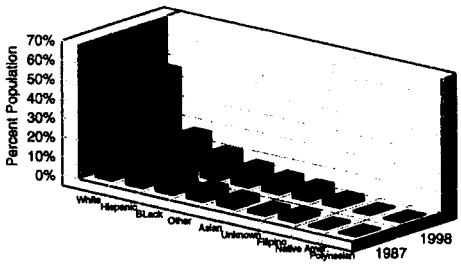


Figure 5 shows ethnicity for the population of persons with autism. Compared to the total population, ethnicity of persons with autism generally conforms to the percentage representations of each ethnic group in the California population. Notable changes in ethnicity during the 11 years of this study show a 13.6 percent drop in White persons with autism and a 6.5 percent increase in the Hispanic population.

Figure 5 - Ethnicity Among Persons with Autism



Cognitive ability varies greatly among persons with autism. Figure 6 shows the distribution of intellectual abilities for the population of persons with autism. Figure 6 shows that 42 percent of persons with autism function intellectually above the level of mental retardation. Nearly 20 percent are in the mild range (IQ 55 to 70). The remaining 37.7 percent have moderate or lower levels of intellectual ability. There was a significant change in the percent of persons with no mental retardation during the 11-year time difference between samples. The current population of persons with autism reflects significantly more persons with no or mild mental retardation and far fewer persons with severe to profound mental retardation.

Figure 6 - Mental Ability and Autism

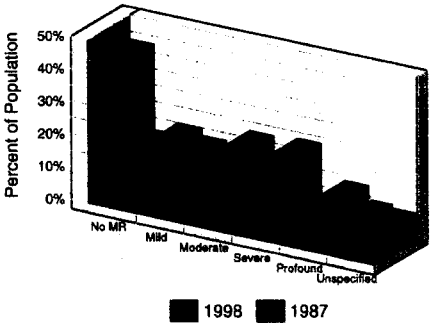
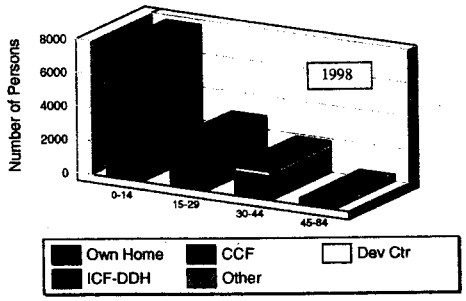
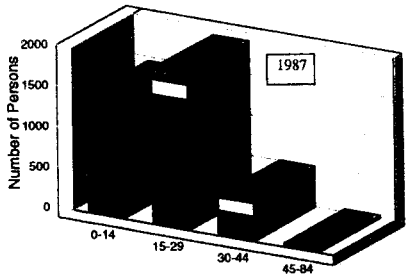


Figure 7 shows type of residence for the entire number of persons with autism categorized by age groups for the years 1998 and 1987. Ninety four percent of persons with autism of all ages live in one of two types of residence: own home and community care facility (CCF). The remaining 6 percent live in the developmental center, ICF-DDH or other[1] type of residence. In 1998, 79 percent (10,035) of persons of all ages lived at home with their families or in an independent living setting. In 1987, 55 percent (2,151) lived at home. The greatest percentage increase (19 percent) between 1987 and 1998 was in the Own Home, birth to 14 age group. As more, and younger, persons with autism came into the system, they were more likely to stay at home. The percentage of persons in the age range 15 to 29 living in CCFs decreased in 1998.

Figure 7 - Residence Type By Age Group

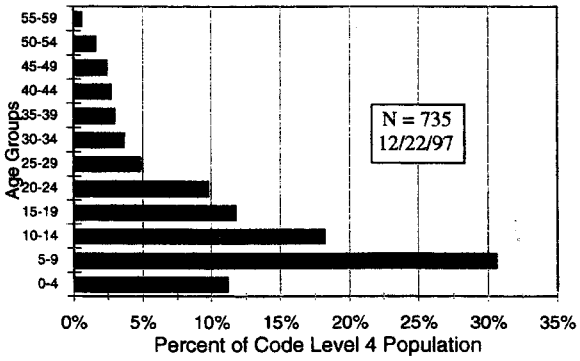




[1] The "Other" category in Figure 8 includes ICF-DD, ICF-DDN, SNF and psychiatric hospitals. The total number of person in the Other residence category total 19.

Figure 8 shows the age distribution of persons with one of the following diagnoses: Asperger's, PDD,NOS, Childhood Disintegrative Disorder or Rett's. All four of these PDDs were combined into one sample taken on 12/22/97. Just more than 30 percent of these other PDDs were in the five to nine year age range. The second highest percent (18 percent) of that group was in the 10 to 14 age range. Nearly half (48.6 percent) of the entire sample was between five and 14 years of age.

Figure 8 - Age Distribution of Asperger's, PDD,NOS, Rett's & CDD



VI. Discussion of Findings

A. An Emerging Group of Consumers

Data covering a period of eleven years, beginning in January 1987 and continuing through December 1998, show that the number of persons with autism, not including other PDD diagnoses, grew faster than the number of persons with other developmental disabilities. Significantly greater numbers of persons with autism are entering the regional center system. In just the past year, there were 1,685 persons with autism taken into the system. This number of persons far exceeded the expected number determined by traditional incidence rates. Rough estimates of the expected number of persons that could potentially be diagnosed annually with autism can be made by multiplying the number of live births in one year in California by the published incidence rate(s). In 1998 the Center for Health Statistics, Department of Health Services estimated 526,501 live births statewide in California. Using DSM IV incidence rates of 2 to 5 persons per 10,000 live births yields an estimate of 105 to 263 persons per year. During

calendar year 1998 there were 11,995 persons with autism or one of the other PDDs and an additional 1,635 persons suspected of having autism. Using published incidence rates that include autism, Asperger's and PDD,NOS, which range from 15 to 20 cases per 10,000 live births, an estimated 790 to 1,053 persons per year could be diagnosed with autism or one of the other PDDs. The number of new intakes has exceeded the annual estimate of persons likely to be diagnosed with autism for the past few years.

Estimates suggest that, compared to the other disabilities, net growth in the number of persons with autism is about 3 percent greater each year. Because the current trend has continued for the past several years, it suggests that relatively faster growth in the number of eligible persons with autism may continue well into the next century. Other government reports, such as the Nineteenth Annual Report to Congress on the implementation of the Individuals with Disabilities Education Act, document substantial increases in autism. Between fiscal years 1994-95 and 1995-96, the 1997 Nineteenth Annual Report to Congress states that the number of children with autism grew by 27.2 percent and was one of "the largest relative increases."

B. Summary of Changes in the Current Population

The data show that younger children constitute the majority of new intakes. A rapidly expanding subpopulation of children diagnosed with one of the other PDDs has emerged since the creation of the PDD diagnoses. This population grew from 38 individuals in 1987 to 785 in 1998. There are an additional 1,635 individuals "suspected" of having autism and 13,496 more undiagnosed children in the early start program. An undetermined percentage of individuals in these groups, upon clarification of their diagnostic status, will further increase the number of persons with autism and/or PDD.

Compared to client characteristics of 11 years ago, the population of persons with autism is younger, exhibits no or milder forms of mental retardation, is more likely to live at home and is more likely to receive an earlier diagnosis. Nearly half of the 1998 population is less than nine years of age compared to only one fourth of the population in 1987.

The number of persons who function intellectually above the range of mental retardation increased from 16 percent to 43 percent, a 26 percent point increase in 11 years. The increases in intellectual gains were relatively broad. Level of intellectual functioning in 29 percent of the population of persons with autism shifted from the moderate range (IQ 40 to 54) to the mild range (IQ 55 to 70) of mental retardation.

By the end of 1998, an individual's chances of remaining in his/her own home increased significantly for children up to 14 years. In the birth to 14 year group, 74 percent live at home. In the 15 to 29 years old group, the greatest proportion of persons with autism live in a CCF.

Except for a 14 percent drop in the number of White persons and a 7 percent increase in Hispanic persons with autism, ethnic representation did not change appreciably in 11 years. Overall, ethnic representation roughly paralleled the state census.

VII. Conclusions

This report was not an investigation of incidence, but was rather an official counting and reporting of the number of persons with autism and other developmental disabilities served by the regional center system over time. The Department's CDER data provide preliminary evidence that support the following two general statements: (1) the number of persons entering the system with autism has increased dramatically over the past 11 years relative to the other three developmental disabilities, and (2) the accelerated rate appears to be sustaining an upward trend which will continue into future years. In light of the information presented in this report, it is reasonable to assume that the population of persons with autism will continue to rise faster, relative to the other developmental disabilities, for the next several years.

The quality and type of information examined in this report were not suitable for measuring incidence in the population of persons with autism. Ascertaining the incidence for autism and the other PDDs will require carefully controlled research. Furthermore, it is far beyond the capability of this Department to undertake such studies. Independent study of the factors that contribute to increases in the population of persons with autism needs to be conducted by academic institutions with the experience and knowledge necessary to conduct such research. Examples of such institutions are Medical Investigation of Neurodevelopmental Disorders (MIND Institute) within the University of California system.

The cause(s) of the increase in the population of persons with autism served by the regional center over the past 10 years is unknown. The sheer complexity of this phenomenon prevents any clear conclusions about the exact determinants of the increase. Speculation about the rise in numbers is abundant, but such speculation is not based on scientific research and typically leads to debate and controversy when offered as a cause. In fact, rampant speculation followed by acrimonious debate about the causes of an increase in autism has provoked one congressman, Representative Christopher H. Smith, to introduce legislation (H.R. 274) aimed at providing a greater understanding. Representative Smith's bill addresses the causes and occurrence of autism and related pervasive developmental disabilities. This measure, entitled the Autism Statistics, Surveillance, Research, and Epidemiology Act of 1999 would provide additional funding for the Centers for Disease Control and Prevention to create a network of epidemiological research centers across the country.

What we do know is that the number of young children coming into the system each year is significantly greater than in the past, and that the demand for services to meet the needs of this special population will continue to grow. If present rates of intake continue, there will be a need for: (1) greater emphasis on long range planning to develop suitable methods of delivering services, (2) strategies for development of new and abundant resources; (3) clinical training of regional center personnel in diagnostic and treatment standards necessary to adequately advise parents and (4) creation of forums for information exchange and collaboration between providers and the families of children with autism. In conclusion, there is a real need to accelerate multi-discipline, multi-faceted research efforts in this area.

VIII. Appendix

A. Diagnostic criteria for 299.00 Autistic Disorder

A. A total of six (or more) items from (1), (2), and (3), with at least two from (1), and one each from (2) and (3):
(1) qualitative impairment in social interaction, as manifested by at least two of the following:

(a) marked impairment in the use of multiple nonverbal behaviors such as eye-to-eye gaze, facial expression, body postures, and gestures to regulate social interaction

(b) failure to develop peer relationships appropriate to developmental level

(c) a lack of spontaneous seeking to share enjoyment, interests, or achievements with other people (e.g., by a lack of showing, bringing, or pointing out objects of interest)

(d) lack of social or emotional reciprocity

(2) qualitative impairments in communication as manifested by at least one of the following:

(a) delay in, or total lack of, the development of spoken language (not accompanied by an attempt to compensate through alternative modes of communication such as gesture or mime)

(b) in individuals with adequate speech, marked impairment in the ability to initiate or sustain a conversation with others

(c) stereotyped and repetitive use of language or idiosyncratic language

(d) lack of varied, spontaneous make-believe play or social imitative play appropriate to developmental level

(3) restricted repetitive and stereotyped patterns of behavior, interests, and activities, as manifested by at least one of the following:

(a) encompassing preoccupation with one or more stereotyped and restricted patterns of interest that is abnormal either in intensity or focus

(b) apparently inflexible adherence to specific, nonfunctional routines or rituals

(c) stereotyped and repetitive motor mannerisms (e.g., hand or finger flapping or twisting, or complex whole-body movements)

(d) persistent preoccupation with parts of objects

B. Delays or abnormal functioning in at least one of the following areas, with onset prior to age 3 years: (1) social interaction, (2) language as used in social communication, or (3) symbolic or imaginative play.

C. The disturbance is not better accounted for by Rett's Disorder or Childhood Disintegrative Disorder.

Diagnostic criteria for 299.80 Rett's Disorder

A. All of the following:

(1) apparently normal prenatal and perinatal development

(2) apparently normal psychomotor development through the first 5 months after birth

(3) normal head circumference at birth

B. Onset of all of the following after the period of normal development:

(1) deceleration of head growth between ages 5 and 48 months

(2) loss of previously acquired purposeful hand skills between ages 5 and 30 months with the subsequent development of stereotyped hand movements (e.g., hand-wringing or hand washing)

(3) loss of social engagement early in the course (although often social interaction develops later)

(4) appearance of poorly coordinated gait or trunk movements

(5) severely impaired expressive and receptive language development with severe psychomotor retardation

Diagnostic criteria for 299.10 Childhood Disintegrative Disorder

A. Apparently normal development for at least the first 2 years after birth as manifested by the presence of age-appropriate verbal and nonverbal communication, social relationships, play, and adaptive behavior.

B. Clinically significant loss of previously acquired skills (before age 10 years) in at least two of the following areas:

(1) expressive or receptive language

(2) social skills or adaptive behavior

(3) bowel or bladder control

(4) play

(5) motor skills

C. Abnormalities of functioning in at least two of the following areas:

(1) qualitative impairment in social interaction (e.g., impairment in nonverbal behaviors, failure to develop peer relationships, lack of social or emotional reciprocity)

(2) qualitative impairments in communication (e.g., delay or lack of spoken language, inability to initiate or sustain a conversation, stereotyped and repetitive use of language, lack of varied make-believe play)

(3) restricted, repetitive, and stereotyped patterns of behavior, interests, and activities, including motor stereotypies and mannerisms

D. The disturbance is not better accounted for by another specific Pervasive Developmental Disorder or by Schizophrenia.

Diagnostic criteria for 299.80 Asperger's Disorder

A. Qualitative impairment in social interaction, as manifested by at least two of the following:

(1) marked impairment in the use of multiple nonverbal behaviors such as eye-to-eye gaze, facial expression, body postures, and gestures to regulate social interaction

(2) failure to develop peer relationships appropriate to developmental level

(3) a lack of spontaneous seeking to share enjoyment, interests, or achievements with other people (e.g., by a lack of showing, bringing, or pointing out objects of interest to other people)

(4) lack of social or emotional reciprocity

B. Restricted repetitive and stereotyped patterns of behavior, interests, and activities, as manifested by at least one of the following:

(1) encompassing preoccupation with one or more stereotyped and restricted patterns of interest that is abnormal either in intensity or focus

(2) apparently inflexible adherence to specific, nonfunctional routines or rituals

(3) stereotyped and repetitive motor mannerisms (e.g., hand or finger flapping or twisting, or complex whole-body movements)

(4) persistent preoccupation with parts of objects

C. The disturbance causes clinically significant impairment in social, occupational, or other important areas of functioning.

D. There is no clinically significant general delay in language (e.g., single words used by age 2 years, communicative phrases used by age 3 years).

E. There is no clinically significant delay in cognitive development or in the development of age-appropriate self-help skills, adaptive behavior (other than in social interaction), and curiosity about the environment in childhood.

F. Criteria are not met for another specific Pervasive Developmental Disorder or Schizophrenia.

299.80 Pervasive Developmental Disorder Not Otherwise Specified (Including Atypical Autism)

This category should be used when there is a severe and pervasive impairment in the development of reciprocal social interaction or verbal and nonverbal communication skills, or when stereotyped behavior, interests, and activities are present, but the criteria are not met for a specific Pervasive Developmental Disorder, Schizophrenia, Schizotypal Personality Disorder, or Avoidant Personality Disorder. For example, this category includes "atypical autism"--presentations that do not meet the criteria for Autistic Disorder because of late age at onset, atypical symptomatology, or subthreshold symptomatology, or all of these.

B. Early History of Autism

Our understanding of autism has evolved from a crude and inaccurate description to a more refined and legitimate scientific knowledge. In the beginning, and partly based on Kanner's perception of autism, it was believed that persons with autism had "good cognitive potentialities." The myth of the autistic child possessing a latent genius endured for several years and has caused great distress for family members and teachers who have nearly always failed to find the key to "unlock" the alleged genius. Another misconception linked to Kanner's belief, and later perpetuated by Bruno Bettleheim, was the view that it was the parents' behavior, particularly the mother's, that caused the autistic condition. Kanner observed that parents in his clinic were from upper-middle-class backgrounds and had a cold manner in dealing with their autistic children. Bettleheim, in the 1960s, picked up this theme and built a theory of the nature of autism in which the emotional coldness of parents was the central cause. The term "refrigerator mom" was used to describe the mother's hopelessness, despair, and apathy which, when projected onto the child, caused the child to withdraw from reality. Bernard Rimland, a parent and founder of the Autism Society of America, in the late 1960s played an important role in changing the prevailing psychoanalytic view of autism that had been popularized by Bettleheim. Rimland put forth a neurologically based approach, which opened the door for the burgeoning biomedical research of today.

The abandonment of a psychoanalytic approach to treating autism led to the rapid growth of research and treatment based on behavioral, cognitive-developmental, and recent medical research. Beginning in the 1960s and continuing through the present, psychological research was applied to the learning of children with autism. Today the integration of basic behavioral research and treatment programs into many different treatment settings has led to substantial knowledge and improved services. Applied behavior analysis has led to a much broader emphasis on educational programming and the need for early teaching of practical skills for community living throughout the life span. The availability and effectiveness of behavioral support services, in conjunction with the concept of normalization and the least restrictive environment, have contributed to the reversal in a trend to institutionalize children with autism. Before effective behavioral support services were so commonplace, children with autism, typically by age nine or 10, were so out of control their parents were compelled to place them in institutions. Unfortunately, the medical profession, faced with little or no alternatives, endorsed the idea of institutionalizing children during the 1960s and 1970s.

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Mr. BURTON. Mr. Rollens, that was a very eloquent statement, and I will just pledge to you personally that we will do everything we possibly can as a committee to find out everything we can. We will ask people from the Surgeon General's office and the Departments of Health to stay. They heard your statement as well, and I will just say to them that this isn't the only hearing we are going to have on this. We are going to be beating on this issue as long as I am chairman of this committee, which hopefully will be for a while.

So I hope that you folks will do everything you possibly can to help us find a solution to this problem, because not only does Mr. Rollens have an autistic child, I have an autistic grandchild. I also have a granddaughter that almost died from the hepatitis B shot, I believe. So, you know, we have people that have had that problem with hepatitis B and autism, and the chairman of this committee has had both with two grandchildren. So I don't think it is just a coincidence.

Ms. Zitzmann.

Ms. ZITZMANN. Mr. Chairman and members of the committee, I would like to thank you for allowing me as a mother to come here today and testify before you. My story will probably be a little different from what you have heard just now.

When two people marry, they have dreams of life together and having a family. One day this becomes true, but something suddenly goes wrong. You are told that your child has problems but they don't know what because they need to do testing. Much later you discover that while traveling to work on the transit system, a bus and two trains into Manhattan, someone infected you with the rubella virus. You find out later it went directly into the developing fetus in the early stages of your pregnancy, causing the disabilities your son now experiences. But you only find this out after your baby is born, because the virus does not show signs of infection on you. The rubella virus does damage while the infant is developing, and now there are vaccines to prevent this.

The guilt you experience when you learn your child is not normal and will never be is very difficult and hard on the family, and you begin to ask yourself, what did I do wrong to have this happen? Thankfully, I have had a very supportive husband in these last number of years.

My story is that Robert, who is now 34 years old, was born with mental retardation and disabilities because of the lack of the vaccination. I was born and raised in Brooklyn and lived in Queens after I got married, but traveled to Manhattan every work day. Perhaps you recall it was mentioned earlier the 1964 New York rubella outbreak that had happened.

Soon after our son was born in 1964, we knew something was wrong. He couldn't nurse, his sucking reflexes were poor. To this day, he cannot suck on a straw, blow out a candle or blow his nose. He was delayed in holding objects in his hands, sitting, walking, and he didn't know how to hold onto you when you picked him up. He had many bouts of respiratory infections and pneumonia. His eyes were also affected and he has been wearing glasses since he was 3, and they continue to deteriorate, and I am being told he will develop cataracts.

He has no speech, therefore, no language skills. He needs to be dressed, undressed, bathed, shaved, toileted, many times because he soils himself still. His foods need to be prepared and carefully selected. He has certain food intolerances. He can feed himself when his food is cut up, most of the time with a spoon, a lot of the times with his hands.

His motor skills and coordination are also poor. Bob will wander off if not watched, and we have had to put bolt locks on our front doors to prevent him from leaving, and we have had to call the police to try to find him. We now have an ID bracelet on him.

All through Bob's growing years, I have met many families who share my experiences due to the rubella exposure and have always been a strong proponent for parents to immunize their children against such viruses, recognizing, however, that the decision remains one of family choice, but also knowing that since the vaccine has been developed, many individuals have been prevented from becoming disabled.

Bob lived at home with us for 21 years, when we made a critical decision in his life and placed him in a private, intermediate care facility for the mentally retarded [ICFMR], which is a Medicaid funded and federally certified residential program. He thoroughly enjoys his home in Wide Horizons. When he comes to visit us, within a few days he signs he wants to go back because he is bored.

Before he moved to Wide Horizons, though, and was living with us, we were not able to go out to dinner together, attend church together, picnics, movies, or vacations. I was changing diapers and pants daily on this young man. Sometimes I had to change and strip him twice during the night, which meant little sleep for both of us.

Bob and others like him need more supervision, more structure, and do well with routine and not so well with changes in their daily life. Because his home is an ICFMR, it means that his medical, dental, therapeutic, and recreational needs are also arranged by the facility through community providers.

As a parent, I needed a guarantee of safety and oversight, because he is so vulnerable. He is happy and doing well, even with all his disabilities. We as a family appreciate having the ICFMR available to us to choose from.

As a citizen, we select Members of Congress to serve as our proxy when it comes to matters of public policy, and I thank you for your time today, and trust that you will keep preservation of family choice foremost in your mind as policies impacting people with regard to vaccines is decided, and I truly hope that this committee will consider looking into why there are reactions to these vaccines when it is supposed to be helping people, not hurting them. I always wonder, if we had had this vaccine back then, what would my son be like today?

Thank you.

[The prepared statement of Ms. Zitzmann follows:]

Voice Of the Retarded

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A Mother's Story:
The necessity for family choice

by Carola Zitzmann
August 3, 1999

When two people marry, they have dreams of life together and of having a family. One day this becomes true, but something goes wrong. You are told that your child has problems, but they don't know what yet, because they need to do some testing. Much later you discover that while you were traveling to work on the transit system (a bus and two trains into Manhattan), someone infected you with the Rubella virus which you find out later went directly into the developing fetus in the early stages of your pregnancy, causing the disability your son now experiences. But you only find this out after your baby is born because this virus does not have to show signs of its infection on you. The Rubella virus does its damage while the infant is developing. There are now vaccines to prevent this.

The guilt feeling you experience when you learn your child is not normal and will never be normal because he has a cognitive disability is very difficult and hard on a Mother. You begin to ask yourself, "what did I do wrong to have this happen?". Thankfully, throughout this time of discovery and the life long challenges ahead, I had a very supportive husband. We have prevailed through these challenges and have been married 36 years.

Let me share with you what transpired before and after the virus permanently disabled my son, Robert, who is now 34 years old, as I feel my story - born of the lack of vaccination - will help you structure appropriate policy for these situations. I was born and raised in Brooklyn. After marriage I lived in Queens and traveled to Manhattan every work day. Perhaps you can recall the 1964 New York Rubella outbreak. Soon after our son Bob was born in 1964 we knew something was wrong. He couldn't nurse, so we had to use large hole nipples on the bottles, his sucking reflex was poor. To this day he cannot suck on a straw or blow out a candle. He was delayed in holding objects in his hands, in sitting, in walking and he didn't hold on to you when you picked him up. He had many bouts of respiratory infections and pneumonia. His eyes where also affected and has been wearing glasses since he was three years old and they continue deteriorate. I am being told he probably will develop cataracts. He has no speech, therefore no language skills. He needs to be dressed, undressed, bathed, shaved and toileted (many times he still soils himself), his food needs to be prepared and carefully selected (his digestive system has trouble with many different types of foods). He can feed himself if you cut up his food so he can use a spoon and sometimes a fork (with lots of coaching). His motor skills and coordination are also poor. Bob will wonder off if not watched and we have had to put bolt locks on our front doors. Yes, he has wandered off on us and we have had to call the police. We put identification bracelets on him with his name address and our phone number.

Bob was diagnosed by the doctors at Columbian Presbyterian Hospital in New York City and Burke Rehabilitation Institute in Westchester County, White Plains, New York. A geneticist and a pediatrician were the first to diagnose the problem. An optometrist fourteen years later confirmed it because he saw the Rubella scar tissue near his retina. All through Bob's growing years, I have

met many families who share my experience due to Rubella exposure and have always been a strong proponent for parents to immunize their children against such viruses, always recognizing, however, that the decision remains one of family choice.

The right of family and guardian choice remains a concern for me. Having a profoundly mentally retarded child means that parenting never ends for that child. Decisions are made daily that work to ensure that he is being cared for appropriately and allowed to develop to his own individual potential. Medical, dental, therapeutic, recreational, residential and host of other decisions constantly besiege my husband and I as Bob's parents and guardians.

A critical decision in Bob's life was where he would live when he reached adulthood. Bob lived at home with us for 21 years, when we decided to place him in a private Intermediate Care Facility for The Mentally Retarded (ICF/MR), a Medicaid-funded and federally-certified residential program. He thoroughly enjoys his home and life at Wide Horizon's. When he comes to visit us, after two days he gives us signs that he wants to go back home because he is bored with us. Before he moved to Wide Horizon's and was living with us, we were not able to go out dinner together, not able to attend church together, picnics, movies or go on vacation. I was changing diapers or pants daily on this young man and sometimes I had to change him and strip his bed twice a night, meaning very little sleep. There was little freedom for us or him.

Despite the many choices and decisions we as parents enjoy (and endure), fundamental decisions such as where Bob should live are constantly threatened. All ICFs/MR or institutions, large or small, are being threatened with closure by organizations, some of which are federally-funded,

whose philosophies disagree with my choices. Bob and others like him need more supervision, more structure, do well with routine and do not do well with changes in their daily lives, especially changes in staff or being moved from home to home. In addition, the fact that his home is an ICF/MR means that his medical, dental, therapeutic and recreational needs are also arranged by the facility, usually through contracts with local community providers. To threaten his home is to threaten every component of his daily well-being, happiness, safety and personal development. As a parent, I need a guarantee of safety and oversight because he is so vulnerable. He is happy and doing well, even with all his disabilities, and his happiness is now being threatened because other individuals and organizations feel the choices I made in his best interest are wrong.

Who are these other organizations? In Utah, and in many other states, it is often the federally funded state Developmental Disabilities Councils and state Protection and Advocacy Systems. These groups are authorized under the Developmental Disabilities Assistance and Bill of Rights Act and receive federal funding through the Department of Health and Human Services (see attachment A). Ironically, their federal funding is used to dismantle the ICF/MR program, also certified and funded through the Department of Health and Human Services. I mention this because as an involved parent of a young man with profound mental retardation and related physical disabilities and medical needs, I have been advocate for Bob his entire life. I have worked to ensure there were early intervention and educational opportunities appropriate to his needs, and as he grew into an adult, secured for him a residential placement that he and I are both delighted with. It seems unfair that my hard work and appropriate choices could be undone, using my taxpayer dollars, because certain organizations who don't even know Bob pretend to know what is best for him. The Developmental Disabilities Assistance and Bill of Rights Act must be reauthorized this year. This

affords members of Congress the opportunity to study these programs to make sure they are doing what Congress intended. It would serve people like Bob well for this Committee to review the effectiveness of these programs (see Attachment A).

Family choice must be paramount, whether we are talking about vaccination requirements or residential choice. As citizens, we elect the members of Congress to serve as our proxy when it comes to matters of public policy. I thank you for your time today and trust you will keep the preservation of family choice foremost in your mind as policies impacting people with mental retardation are developed.

ATTACHMENT A

(The full presentation, including the attachments cited within this document are available upon request)

Voice Of the Retarded

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Developmental Disabilities Assistance and Bill of Rights Act
1999 Reauthorization

Considerations for Congress
May 1999

I. Introduction

Voice of the Retarded (VOR), a national non-profit advocacy organization, respectfully submits the following presentation in support of necessary amendments to the Developmental Disabilities Assistance and Bill of Rights Act (DD Act), 42 USC §6000 et seq. The foundation of our request can be found at Attachment 1, which represents a proposed bill, ready for introduction, that incorporates the amendments VOR requests of the 106th Congress.

The DD Act is scheduled for Reauthorization this Congressional session. This process affords Congress the opportunity to improve a federal law that is, to some extent, failing to protect people with the severest and most profound forms of mental retardation.

The DD Act programs are: state developmental disability councils (DD Councils); state protection and advocacy agencies (P&As); and state university affiliated programs (UAPs). The DD Act creates these programs and authorizes federal funding for activities consistent with the purposes and policies of the Act. The U.S. Department of Health and Human Services (HHS) is the agency charged with overseeing the activities and budget of the DD Act programs. In Fiscal Year 1999, these programs received $109 million in federal funding. These programs have been level funded for the past three years, with the DD Councils receiving $64.8 million, P&As receiving $26.7 million, and UAPs receiving $17.5 million. The President's Fiscal Year 2000 budget recommends level funding. More detailed background information on the DD Act programs follows in Section III.

VOR submits that the DD Act programs, federally-funded to serve people with developmental disabilities, while very successfully supporting people with mild and moderate mental retardation by fostering in-home supports and establishing self-advocacy groups across the country, are not effectively serving many people with severe and profound mental retardation. Many state DD Act programs negatively impact family rights. They also negatively impact the rights, health and safety of people with severe and profound mental retardation. The well-intentioned process of the DD Act to give people with developmental disabilities and/or mental retardation increased access to long term care supports and a voice in public policy discussions has aged into a system that collaborates to eliminate options (i.e., Intermediate Care Facilities for the Mentally Retarded (ICF/MR)), and exclude parent/guardian input as professional staff routinely set policy and decide

what is best for people with mental retardation and their families. In addition, the very programs being targeted (i.e. ICF/MR) by the HHS-funded organizations are also, through Medicaid dollars, HHS-funded. Documentation collected by VOR indicates that HHS is unaware of the bureaucratic in-fighting threatening its agency. This raises serious questions about the financial accountability and oversight of the DD Act programs (see e.g, Attachment 2).

By way of clarification, the attached revision is not meant to dismantle the DD Act programs. Rather, VOR seeks to add more balance in the power structure and, through greater accountability measures, eliminate what VOR views as some abuses in the appropriations process. By striking a better balance, people with mental retardation and developmental disabilities will reap the benefits, including better application of the funding earmarked for their support network.

II. Outline of Concerns

The DD Act programs tread on family rights and on the rights of people with severe disabilities, including people with severe and profound mental retardation. VOR's concerns fall into four main categories:

1. **Family Choice**
2. **Financial Accountability and Oversight**
3. **Class Action Lawsuits**
4. **Lobbying by Federally-Funded DD Act Programs**

These concerns are supported by the attached documentation. A detailed report of these four areas follow in Section IV.

III. The Developmental Disabilities Assistance and Bill of Rights Act: Background

The DD Act indicates that its purpose is to "assure that individuals with developmental disabilities and their families participate in the design of and have access to culturally competent services, supports, and other assistance and opportunities that promote independence, productivity, and integration and inclusion into the community." 42 USC §6000(b) (1996). This charter was based on Congressional findings (42 USC §6000(a) (1996) (emphasis added)) that noted, in part,

> (6) individuals with developmental disabilities often require **lifelong specialized services and assistance**, provided in a coordinated and culturally competent manner by many agencies, professionals, advocates, community representatives, and others to eliminate barriers **and to meet the needs of such individuals and their families**;
>
> (7) a substantial portion of individuals with developmental disabilities and their families **do not have access to appropriate support and services from generic and specialized service systems and remain unserved or underserved;**
>
> (8) family members, friends, and members of the community can play an important role in enhancing the lives of individuals with developmental disabilities, **especially when the**

family and community are provided with the necessary services and supports;
***

(10) the goals of the Nation properly include the goal of providing individuals with developmental disabilities with the opportunities and support to --

(A) make **informed** choices and decisions;
(B) live in homes and communities in which such individuals can exercise their full rights and responsibilities as citizens;
(C) pursue meaningful and productive lives; .
(D) contribute to their family, community, State and Nation;
(E) have interdependent friendships and relationships with others; and
(F) achieve full integration and inclusion in society, **in an individualized manner, consistent with unique strengths, resources, priorities, concerns, abilities, and capabilities of each individual**.

Consistent with the above findings, which emphasize person-centered supports, the 103rd Congress, Committee on Energy and Commerce, submitted the following report language:

"The Committee recognizes that, with the appropriate resources and support, many individuals with developmental disabilities will live lives that are fully integrated into their respective communities. This potential, however, should not be seen as limiting the choice of individuals and their parents to seek living arrangements that are most suitable to their needs and wishes, whether they be in the community or in institutions ...

Furthermore, the Committee would caution that goals expressed in this Act to promote the greatest possible integration and independence for some individuals with developmental disabilities not be read as a Federal policy supporting the closure of residential institutions. It would be contrary to Federal intent to use the language or resources of this Act to support such actions ..." (House Report No. 103-378, Nov. 18, 1993; see also, Attachment 3, pages 7 and 8).

To summarize the focus of the DD Act, its directives call for person-centered, individualized supports developed based on individual and family input. This is the essence of the DD Act and its well-meaning intent. Indeed, as noted above, the DD Act programs are to be applauded for their support of people with mild and moderate mental retardation who benefit from self-advocacy training, competitive and supportive employment environments, and in-home supports. As the following presentation and attachments illustrate, however, many DD Act programs have ignored the Report language, and have placed an inappropriately narrow emphasis on the "inclusion" objective within the Act. The often over-zealous advocacy in favor of community-based care to the exclusion and elimination of institutional care by many DD Act programs has turned a well-meaning law into a weapon that disproportionately harms people with severe and profound mental retardation.

IV. DD Act Programs: Detailed discussion of VOR's concerns

VOR is a national organization advocating on behalf of all people with mental retardation. Our membership is comprised of thousands of families, organizations, professionals and providers.

We are the only national organization that accepts developmental centers (a/k/a institutions) as one choice of care in a full array of quality residential care settings. Our mission statement clearly indicates support for every conceivable configuration of quality residential option, including own-home, independent living, other community-based options, and institutional care for some individuals with severe and profound mental retardation.

Other federally-funded organizations, including the DD Act programs, are working hard to eliminate institutions as one option of care for any individual with mental retardation. The three state-based, federally-funded DD Act programs are: developmental disabilities councils (DD Councils), protection and advocacy systems (P&As), and university affiliated programs (UAPs). In Fiscal Year 1999, these programs received $109 million in federal funding. These programs have been level funded for the past three years. The President's Fiscal Year 2000 budget recommends level funding.

We submit that many of the major activities of the three DD Act programs, while often benefitting people with mild or moderate mental retardation, are contrary to the intent of the DD Act, and certainly contrary to the best interests of many people with severe and profound mental retardation and their families. Our concerns, together with suggestions to correct these concerns, follow.

(A) Family Choice

> "[Y]ou must understand that we believe the institutional congregate care model has proven to be abusive and neglectful. Congregate settings, such as Florida's Developmental Services Institutions, constitute a despicable way for government and society to treat people who happen to have a developmental disability." Pat Wear, Deputy Director and Francis D. Flood, Individual Advocacy Unit Director, Advocacy Center for Persons with Disabilities, Florida's Protection and Advocacy agency, April 17, 1998 letter to parent who wrote in support of institutional care, Attachment 4.

> "Many groups which once focused on providing help and information to handicapped people and their families, now focus on supporting the careers of people in the advocacy business. These groups espouse an ideology that is not based on either principle or a truthful assessment of the problems facing people with disabilities, but on the need by advocates to ensure a steady flow of funding to their organizations and an ever-expanding role for themselves." Jill Barker and Marie McKeever, Parent Watch, May 1994, Attachment 5.

Description of the problem

The DD Act emphasizes that individuals with developmental disabilities and their families shall be the primary decisionmakers regarding the services and supports received and policies developed (42 USC §6000(c)(3)). The DD Act's 1993 report language also indicates that the Act's findings, purposes, policies and goals that promote the greatest possible integration and independence for some individuals with developmental disabilities shall not be read as a Federal policy supporting the closure of residential institutions (Attachment 3, pages 7-8).

Despite these clear policy directives, parents and family members (also taxpayers) in support of institutional care are consistently excluded from policy discussions, and the actions by all three

DD Act programs evidence a bias against large residential settings for people with mental retardation.

There is burgeoning evidence that deinstitutionalization is inappropriate for some people with profound mental retardation, especially for those people who experience significant medical and behavioral limitations in addition to their multiple disabilities. National federally-funded organizations continue to leverage their financial strength to pursue a community-only ideology and work to close all institutions with little or no apparent concern for the severely impaired people affected by their actions. While their actions have successfully expanded community-based options and supports for people with mild mental retardation, this progress has often been at the expense of people with severe and profound mental retardation.

VOR is concerned that aggressive deinstitutionalization efforts by advocates and policymakers is occurring too rapidly, with inappropriate planning, and insufficiently identified community-based resources and quality assurances. In March 1993, then-Representative Ron Wyden, Chairman of the Subcommittee on Regulation, Business Opportunities, and Technology, noted in his special report, "Out of Sight, Out of Mind?" that, "growth in this industry [small community-based service providers] has out-stripped the ability of many state agencies to adequately oversee conditions in these facilities."[1] Indeed, a 1996 peer-reviewed research study found the risk of mortality for individuals with severe disabilities was 72% higher in community settings than in institutions[2]. These mortality findings have been confirmed time and again by Dr. Strauss and his team[3]. In addition, recent investigative series by *The Washington Post* (March 14, 1999 - March 17, 1999)[4] (Attachment 6) and the *San Francisco Chronicle*[5], detail the horrors of deinstitutionalization

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[1]See also Peter Dobkin Hall, "There's No Place Like Home: Contracting Human Services in Connecticut, 1970-1995, Yale University, February 1995.

[2] David Strauss and Theodore Kastner, "Comparative Mortality of People with Mental Retardation in Institutions and the Community," American Journal of Mental Retardation, 1996, Vol. 101, No. 1, 26-40 (July).

[3] See e.g., David Strauss and Robert Shavelle, "Mortality of Persons with Developmental Disabilities After Transfer Into Community Care: A 1996 Update," American Journal on Mental Retardation, 1999, Vol. 104, No. 2, 143-147 (March), finding an 88% increase in risk-adjusted mortality in community-based settings over that expected in institutions.

[4]The *Washington Post* investigative series details the abhorrent conditions of the community based care homes in the District of Columbia following the closure of Forest Haven, an institution for persons with mental retardation (Attachment 6). The National Association of Developmental Disabilities Councils (NADDC) published "Deinstitutionalization - From Theory to Practice" in August 1994 (Attachment 7). Ironically, the Preface reads:

> "Halfway between Washington, D.C. and Baltimore, Maryland, there is still a directional sign that reads 'Forest Haven.' If you follow the sign you drive into an 800 acre complex with 21 large buildings. Some are boarded up, some are now used by a drug treatment program and some house youth placed by the criminal justice system. But no matter how much you see and wonder, you cannot understand and appreciate that this was really home to more than 3,000 people with disabilities. You begin to imagine the moments, the days or the years of those who have lived the

gone wrong. Quality assurance concerns in community-based settings following deinstitutionalization efforts have been documented in California, the District of Columbia, New Mexico, Pennsylvania, New York, Georgia, Florida, Illinois, Texas, Oregon, Washington State, and others.

Despite this growing evidence, a majority of DD Councils and P&A agencies note "deinstitutionalization" as a priority area for focus in their filing documents. In over 90% of P&A's Statement of Objectives and Priorities, deinstitutionalization is noted as a priority. VOR knows from the communication it receives from members and non-members across the country that a high satisfaction rate exists among families whose family members currently receive care in ICFs/MR settings. The Massachusetts council reports indicate that its constituency ranks deinstitutionalization as achieved through litigation as a low priority (Attachment 8, State Plan Survey, Table 5). Despite favorable reviews by families benefitting from ICF/MR care, Council and P&A activities indicate deinstitutionalization, at the expense of family choice, remains a high organizational priority:

- A **California** bill (AB 1200, 1998), which would have brought state law into conformity with the DD Act provision that recognizes families as primary decision makers, did not pass. AB 2100 was sought by Sunny Maden, a parent whose decisions regarding the placement of her son have been continually challenged in the court system. AB 2100 was supported by the Arc of California, CASH/PCR (a statewide family organization), and the State Developmental Disabilities Council. Arrayed against the bill were P&A, ARCA, and United Cerebral Palsy (Attachment 9).

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experience. Like many large public institutions for people with developmental disabilities, Forest Haven is now closed. Yet, despite what we have learned, there are still hundreds of similar 'facilities' still flourishing. These institutions provide us with a challenge and an opportunity to create humane, effective and vibrant alternatives in the community for those citizens who are often the most misunderstood."

The monograph published by NADDC, the national leadership association for state DD Councils, also claims:

"Although ['dumping'] may have been the case with some other populations, when people with developmental disabilities move to the community, it is almost always a careful, meticulous process, with many protections and safeguards in place" (Attachment 7, p. 7).

Yet the *Washington Post* reports that a great majority of Forest Haven's former residents receive grossly inadequate services and supports in a community-based care system woefully lacking in oversight and monitoring. Following the Forest Haven closure, more than 350 incidents of abuse, neglect, molestation or stealing have been documented in group homes and day programs in the 1990's, according to the records of four District agencies and federal and DC courts reviewed by the *Post*. It was also noted that, "Those serious incidents involved companies that collectively run 70 percent of the city's group homes. Yet in that time, the District government levied not a single fine against a facility operator for maltreating the retarded" (Attachment 6).

[5] Over 50 articles throughout 1998 were published on this issue in the *San Francisco Chronicle*. To access the same, visit www.psych-health.com, news link.

- A **Florida** father writes, "As a parent of a severely mentally retarded son residing at Gulf Coast Center, Ft. Myers [Florida], for the past 30 years, once again I must voice my CHOICE along with his caregivers as to how he will reside and be care for, not some taxpayer funded group such as the Advocacy Center [P&A]...The Advocacy Center has not, and is not an advocate for me or my son and as a 35 year volunteer for ALL DD in this state, the last few years with the so-called 'watch-dog' Advocacy Center has only demeaned the Governor's office and the State of Florida" (Attachment 9, emphasis in original; see also Attachment 23, and discussion on pages 16 and 23).

- In a class action lawsuit against Rainier Habilitation Center, the **Washington** State P&A called the conditions at Rainier "deplorable, unlawful and harmful." Friends of Rainier, the family organization strongly and vocally disagreed, noting that Rainier provides a stable and safe environment for their family members. The Judge sided with the families and denied P&A's motion for class certification. The case, now involving only 3 plaintiffs, will be resolved shortly (Attachments 9 and 10; see also discussion of this case on page 8).

- The Mental Retardation Association of **Missouri** (RAM), a family organization, also questions the Missouri DD Council's support for state habilitation centers ("institutions"). "Their mission is to include all developmentally disabled people in community life regardless of their need for a protective environment" (Attachment 9). An August 1997 letter from RAM to VOR further details a meeting with DD Council representatives, stating in part, "Kay Conklin responded by saying the federal ruling had been changed and now the Council is to develop goals to expand and enhance community services and it does not include habilitation centers" (Attachment 9). Of course, this statement is inaccurate.

- A **New York** State parent wrote to inform VOR that, "I've been told I'm the most involved person at Monroe Developmental Center, yet I was not informed [by the DD Council] of the forum through proper channels. Because of this I called a number of Developmental Center parents and found that not one of them had been told about the forum ... if the DD Council truly wants 'open communication' they must first ensure that all individuals and families served should be notified of their forums" (Attachment 9). The New York DD Council's state plan indicates that it must provide for, in part, the elimination of inappropriate placement of persons with developmental disabilities in institutions (Attachment 9).

- Concerns raised by **Utah** families prompted the Governor's Office of Planning and Budget to request formal comments from the Utah DD Council regarding concerns that had been brought to the attention of his office. Specifically, family members and other concerned citizens raised questions about the membership of the council, the anti-institution activities by the Coalition for People with Disabilities, the anti-institution activities of the Partners in Policymaking program, and the Council's leadership (Attachment 9; see also page 15 for more detail).

  Contrary to federal law, an announcement by the Utah DD Council seeking nominations for a vacant council position fails to indicate that a qualified nominee may be someone who is currently institutionalized (or parent/guardian of such a person). (Attachment 9).

- An **Iowa** mother wrote:

> "It was on the day we had her [our daughter] evaluated that it came out in the Iowa papers that the Governor had stated there would be no more admissions to the State Schools. One of the main reasons this happened was because Iowa Protection and Advocacy had filed a law suit against Governor Branstadt and the State of Iowa trying to close down the State Institution...I called Iowa Protection and Advocacy during my fight [to get my daughter admitted] — little did I know that they were the ones stopping my daughter from getting what she needed..." (Attachment 9).

- The **Michigan** P&A writes, "As the leading legal advocacy organization for individuals with disabilities in the state of Michigan, MPAS cannot stand idle while our clients are left in large institutions, and are thus, subjected to continued segregation and isolation from society..." (Attachment 9).

- The **Texas** DD Council distributed an April 1992 alert that asked recipients to "Show Your Thanks and Support Now for Closure Decision." This release was in response to the decision to close Fort Worth and Travis State Schools. VOR members - parents and family of the residents impacted - strongly opposed the closure decision (Attachment 9).

The U.S. Supreme Court (Heller v. Doe, 509 U.S. 312 (1993), Medicaid law (Social Security Act, §1915(c)(2)(C); 42 CFR 441.302(d)), and the DD Act (42 USC §6000(c)(3)) recognize the value of family input into decisions impacting the well-being of their family members. In response to a class action lawsuit filed by the Washington state P&A against Rainier Habilitation Center, Federal Judge Franklin Burgess sensitively determined that P&A's objectives were not superior to family opinion:

> "Considering the arguments of the parties, the Court concludes that the parents and legal guardians who are represented by FOR [Friends of Rainier] have the closest interest in the welfare of their charges who are Rainier residents and therefore should be included in the process of deciding the issues raised in this case." (Attachment 10).
>
> "At this point, the prerequisites to a class action, enumerated in Fed. R. Civ. Pr. 23(a) do not appear to be satisfied, particularly as to whether the claims of the representative parties [P&A] are typical of the putative class [Rainier residents] and whether the representative parties will fairly and adequately protect the interests of the class." (Attachment 10).

The truths that appear self-evident are continually ignored by many DD Act programs across the country, despite wise guidance offered by the DD Act and the former Commissioner of the Administration on Developmental Disabilities, Robert Williams. Current Deputy Secretary Williams recognized the value of family/guardian input. In 1997, he authorized and funded three Parent Forums in Florida, Tennessee and Washington state[6] (Attachment 11). The moderators of the

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[6] The Parent Forums, and a Community Quality Action project, represents a rare instance in which the DD Act programs agreed to communicate and collaborate with VOR on shared issues. This

program and its participants noted the value of including a variety of viewpoints. It was quickly evident that the participants, regardless of viewpoints and experiences possessed, had more in common than not. Louisiana, under the leadership of Sandra Held, VOR Board Member and former member of the Louisiana DD Council executive committee, has since followed the Parent Forum model and is able to cite similar success (Attachment 12). DD Councils and P&As do a disservice to this lesson learned when their activities continue to reflect an anti-institution bias.

Solution

The proposed amendments to the DD Act work to correct these failings by (a) maintaining the Act's clear policy directive recognizing decisions of parents and family as primary for people with severe and profound mental retardation; and (a) strengthening the Congressional intent as noted the 1993 report language (Attachment 3). The revision proposes a statutory scheme that builds on family and individual choice in residential settings, regardless of type and size. For example (Attachment 1):

Pages 4-7: Title II, Clarification of Certain Congressional Policies, Subtitle A - Choice of Residential Setting; Class Actions; Lobbying

Pages 10-12: Title II, Subtitle B, Sec. 212(b) - Additional Definitions. See especially, Sec. 212 (b)(1)(B) Systemic Change; Sec. 212(b)(2)(B) Facility; and Sec. 212(b)(3)(B) Advocacy Activities.

Page 12: Title II, Subtitle B, Sec. 213 - Rights of Individuals with Developmental Disabilities.

Page 13: Title II, Subtitle B, Sec. 214 - Conditions for Receipt of Financial Assistance.

Page 22: Title III, Subtitle B - Federal Assistance to State Developmental Disabilities Councils, Sec. 312 State Developmental Disabilities Councils and Designated State Agencies (membership composition).

Page 27: Title III, Subtitle C - Protection and Advocacy of Individual Rights, Sec. 321

Pages 28-30: Title III, Subtitle D - University Affiliated Programs, Sec. 331(2) Grant Authority (authorizing grants for the study of developmental medicine and institutional outreach).

(B) Financial Accountability and Oversight

"[To] effectively manage its ... grant-making activities, HHS must have access to data about its programs and their effects that are both reliable and appropriate to the task." GAO/OCG-99-7, January 1999, p. 24.

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cooperation followed a June 1996 Statement of Shared Principles. Collaboration between state DD Councils and VOR organizational representatives was sought, with limited responses (Attachment 11).

"While P&A systems use many methods to protect people with disabilities, data on how funding is directed toward different methods is not collected." Donna Shalala, Secretary, U.S. Department of Health and Human Services, October 18, 1997, Attachment 2.

(1) Description of the problem:

The current mechanisms in place to ensure financial accountability and oversight are lax at best. The DD Act requires self-reporting and evaluation. Correspondence from HHS indicates that "While P&A systems use many methods to protect people with disabilities, data on how funding is directed toward different methods is not collected. [P&A developed] Program information on how individual cases are resolved, however, indicates that very little money goes toward litigation." (Attachment 2).

Information presented in subsection C, however, indicates that P&A and public interest law centers were involved in 33 class action lawsuits (Attachment 22). P&As' Annual Program Performance Reports for Fiscal Year 1997, indicate class action litigation against institutions has, over time, been initiated in California, Maryland, New Mexico, Utah, Washington State, Florida, Alabama, Kentucky, Montana, and South Carolina (Attachment 13; see also Attachment 14, "Persons served by P&A systems"). Not noted in Attachment 13 are class action lawsuits filed in Iowa, Connecticut, Wisconsin, and two in Michigan. In addition, the Texas Protection and Advocacy served as intervenor in a Texas class action. Additional class action litigation involving education, waiting lists, voting, transportation, housing and other issues have also been filed by P&A. Despite what Secretary Shalala's records may indicate (or not indicate), significant resources are devoted to litigation.

In support of enhanced fiscal accountability, the U.S. Government Accounting Office (GAO) recently noted that

> "to effectively manage its ... grant-making activities, HHS must have access to data about its programs and their effects that are both reliable and appropriate to the task. These data would allow HHS to know whether or not it is accomplishing its goals and how its programs affect the American people. They also would provide the Congress the information it needs to evaluate the Department's success in meeting its goals. However, data needed to manage and evaluate HHS' programs are often unavailable, inaccurate, or inconsistent. **Obtaining comparable data from programs carried out by state and local partners is particularly difficult.**" [GAO/OCG-99-7, Major Management Challenges and Program Risks: Department of Health and Human Services, January 1999, p. 24, emphasis added].

Secretary Shalala's October 1997 letter squarely illustrates that HHS does not have access to data about its programs and their efforts that is both reliable and appropriate to the task, as GAO recommends. To the contrary, data on how funding is directed toward different methods of protection and advocacy is not collected. To exacerbate this situation, HHS-funded P&A's most frequent targets are HHS-funded Intermediate Care Facilities for the Mentally Retarded (ICFs/MR, a/k/a "institutions"). HHS, apparently without knowledge, is funding the very actions that may prove to be the demise of one of its own programs.

Other activities by certain P&A and DD Council programs are also suspect and raise a question as to the oversight and accountability mechanisms in place:

- An independent investigation in **Connecticut** has revealed that the Connecticut Council on Developmental Disabilities (CCDD) may be involved in a "pattern of mischaracterization and questionable activity dating from at least 1990 to the present" (Attachment 15). Specifically, it is alleged that in 1990 the CCDD reported funding an entity called the Connecticut Coalition for Inclusive Education (CCIE). Related documents, however, reveal that funds designated for CCIE were actually granted to Arc/CT, and that CCIE was not even incorporated until February 23, 1999. The CCIE registered agent is Margaret Dignoti, the executive director of Arc/CT, and a registered lobbyist with the state. Minutes of meetings held by CCDD reveal that the past chief executive officer of CCIE is the treasurer of Arc/Ct (Attachment 15).

  The investigator in the above situation states, "It seems evident that an enormous conflict involving CCIE, Arc/CT and WeCAHR exists, as well as a high risk that federal and state funds can be misappropriated. The legitimacy of CCIE is highly suspect ... Furthermore, Ms. Dignoti's multiple roles as plaintiff [in a class action lawsuit against Southbury Training School], lobbyist, registered agent and direct or indirect recipient of state and federal funds is troubling to me" (Attachment 15).

  The investigator quoted above also cites alleged bid-rigging for advocacy services by Connecticut's P&A agency.

- The **New Mexico** Developmental Disabilities Council recently benefitted from the Monitoring and Technical Assistance Review System (MTRAS), a review by the Administration on Developmental Disabilities (ADD). Three areas of non-compliance were noted in the August 10, 1998 report, including (1) current status of Council members; (2) the process of directing the expenditure of funds for grants, contracts, and other activities authorized by the State Plan (it was noted that the "RFP, scoring, and contract formats as submitted provide insufficient procedural direction and controls to assure Council oversight and compliance with Federal procurement procedures"); and (3) non-compliance with the DD Act's requirements for hiring sufficient numbers and types of staff so as to provide a substantial level of financial expertise capable of maintaining credible records and timely submission of Federal financial reports.

  Additional recommendations for improving the Council's performance were also included the ADD's report (Attachment 16).

  A December 7, 1998 independent auditor's report on compliance and on internal control over financial reporting of the New Mexico DD Council (Attachment 16) also found:

  * The Council failed to timely submit all required Federal Financial Status Reports to its federal agencies. In addition, the supporting grant expenditure data attached to the reports was not orderly and difficult to follow.

  * Until June 1998, documentation to support each draw of federal dollars, was rather informal and was summarized in hand writing or on a loose leaf paper.

* The Council is not reconciling its AFRAS general ledger account balanced to the Department of Finance and Administration CFRAS general ledger account balances.

* The Council failed to pay some vendor invoices within the time prescribed. 48% of the payments tested were made after thirty days had elapsed from the invoice date.

It is also being alleged by the Brain Injury Association of New Mexico (BIANM) that the New Mexico DD Council has violated several state laws regarding the RFP process for an advocate training program. BIANM has presented its complaint to the New Mexico Attorney General. The subject grant was awarded to The Arc, whose executive director is John Foley. At this same time (Fall 1998), Mr. Foley also served as a member of the granting agency, the DD Council, as a member of the University Affiliated Program, and as Chairman of the Board for New Mexico P&A (Attachment 16).

- Collaboration between the three DD Act programs is enhanced by the practice of "shared" board positions, despite a policy directive issued by the Administration on Developmental Disabilities that prohibits this type of practice. The policy directive states, "ADD's longstanding policy on this matter is that individuals who are currently members of the DDC may not serve on P&A governing boards...in the interest of facilitating Federal monitoring of P&A independence, ADD maintains the policy that the DDC and P&A remain separate." Despite the clarity of this directive, the practice persists[7] (Attachment 17).

- The February 9, 1998 minutes of the American Association of University Affiliated Programs (AAUAP) Board of Directors meeting indicate problems with tax filing, grant documentation and embezzlement. AAUAP, the leadership organization for state UAP's, offer national technical, research and advocacy guidance to its state UAP members (Attachment 18).

The late George O'Donnell, former member of the Wisconsin DD Council and parent, wrote in 1995,

> "I was appointed as the first Chairperson of what was then designated as the 'State, Planning and Advisory Council on Developmental Disabilities' [in 1972]...That event occurred over 23 years ago; but, to my knowledge, there has never been an objective, comprehensive evaluation of the benefits derived for the State of Wisconsin as a result of the activities of the Developmental Disabilities Council...Such an evaluation is an excellent idea, not only for the Council, but for all governmental

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[7] Coalition between the three DD Act programs is persistent. While collaborative efforts which maximize the use of limited resources are typically beneficial, the collaborative efforts of the DD Act programs with each other and other organizations that aim to eliminate institutions as one option of care have significantly reduced the benefit of diversity. These organizations are often "closed" to opinions that differ from their own agenda. A lack of diversity in opinion results, checks and balances erode, and the machine moves forward without the benefit legitimate debate regarding the appropriateness of their actions.

agencies, to ensure their relevance to today's problems, their effectiveness in serving the public and the legitimacy of their activities ...

"Initially, as noted, the primary function of the Council was planning and the administration of available federal funds. Accordingly, new 'plans' were dutifully submitted, year after year, from 1972-1994. Yet, the record will demonstrate that, not one of these plans has been adopted, or even seriously considered for adoption, by either the Governor or the State Legislature ..." (Attachment 19)

Mr. O'Donnell's words represent the view of many families frustrated by the fact that their taxpayer dollars are being used to fund an agenda that works contrary to their principles, their desires and what they know to be in the best interest of their family members. Adding to the frustration is the realization that the state and federal governments have little control and awareness of how these funds are being spent and whether the federal dollars are effectively serving all people with mental retardation and developmental disabilities.

Solution

The proposed amendments to the DD Act work to correct these failings by suggesting independent audits of the programs' activities and spending every three years, in addition to the self reporting now required. For example (Attachment 1):

Page 13: Title II, Subtitle B, Sec. 214 Conditions for Receipt of Financial Assistance.

Page 15-20: Title III, Subtitle A - General Provisions, Sec. 301 Review of Programs (requiring periodic reviews by the Comptroller General of the United States at least every three years to determine the effectiveness of the programs in carrying out the purposes of the DD Act, and public review of the report); and Sec. 302 (reports required, including a designation of how federal funding was spent);

Page 22: Title III, Subtitle B - Federal Assistance to State Developmental Disabilities Councils, Sec. 312 (providing for "Independent Review of Council Activity" by the Secretary).

Page 28: Title III, Subtitle C - Protection and Advocacy of Individual Rights, Section 321(providing for an "Annual Federal Programmatic and Administrative Review" by the Secretary).

Page 30: Title III, Subtitle D - University Affiliated Programs, Section 332 (providing for federal regulations establishing standards for University Affiliated Program activity).

(C) Class Action lawsuits

"...P&A's have not 'inappropriately' spent federal monies. Rather, they have through their statutory mandate, uncovered serious abuse and neglect as well as unexplained deaths of persons with

developmental disabilities. This activity has taken place in both large public facilities and a variety of community programs. P&A's are a constant presence in these facilities and are able to maintain contact with the most vulnerable population in the disability community. Just because you and your colleagues do not like the results of our activities does not mean that funds have been misspent..." Curt Decker, President, National Association of Protection and Advocacy Systems, Letter to Polly Spare, President, VOR, October 27, 1998, Attachment 20.

Description of the problem

Curt Decker, Executive Director of the National Association of Protection and Advocacy System was clearly upset when he penned the above letter (Attachment 20). Despite his passion, he is wrong. Every taxpayer, including VOR's members, must have the opportunity to express an opinion on how public monies are spent, especially when serious, legitimate questions can be raised regarding the lack of accountability for the funds appropriated to some DD Act programs, as noted above in Section B[8].

The purpose of each state Protection and Advocacy System (P&A) is to protect the legal and human rights of individuals with developmental disabilities. 42 U.S.C. §6041 (1996). The P&A system has the authority, in part, to-

> "(i) pursue legal, administrative, and other appropriate remedies or approaches to ensure the protection of, and advocacy for, the rights of such individuals within the State who are or who may be considered for a change in living arrangements, with particular attention to members of ethnic and racial minority groups; and
>
> "(ii) provide information on and referral to programs and services addressing the needs of individuals with disabilities ... 42 U.S.C. §6042(a)(2)(A) (1996).

The P&A system also has the authority to investigate incidents of abuse and neglect of individuals with developmental disabilities if the incidents are reported to the system or if there is probable cause of abuse and neglect. 42 U.S.C. §6042(a)(B) (1996).

The DD Act is silent on the availability of class action litigation as a vehicle to accomplish systems change, and the Act does not indicate a bias against a particular residential setting. Rather, it recognizes that abuse and neglect is unacceptable regardless of setting. P&A activities, to the extent they work to correct individual incidences of abuse and neglect, are to be encouraged. P&A activities, to the extent they work to correct systemic incidences of abuse and neglect plaguing a facility (community-based or institutional), are to be encouraged. P&A activities, however, disproportionately impact institutional settings and do so without the input or blessing of the individuals and family members impacted by the objective (closure) of the P&A action.

When a P&A agency leverages their legal authority with respect to a residential setting, it

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[8] The National Alliance of the Mentally Ill (NAMI) and certain local AMI organizations share VOR's concern (Attachment 21).

is the large public facility that is the target. P&A's dual purpose - protection and advocacy - often translates to expensive and complex class action litigation. P&A has never filed a class action lawsuit to redress the abuses found in the community-based system of care serving people with mental retardation and related disabilities.

To paraphrase an October 20, 1997 letter, HHS Secretary, Donna Shalala, notes that although data is not collected on how protection and advocacy spends their federal dollars, she suspects that very little goes to litigation (Attachment 2; see also Subsection B, Financial Accountability and Oversight, above). Yet a May/June 1997 article in Mental Retardation, entitled "Class-Action, Civil Rights Litigation for Institutionalized Persons with Mental Retardation and Other Developmental Disabilities: A Review," indicated that there were 70 complaints filed on behalf of institutionalized persons with mental retardation and related disabilities since 1971. Thirty-three cases involved attorneys from protection and advocacy agencies and public legal assistance programs, such as public interest law centers. Only nine cases involved private attorneys. Of the 70 cases, 48 were certified as a class action, meaning the litigation impacted the entire population of residents at a particular facility, versus just one individual. (Attachment 22). Because system wide changes can be accomplished using class action litigation, this costly litigation vehicle has been pursued by protection and advocacy agencies against large residential facilities in California, Connecticut, Maryland, New Mexico, Utah, Iowa, Washington State, twice in Michigan, and Florida. P&A has also served as intervenors in Texas (see for e.g., Attachments 9, 10, 13, 14, 16, 22-25, 29).

Despite the overwhelming evidence of problems plaguing many community-based settings (see subsection A, above) VOR is not aware of any class action litigation involving conditions at community-based facilities for individuals with mental retardation.

Parents, family members and guardians of the residents harmed by class action litigation often disagree with the allegations of P&A regarding the care they experience at the facility being litigated against (see subsection A, above). Despite the DD Act's express policy to treat family members as "primary decisionmakers" and key participants in policymaking, they are rarely consulted prior to the initiation of an action. Some specific examples from Florida, Washington state, California, New Mexico, Connecticut, and Utah help highlight the significance of this issue:

- **Florida's** P&A has two lawsuits pending. One challenges the care received at privately-operated institutions (Cramer v. Chiles); the other challenges the care received at publicly-operated institutions (Brown v. Chiles) (Attachment 23; see also Attachment 9). The family members impacted vehemently opposed P&A intrusion.

- **Washington State's** P&A unsuccessfully brought a class action lawsuit against Rainier Rehabilitation Center. Citing the objections by the family/guardian association, the Judge denied P&A's motion for class certification, and granted the family association's motion for intervention. Until the Judge ruled favorably, the families were faced with having to raise over $100,000 to support their intervention; P&A used federal taxpayers dollars to support its position.

Parents and family members from Washington state have written Congress requesting that

it limit P&A's ability to file class action lawsuits (See Attachment 24).

- **California's**P&A brought a lawsuit against California's developmental Centers (Coffelt v. DDS). In response, the State settled and pursuant to the Coffelt settlement agreement aggressively pursued deinstitutionalization. Over 2,000 people were transferred from California's developmental centers in a two year time period. In response, researchers have found that the risk of mortality is 88% higher in community-based centers, the *San Francisco Chronicle* has released over 50 articles exposing California's inadequate community-based care system (see footnote 5), the Health Care Financing Administration revealed significant problems with the community-based waiver program and threatened to pull all federal support unless certain issues were addressed, and a lawsuit has been filed by an institution physician against the state alleging that center residents are being recommended for transfer who are not medically able to accommodate a community-based setting (the Cable lawsuit). The federal judge agreed and instituted a preliminary injunction to halt the transfers, unless chosen by the individual or family member, citing the immediate risk of grave danger. The Cable lawsuit is being supported by several family organizations. Despite the bald evidence of deinstitutionalization gone wrong, P&A is supporting the state. The families are working to raise hundreds of thousands of dollars to support their intervention; P&A is using federal taxpayers dollars to support its position.

  Parents and family members from California have written Congress requesting that it limit P&A's ability to file class action lawsuits (See Attachment 24).

- **New Mexico's** P&A brought two class action lawsuits against Los Lunas State Hospital and Fort Stanton State Hospital. Both centers are now closed. Family members successfully intervened in the Los Lunas lawsuit to object P&A's claims and their status as representatives for the resident class. Since the closure of both hospitals, reports have been received citing higher incidences of abuse, neglect, and death among the New Mexicans with mental retardation. In response, the Handicapped Law Compliance office, New Mexico Regional office, filed a complaint against the state and P&A, alleging in part, "State representatives threaten parents, guardians, guardian ad Litems, medical and mental health professionals, and others when they do not agree with or question the choices of the state representatives" (Attachment 29).

- By analogy, Southbury Training School in **Connecticut** is the subject of a class action lawsuit modeled after similar P&A lawsuits. The family guardian association has long opposed the action, and in April 1998, 611 residents of Southbury Training School and their 726 guardians filed a motion seeking an order that would, in part, direct that the 611 residents be removed from the plaintiff class. The motion filed was supported by more than 84% of the residents who had guardians. This motion, by the overwhelming majority of class members to be excluded from the class, is unprecedented in class action litigation. Since the purpose of class actions is to provide an efficient means for people sharing the same interest to be heard, this motion raises an important legal issue -- can the majority of the members of a class who wish not to be a part of the class, and oppose the position taken by the class representatives, be held captive in the class? VOR would contend that similar P&A actions

hold residents of the centers captive to their advocacy.

- In 1989, the **Utah** P&A filed a class action lawsuit against the Utah State Developmental Center that was argued in court for three years. In 1993, the Lisa P. settlement was signed. During this time frame very little if anything was ever said to the family members and guardians of the residents impacted. On February 1, 1999, in response to the ongoing activities of P&A in the Lisa P. lawsuit, Dean Robinson, a parent of two sons residing at Utah State Developmental Center, presented testimony to the Health and Human Services Sub-Appropriations Committee of the Utah State Legislature (Attachment 25), stating,

> "The process has taken 5 years. However, I am here today to tell you that even though the final reviews were completed in 1998, the Disability Law Center [P&A] is not letting up. As it now stands, every individual who resides at the Developmental Center has been evaluated. There are a large number who have gone through the evaluation process who are waiting for placement in the community. I should mention that many of these individuals have so many problems that community providers are reluctant to take them. The bottom line is, they just can't afford to provide the same level of care they are receiving at the Developmental Center...
>
> "I would like to ask this committee today, to launch a thorough investigation into what this lawsuit has cost the state to this point and what it will cost in the future. I am confident that Judge Hansen had no idea what would happen to parents and how much pain and suffering this lawsuit has caused. He probably thinks that freedom of choice is being exercised but just the opposite has taken place ...
>
> "As an example as to what can happen when a parent disagrees with the process, I would like to read a signed statement from a parent who went to battle with the Disability Law Center [P&A] in order to keep their child at USDC. I have received permission to read his signed statement of a private conversation with one attorney at the [Disability Law] Center:
>
> > Attorney: 'We will be going to court and it will be costly. It will cost you some money.'
> >
> > Parent: 'Well, I've spent a lot already on my son's welfare. I don't care as long as I win.'
> >
> > Attorney: 'The State has more money than you have. I'll keep you in court until we break you.' ..."

VOR has attempted to curb the assaults felt by families and guardians when class action litigation is filed by advocacy organizations, such as P&A, who have little knowledge of the day-to-day needs of the individuals who call the institution home. In 1997, subsequent to several efforts in the federal appellate courts, VOR filed a Petition for Certiorari in the U.S. Supreme Court which asked, in part,

> Was class representation improperly granted to an advocacy group, claiming the right to litigate and decide for all members of a class of severely disabled individuals, when an intervening party representing parents and guardians of class members advocated a contrary interest? [Petition for Writ of Certiorari, Parent Guardian Association of Arlington Developmental Center v. People First of Tennessee, September 11, 1998.] (See Attachment 10).

Although the petition in People First of Tennessee was denied, a similar petition was accepted by the U.S. Supreme Court recently that will address the appropriateness of institutional care for some people with severe and profound mental retardation (Olmstead v. L.C. and E.W.). As in its original petition, VOR asserts in its *Amicus Curiae* brief in Olmstead that choice in residential setting based on legitimate need must be available to individuals with mental retardation and their families. It is this basic tenet that P&As, through their class action activities, continually ignore.

This situation becomes even more alarming when, as noted above, the very programs the DD Act programs target with lawsuits and other advocacy activities are also funded by HHS. In essence, HHS, seemingly without knowledge, is providing federal funding to organizations who turn around and use that same money to challenge HHS programs.

Solution

The proposed amendments to the DD Act work to correct these failings by prohibiting class action activity against residential centers by any of the DD Act programs unless a majority of the residents, or when appropriate, their family members and/or guardians support the action. This prohibition is similar to a restriction placed by Congress on the Legal Services Corporation in Fiscal Year 1996. Like the proposed amendments to the DD Act, receipt of federal funding by the Legal Services Corporation was conditioned upon a restriction of class action activity. The LSC prohibition is broader than the more narrow restriction requested by VOR. The benefit of individual advocacy, including individual legal representation, is maintained. For example (Attachment 1):

Pages 5-6:	Title II - Clarification of Certain Congressional Policies, Subtitle A - Choice of Residential Setting; Class Actions; Lobbying, Sec. 201.
Page 14:	Title II, Subtitle B, Sec. 214(b) Conditions for Receipt of Financial Assistance, Protection and Advocacy.
Page 18:	Title III, Subtitle A, Sec. 302(3) (requiring that P&A reports segregate any amounts that have been expended to conduct class action lawsuits.
Page 24:	Title III, Subtitle C - Protection and Advocacy of Individual Rights (encourages individual representation; maintains process to reach individuals and records to investigate and redress cases of abuse and neglect; and maintains family/guardian involvement).

(D) Lobbying by DD Act programs

"'Planning' by the Disability Councils has become an anachronism utilized to justify intensive advocacy activities on behalf of goals and objectives formulated by the federal Department of Health and Human Services in Washington, D.C. In fact, the 'Councils' have become self perpetuating advocacy 'machines' which are fully supported by federal funds...[i]t is doubtful, indeed, that the average taxpayer would support these Council advocacy activities as legitimate Federal expenses. When, as a citizen and taxpayer, I go to the State Capitol, or to Washington, D.C., to advocate for services and justice for mentally retarded persons, I do so with my own money, or money allocated

to me for these purposes by parents and guardians of mentally retarded persons who receive absolutely no federal funding. While I am prepared to listen to other points of view on these occasions, I strenuously object to being confronted by full time professional persons whose expenses are being paid by my taxes in the form of federal grants, or who enjoy the benefits of liberally compensated positions in the federal bureaucracy..." George O'Donnell, December 19, 1995, Attachment 19.

Description of the problem

Most developmental disabilities councils have legislative coalitions which work to lobby and/or train others to the lobby. Oftentimes, the coalition's budget is the greatest line item on the state developmental disabilities councils budget (see e.g., Attachments 26-28).

As noted above, the DD Act programs have successfully supported persons with mild and moderate mental retardation by fostering in-home supports and establishing self-advocacy groups across the country. This activity has meant that thousands of individuals with mental retardation and their family members have been afforded a voice in policymaking arenas. This progress, however, has evolved to the extent people with severe and profound mental retardation who require more intensive and specialized supports are often harmed by the programs' "community-only" agenda. The ramifications of total deinstitutionalization - growing incidences of abuse, neglect and death, and an expanding waiting list - ironically exacerbate the need for more money, more community-expansion, more lobbying. The DD Act programs, through their advocacy to close institutions, have raised expectations for the delivery of community services and supports a growing number of clients. In reality, however, follow-through is often not present (see footnote 4, above). The focus for the councils then necessarily shifts to advocacy to respond to the problem they contributed to in the first instance. With the growth of the systems and the increased expectations, the need for respite care also grows. The DD Act program activities eliminate a service, create a need, and create a reason for lobbying. They self-perpetuate their existence at the expense of people with severe and profound mental retardation.

Some examples of lobbying activity follow:

- A September 1995 letter from a **Washington** state advocate for individuals with mental retardation highlighted the significant amount of funding ($213,000) received by Washington state's DD Council to lobby for the closure of state-operated institutions. This figure includes funding for a "legislative consultant," for the "Assembly for Citizens with Disabilities," for a contract with the Arc of Washington for education on federal lobbying, and an "Advocacy Coalition" (Attachment 26).

- The **Utah** DD Council earmarked $203,600 out of its $356,766 budget for legislative advocacy in 1998. Of that $203,600, $99,600 is targeted for the Legislative Coalition for People with Disabilities, and $85,000 for Partners in Policymaking[9] (Attachment 27; see also Attachment 28). Both are on-going projects; Partners in Policymaking in its fourth year of

[9]In 1994, Partners in Policymaking received only $10,000 from the Utah DD Council.

funding. The published purpose of the Legislative Coalition for People with Disabilities, a group that has received steady increases in funding for the last several years[10], is "to advocate year-round for, and positively affect, legislation, public policies and funding that affect persons with disabilities and their families."

In 1998, the Utah legislature passed "intent" language in response to the DD Council's lobbying activity that stated,

> "It is the intent of the Legislature that no public money be used by the Governor's Council for People with Disabilities to develop, train for, or promote legislative lobbying efforts. Therefore, the funds appropriated by this Act for the use of the Council shall be used to develop services and supports for the people with disabilities in areas where the Council has identified weaknesses or gaps in the system."

Due to successfully lobbying by the Utah DD Council, this intent language was deleted from Utah's Fiscal Year 2000 budget. It was noted that the language is in conflict with federal and state directed functions of the Council. A budget review of the Council was recommended.

- Partners in Policymaking is a program that is offered in many states. A review of thirteen DD Council State Plans shows that $1,413,692 in public money (state and federal) has been spent by these states to train people with developmental disabilities and their families to become effective advocates in influencing public policy at all levels of government[11] (Attachment 28).

Other examples of the Partners in Policymaking program include:

> The **Illinois** DD Council recently distributed a "Funds Available" release that sought proposals to replicate its Partners in Policymaking project. The Illinois Council indicates that $140,000 per year for three years ($420,000) is available to replicate the program designed to provide state-of-the art knowledge about issues related to disability and to develop competencies of the participants to become effective advocates in influencing public policy at all levels of government (Attachment 28).
>
> The **Texas** DD Council's three year plan projects state and federal funding totaling $669,000 for a program aimed at strengthening "the self-advocacy and leadership skills of Texans with disabilities and their families." To further this objective, Partners in Policymaking is proposed. (Attachment 28).

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[10] In 1994 it received $65,525 and in 1995, it received $87,796.

[11] VOR does not object to the intent of Partners in Policymaking to offer young families and self-advocates the opportunity to speak out and be heard on issues impacting their daily well-being. VOR objects to the highly selective process in which Partners in Policymaking students are selected (young families and self-advocates, often strong proponents of deinstitutionalization), and the fact public dollars are used to finance what amounts to a lobbying activity. Budget amounts for each states' Partners in Policymaking program is not readily available.

As noted above, the deinstitutionalization activities pursued by many DD Act programs lead to growing waiting lists for community-based services. The DD Act programs then respond to this need, through lawsuits and lobbying, that was exacerbated by their actions. For example,

- The DD Council in **Massachusetts** cites a recent national survey that estimates that more than 60,876 persons with mental retardation and other developmental disabilities are on waiting lists for residential services in 37 states. "Because community residences were historically intended for people leaving state institutions, families that have kept their children at home have not always been able to benefit from these services." (Attachment 8, pages 14-15). A higher incidence of people with mental retardation receiving support in nursing homes is another impact felt when institutions are closed prior to having a community-based system in place able to accommodate challenging medical and support needs of this population. Despite the acknowledged waiting list crisis and nursing home placements, the DD Act programs in Massachusetts still pursue deinstitutionalization.

  Lawsuits challenging the waiting list and the appropriateness of nursing home care for people with developmental disabilities were recently filed in Massachusetts.

- In its Three Year State Plan, the **New Mexico** Developmental Disability Planning Council, brags that it ranks in the top five in the nation on a number of measures including deinstitutionalization (Attachment 29, page 14). Other parts of this same document, however, help place this statement in context:

  > * Page 14 - 15: "The growth and development in New Mexico's system of services and supports has not eliminated the waiting lists, which have increased, particularly since 1995 when a new administration froze admissions to programs because of fiscal concerns. These concerns, as well as the concerns regarding the ability of community programs to meet the needs of people with complex needs have resulted in some backlash and risk to the system...The choices available to people with developmental disabilities and their families may be reduced..."
  >
  > * Page 26-27: "The need for successful community placements has become especially obvious when the court order dictated that we find alternative placements for previously institutionalized individuals ... There are many concerns about the ability of the system to meet the needs for community placements. Many consumers and providers are concerned about the ability of community programs to serve their present population and people with dual diagnosis, traumatic brain injury and severe and profound disabilities. More community living accommodations are needed to met the needs of those not receiving services and those who need to transition out of institutions." (Attachment 29).

  The New Mexico P&A agency participated in the lawsuits to close all institutions in New Mexico (Attachment 29, page 12). The New Mexico P&A recently filed another lawsuit to address the waiting list crisis that arguably developed due to the prior lawsuits P&A filed against the New Mexico centers, and council activities. In response to P&A activities, the

Handicapped Compliance Office, New Mexico Regional Office, filed a complaint (see Attachment 29; see also page 15, above).

- The **Pennsylvania** Developmental Disabilities Council's "vision" is "full participation in community life for all" (Attachment 30, page 5). The three-year state plan indicates that not living in one's own home or holding the lease for a house or apartment is "virtual homelessness" (Attachment 30, page 5) and it indicates that "The Council will increase the availability of adequate numbers of living options and other social and community supports for people of all ages with developmental disabilities by promoting the shift of public resources from facilities that segregate on the basis of disability to community supports." (Attachment 30, page 27).

  Aggressive downsizing efforts have been the norm for the Pennsylvania DD Council and P&A for many years. Pennsylvania has over 14,500 people on its waiting list; the Pennsylvania P&A recently filed a lawsuit to address the situation. VOR family advocates in Pennsylvania are concerned that Pennsylvania P&A and council will pursue deinstitutionalization even more aggressively in a fruitless attempt to accommodate people on the waiting list.

- **Florida's** Developmental Disabilities Council's Three Year Plan states, "Florida's Developmental Disabilities Council supported the Legislature's decision to eliminate private ICF/DD facilities. It believes that this change will provide even greater opportunities for community inclusion and result in a more efficient use of state and federal funds." It also calls for reducing the population of Florida institutions by 50% by the end of 2000 (Attachment 31).

  Ironically, the law supported by the Florida DD Council and passed by the state legislature in June 1996, was challenged in federal court by Florida's P&A (Cramer v. Chiles). The Florida P&A's initial position in Cramer surprised advocates familiar with their anti-institution stance. The injunction sought, however, merely allowed P&A to collaborate with the State of Florida in drafting a court-ordered transition plan. The proposed transition plan, like the Florida law, included language which called for the closure of all private ICF/MRs with over 24-beds. Many affected families contacted P&A to demand that they stop misrepresenting their position. Some families, including Mr. Cramer, lead plaintiff, fired P&A. Despite these objections, Florida's P&A developed a Settlement Agreement with the State of Florida which incorporated the Transition Plan. Family members wrote to P&A expressing their opposition to P&A's actions. In response to one such letter, Pat Wear, Deputy Director and Francis Flood, Individual Advocacy Unit Director, responded in part -

> "We have received your letter dated April 6, 1998, in which you express concern over recent legal action taken by the Center. We regret that you are unhappy with our efforts. However, you must understand that we believe the institutional congregate care model has proven to be abusive and neglectful. Congregate settings, such as Florida's Developmental Services Institutions, constitute a despicable way for government and society to treat people who happen to have a developmental disability ... Again, we regret that you disagree with us, but

feel it is not possible to fulfill our congressional mandate without taking further action. " (Attachment 4).

As noted above in Section III, nothing in the DD Act mandates institutional closure. To the contrary, it supports person-centered supports, regardless of setting. A lawsuit which preceded Cramer v. Chiles, successfully addressed the waiting list issue in Florida.

The above examples offer confirmation for the claim that certain activities by the DD Act programs aimed at downsizing and closing institutions have lead to the need to address the resulting waiting list. Many states are now, at the urging of advocates, appropriating public dollars to help redress the waiting list. Significant proposals have been included in the Governors' Fiscal Year 1999-2000 budgets in Florida, New York, California, Massachusetts, Pennsylvania, New Jersey, Utah, Georgia, and New Hampshire. Other state legislatures, such as Minnesota, are also considering increased funding for the waiting list. Florida, California, Utah, and Pennsylvania have filed class action lawsuits to close institutions in past years, and New Jersey, New Mexico, Florida and Pennsylvania P&As have filed a lawsuit to address the waiting list (Attachment 13; see also subsection C, above). Using federal money to solve one alleged problem only to create another is an ineffective use of scarce resources.

Solution

The proposed amendments to the DD Act work to establish a better balance in advocacy activities by the DD Act programs. The proposed amendment do not prohibit lobbying by the DD Act programs. Rather, the proposed amendments encourage advocacy activities that work to further choice in residential options. For example (Attachment 1):

Pages 4-7:	Title II, Clarification of Certain Congressional Policies, Subtitle A - Choice of Residential Setting; Class Action; Lobbying, Sec. 201.
Pages 10-12:	Title II, Subtitle B, Sec. 212(b) Additional Definitions (see especially Systemic Change, Facilities, and Advocacy Activities).
Page 12:	Title II, Subtitle B, Section 213 Rights of Individuals with Developmental Disabilities.
Page 13:	Title 11, Subtitle B, Section 214 Conditions for Receipt of Financial Assistance.

Mr. BURTON. Thank you, Ms. Zitzmann. Thank you very much. Ms. Spaith.

Ms. SPAITH. Thank you for inviting me here today. I will preface what I am about to say with the fact that the opinions that I will express in my testimony are my own personal beliefs and not those of the organization for which I work. I would like to request that my formal official testimony be entered in as part of the official transcript for today's hearing, and I will just talk to my abbreviated testimony in the interest of time.

Mr. BURTON. That's fine.

Ms. SPAITH. I have served at the Department of Defense and in the U.S. Naval Reserve now for 26 years, 5 months. The last 4 years have been in the Office of the Secretary of Defense, Acquisition and Technology, Nuclear, Chemical and Biological Matters, which is now called Defense Threat Reduction Agency, and I work in chemical and biological elimination. My official title is International Project Manager, Biological Weapons Proliferation Prevention.

I manage a team of scientists, veterinarians, and technicians in collaborative research with the Russians at the Russian Biological Weapons Institutes. I travel to Russia, to the various institutes where dangerous pathogens are stockpiled, both bacterium and viral.

In August 1988 I was told by my supervisor to get my shots prior to my first deployment to Russia. I received typhoid, hepatitis A, and tetanus diphtheria vaccines at my agency, Defense Threat Reduction Agency, in late August, early September. I received one anthrax and one botulism vaccine at the U.S. Army Medical Research Institute for Infectious Diseases at Fort Detrick, MD in September and one additional anthrax vaccine in January 1999.

I was never told that any of the vaccines that I was receiving were experimental or investigational, and, in fact, the botulinal toxin, bot-tox, was investigational.

The blood work-up that was done at Fort Detrick indicated that I fell into the normal range—this was prior to receiving the vaccines—I fell into the normal range in terms of the assessments that were conducted on my blood at that time, which was chemistry and hematology.

After receiving the vaccines, my blood chemistry changed significantly. A blood work-up was done at Walter Reed during a routine occupational health physical, and showed that I was anemic in the tests that they did run at that time, and a physical exam by the doctor revealed that I had a severely enlarged thyroid. There had been at that point no followup by any of the medical personnel at Fort Detrick.

My first real symptoms began in October 1998 with significant loss of energy. I had trouble sleeping, which exacerbated the problem. In November 1998, I started having severe headaches in the very back of my head, where I have never had headaches before, way back here. I developed acute diarrhea. I had hair loss, blood sugar problems, mood swings, sleep deprivation, and acute anxiety.

By December 1998, I had menstrual cycle interruptions, increased PMS symptoms, abnormal feelings of tension, tremen-

dous—tremendous hair loss, extreme fatigue and loss of energy, severely reduced reflexes, and psychological problems.

I had been completely healthy with no medical problems prior to receiving the vaccines. I ran 2 miles every day prior to receiving the vaccines. Every day of my adult life I have done this. I have not been able to resume that activity.

I might also mention as an aside, each time I went to Fort Detrick, MD for my vaccines, I was bled. In other words, they drew blood each time, and I had to prove two different ways that I was not pregnant prior to them administering the vaccines to me. One was that I had to be on the first day of my menstrual cycle to receive the shot. The other was they drew blood and made me wait for 2 hours to prove through the blood test that I was not, in fact, pregnant before they would administer the shot.

This is basically why I believe that the vaccines I received at Fort Detrick, combined with the ones that I received at my own agency, and their cross-reactivity, contributed to or directly caused my illnesses and conditions.

By December 1998, I was terribly distraught and suffering, and having psychological problems. I went to an endocrinologist specialist. She conducted blood work and it revealed that I had no thyroid function at all, whatsoever. It was completely dead and not functioning. She told me that I had Hashimoto's Disease. She started me on Levathoid, which is a synthetic thyroid medicine.

The thyroid regulates the pituitary gland and regulates messages from the brain. However, my thyroid produces no thyroxin, which results in mixed signals that my body was receiving from my brain. As messages were sent from my pituitary, and my brain to my thyroid, there were no receptors to stimulate secretion of the thyroid gland hormone and no thyroxin was produced, so the messages go right back up in a closed loop. I was not performing in quite the organized way as people whose thyroids function properly. I am currently on three types of medications. The Levathoid is for the thyroid condition and I am also on Paxol and Adavan.

What caused my thyroid to stop functioning? That is the question that I have. There is no history of this in my family. I believe it was the vaccines that caused the change in my brain chemistry and my thyroid to stop functioning, which have further resulted in this very debilitating auto-immune deficiency which I am classified as having.

While I have had some favorable progress from the medications, I believe that my health will never be restored as it was before I received the vaccines. My psychological problems continued and worsened. I was over-reacting to situations and having terrible mood swings, still not sleeping. I could get upset very easily over the least little things. I developed a great deal of difficulty in my inter-personal relationships at work, particularly when I thought people were not cooperative. I got overly upset and said things that were not characteristic of me. I felt out of control, filled with anxiety, and nothing but despair. I was also disoriented and I had a great deal of difficulty focusing. I basically thought I was losing my mind.

At work the situation became so bad that my supervisor found my behavior to be so out of character, and my personality so radi-

cally changed, that I was called in and counseled on my behavior problems and given a letter of reprimand. This had never before happened to me. It was an emotional nightmare, and it was the lowest point in my career.

Then I realized that if management thought that I had changed that much, that something was seriously wrong with me, enough to write me a letter of reprimand, that I had better get back to a doctor. So I went back to the endocrinologist, and I discussed it with her, and I told her exactly what was going on. She immediately referred me to the mental health facility. I went that same day. I was diagnosed with depression and anxiety disorder, those are the other two medications that I am taking.

I learned that anxiety disorder is a biological malfunction in the body and not just something which is in your mind. It stems from a malfunction in brain chemistry. Depression, on the other hand, is a whole body illness and it affects the nervous system, mood swings, thoughts, and behavior. It, too, begins with a disturbance in the part of the brain that governs moods.

Medical experts believe that thyroid disorder, as well as chemical imbalances in the brain, can actually cause depression. I attended classes at my HMO's mental health facility where I learned these facts, as well as new skills to cope with my disorders.

I believe that my agency placed me in harm's way and then abandoned me in my personal crisis. Instead, they told me I had behavior problems and wrote me a letter of reprimand.

Now, I am worried about blood pressure, it has always been very low and now it is very high, and the doctors are monitoring that. I also recently discovered that I have arthritis in several parts of my body. I am now taking anti-inflammatory drugs and waiting to get scheduled to see a bone specialist. That is on top of the other three medications.

Again, no one in my family has any history of these disorders or illnesses. I continue to perform my job, however, I will not take any more vaccines. I will be on the synthetic thyroid stimulating hormone every day for the rest of my life. As for the other two psychotropic drugs that I am taking, I will continue for as long as the doctors feel it is necessary.

I would like to ask a question. I have a daughter who is a First Lieutenant in the Air Force, and since we share the same DNA and biological make-up, wouldn't it make sense that she not be forced to have to take these shots, considering what she has inherited from me and my predispositions? I am very concerned for her. The Air Force has told her that she and the other people at her command, which is Space and Missile Command in Los Angeles, will have to take the anthrax vaccines. It is either that or they will leave the service. I have great concerns for her. She has got an application in to become a pilot.

[The prepared statement of Ms. Spaith follows:]

1 August 1999

Congressman Dan Burton
Chairman, Government Reform Committee
U.S. House of Representatives

Dear Mr. Chairman,

The following text is my official, formal statement of testimony for the record. I ask that this be entered into the official transcript. I have worked for the Department of Defense, including military service in the USNR, since March 5, 1973. For the last four years, I have served in the Office of the Secretary of Defense (Acquisition & Technology), Nuclear, Chemical & Biological Matters, now Defense Threat Reduction Agency (DTRA). I am in the Cooperative Threat Reduction Directorate in the Chemical and Biological Elimination Branch. My official title is "International Project Manager," Biological Weapons Proliferation Prevention. As such I manage a team of scientists, veterinarians, technicians,National Academy of Sciences personnel, academicians, military experts, and contractors in a cooperative effort of Collaborative Research on dangerous pathogens at Russian Biological Weapons (BW) Research Institutes and laboratories. This involves my travel to Russian Research Institutes where stockpiles of dangerous bacteriological and viral pathogens such as Anthrax, Tularemia, Plague, Melioidosis, Smallpox, Monkey pox, and others are stored. My first trip was last September 1998.

In early August 1998 I was told by my supervisor to get my shots prior to my deployment scheduled for September 1998 to Moscow, Obolensk, and Serapuchov, Russia. Having served in the military as well as DoD I did what I always have and I followed the orders. At DTRA our Safety and Occupational Health Navy corpsman administered to me the Typhoid Vaccine (live oral, 4 capsules); Hepatitis A #1 (1.0cc); and Tetanus/Diphtheria (0.5cc). Next I traveled up to U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID) at Ft. Detrick MD and received my Anthrax Vaccines on two separate occasions and Botulism Vaccine (Botulinal Toxoid, a "live" vaccine commonly known as "Bot Tox" which is an Investigational New Drug (IND) protocol governed by the FDA.) The timeframe for all of these vaccines was late August and early September 1998 with the exception of my second Anthrax Vaccine administered in January 1999.

The medical personnel at USAMRIID Ft. Detrick, MD drew blood and worked up a profile of my blood prior to my receiving the vaccines at USAMRIID. In that blood work up, my records indicate that I fell into the normal range in terms of the blood assessments done on the chemistry, hematology, and automated differential of my blood (including a urinalysis) conducted by the Clinical Pathology Branch. That is not the case today. My blood chemistry changed significantly after receiving the vaccines and was noted in the blood work up done in February 1999 through my HMO. I was never made aware that one of the vaccines I was to receive at Ft. Detrick was experimental. I was, in essence, a guinea pig. In addition to the one vaccine that I received being experimental, it also happens to be the one which caused all the

health problems for the Persian Gulf War veterans according to *Citizen Soldier*, the advocacy group in New York. There never was nor has there ever been any follow up by any medical personnel at Ft. Detrick or anyone in my management at DTRA vis-a-vis my health since I received the vaccines and since I became sick.

The first symptoms I noticed started in October 1998 when I began to experience a significant loss of energy. I was having trouble sleeping as well and this exacerbated the lack of energy problem. In November I began to experience severe headaches (in the very back of my head where I have never had a headache before), acute diarrhea, hair loss, blood sugar problems, mood swings, sleep deprivation, and acute anxiety. By December I had menstrual cycle interruptions, increased PMS symptoms, abnormal feelings of tension, tremendous hair loss, extreme fatigue and loss of energy, severely reduced reflexes, and psychological problems. Many of these symptoms were then noted by my physicians. Of particular note was the fact that when I finally got to see a specialist in endocrinology for my severely enlarged thyroid, she found almost no reflexes. I was completely healthy with no medical problems prior to receiving the vaccines. In fact, I was athletic and have run 2 miles almost every day of my adult life. My energy level was so diminished after receiving the vaccines and becoming sick that I have not been able to resume my running since last October 1998. This is why I believe that the vaccines I received at Ft. Detrick combined with the other vaccines administered by my agency (and their cross-reactivity), contributed to or directly caused my illnesses and conditions.

By December 1998 I was terribly distraught. I was suffering and it was not until I went to Walter Reed Army Hospital for my occupational health physical that a doctor examined me and found problems in my blood and discovered my grossly enlarged thyroid. This prompted me to get scheduled to see an endocrinologist specialist. I was also having psychological problems. I was overreacting to situations and having terrible mood swings. I would get upset easily over the least little thing. I was having difficulty in my interpersonal relationships at work, particularly when people were not cooperative. I would get overly upset and say things that were not characteristic of me. I felt out of control, overly anxious, and filled with despair. I was also disoriented and had a great deal of difficulty focusing. I thought I was losing my mind. At work, this situation became so bad that my supervisor found my behavior so out of character and my personality so radically changed that he called me in his office and counseled me on my "*behavior problems*," and wrote me a letter of reprimand for being rude to someone over the phone who had complained about me. This has never happened in my 26 years of service. This was the lowest point in my career and I knew at that point that if management thought something was seriously wrong with me, enough to write me a letter of reprimand, then I had to go back to the doctor and discuss these problems. I did just that and explained what was happening to my health, my personality and my interpersonal relationships. The doctor immediately referred me to the Kaiser Mental Health facility and made an appointment for me to see a therapist that same day.

I was diagnosed by the medical specialists as having multiple illnesses namely, an auto immune deficiency and Hashimoto's Thyroiditis which is a disease, anemia, hypoglycemia, depression, hormone imbalance, anxiety disorder, and psychological and physiological disorders. **I was told that my thyroid was dead and**

completely not functioning. It is the thyroid that regulates the pituitary gland and regulates messages from the brain to produce thyroxin. However, in my case, my thyroid was producing no thyroxin and the residual levels left in my body were almost virtually nonexistent. This results in mixed signals my body was receiving from my brain. In my cursory understanding of my condition, as messages are sent from my pituitary gland in my brain to my thyroid, there are no receptors to stimulate secretion of the thyroid gland hormone and no thyroxin is produced so the messages go back up in a closed loop. Thus I was not performing in quite the organized way as in people whose thyroid functions properly.

I am currently on three different medications and have been since the end of February 1999. I was amazed to learn that anxiety disorder is a biological malfunction in the body and not just something which is in your mind. Rather, anxiety disorder stems from a malfunction in brain chemistry. Depression, on the other hand, is a whole-body illness and affects the nervous system, mood swings, thoughts, and behavior. It too begins with a disturbance in the part of the brain that governs moods. Medical experts believe that thyroid disorder as well as chemical imbalances in the brain actually cause depression. I have learned these facts through my independent research and the training courses I attended at my HMO's mental health facility. But the question that begs is "What caused my thyroid to stop functioning?" There is no history of this in my family. I believe it was the vaccines that caused the change in my brain chemistry and my thyroid to stop functioning which have resulted in this very debilitating auto immune deficiency.

Since starting the three medications in February 1999, I have begun to see some favorable progress. However, I believe my health will never be restored as it was before I received the vaccines. My agency (DTRA) placed me in harm's way and then abandoned me in my personal crisis. Rather, my management told me I had behavior problems and counseled me to correct those problems because it was affecting my job performance. I was then and still am very sick but I am working very hard to cope with my problems. At the classes I attend at Kaiser's mental health facility I have learned new skills for dealing with my disorders. Recently, my doctors noted that my blood pressure was very high and they are monitoring this. It should be noted that I have always had low blood pressure. Now I must have my blood pressure taken daily to monitor it. If this new health concern continues, my doctors will have to prescribe additional medicine for this disorder. And recently and most disturbing to me is the fact that my doctors have discovered arthritis in several parts of my body through X-ray testing. I am in constant pain and now on anti-inflammatory drugs in addition to the other 3 medicines I take. I have been told by my doctors that arthritis, both osteo and rheumatoid, are related to auto immune deficiencies. I am currently waiting to see a bone specialist. Once again, there is no history of this in my family nor is there any history of any of my disorders in my family.

These disorders are all related and associated with an auto immune deficiency. I can only learn new skills to deal with my illnesses - I can not make them go away. I have continued to manage my illnesses and perform my job. I have not resumed nor will I take any more vaccines ever again. I will have to take the synthetic thyroid stimulating hormone every day for the rest of my life. My dosage is monitored and altered as my symptoms change. As for the other two psychotropic drugs I am taking, I

will continue to take them until my health providers believe I can function without the drugs. This has been and continues to be a terribly jarring and debilitating experience for me and one I shall never fully recover from.

My daughter, Angela Camille Spaith, is a 1st Lieutenant in the United States Air Force. She is stationed at Space and Missile Command, Los Angeles AFB, CA. She has been told by her Command that she too must receive the Anthrax vaccine. Based on my genetic structure and the likelihood of passing on my predispositions along with my genetic material to my daughter, should she be required to receive these vaccines? I believe that I experienced deleterious affects from the vaccines and that my daughter would also since she shares my biological makeup.

I appreciate your concerns for this matter and thank you for the opportunity to come before your committee and testify.

Sincerely,

Antonia C. Spaith

Antonia C. Spaith
7504 Walnut Hill Lane
Falls Church, VA 22042

Mr. BURTON. Does that conclude your remarks, Ms. Spaith?

Ms. SPAITH. Yes, sir.

Mr. BURTON. Well, in answer to your last question, there are a number of Congressmen, myself included, that have legislation that is going to be introduced and will be pending—we had a press conference today—that would allow members of the Armed Services to decline to have the anthrax shot. But we are working on that right now.

Ms. Cole.

Ms. COLE. I have a poster with some children on it. Could somebody put that up, please?

Mr. BURTON. Would somebody post that, please?

Ms. COLE. I want to show you mine. This is Christopher.

Mr. BURTON. How old is Christopher?

Ms. COLE. Christopher was 12 when he passed away.

Mr. Chairman, members of the committee, thank you for letting me speak to you today.

My name is Rebecca Cole and I am from Chapel Hill, NC. I am the mother of five children. I am here today because I faced the worst nightmare any parent can possibly face. There is no experience on Earth that compares to the horror and devastation of losing a child. It is shattered dreams, crushed wishes, and a future that suddenly vanishes before our eyes. It cannot be wished away, slept away, prayed away, or screamed away. It is darkness, agony and shock. It leaves our hearts broken, bleeding and bursting with pain and it changes us forever.

My life changed forever on June 30, 1988 when I had to stand by helplessly as an infectious disease claimed the life of my oldest child, Christopher Aaron Chinnes, at the age of 12.

Christopher was a beautiful little boy who had light blond hair and deep brown eyes. He was full of compassion, joy and energy. He loved baseball and every living creature on the Earth. He wanted to be a scientist or doctor. I can honestly say that my son was one of the most beautiful human beings I have ever known, and I am proud to have been his mother.

Christopher was born a very healthy child but at the age of 8 he developed asthma. It was never a problem for him and it never kept him from doing the things he loved. But, on June 16, 1988, 4 years after he was diagnosed, he suffered his first and only severe asthma attack. He had to be hospitalized and was treated with all of the normally prescribed drugs including a corticosteroid. For those who don't know, corticosteroids are anti-inflammatory drugs. They are used routinely in asthma, arthritis, and allergies. Oral surgeons also prescribe them for swelling in the gums.

Well, Christopher was released from the hospital 4 days later with several medications to finish at home, and he was well on his way to recovery. On June 23rd, exactly 1 week after the asthma attack, he broke out with the chicken pox. "Don't worry, you will get over it," I told him. What I didn't know was that the corticosteroid had lowered his body's immune response and he could not fight the disease.

The chicken pox began to rampage wildly through his young body. As I drove him to the emergency room on June 27th my four younger children watched silently in shock and horror as their

brother went into seizures, went blind, turned gray, and collapsed due to hemorrhaging in his brain. That afternoon Christopher was flown from Camp Lejeune's Naval Hospital to East Carolina University School of Medicine's Medical Center, but the chicken pox was uncontrollably sweeping through him like a wildfire, and there was nothing anyone could do.

The next day he suffered cardiac arrest and slipped into a coma. As my beautiful little boy lay swollen beyond recognition and hemorrhaging from every area imaginable including out into the blisters on his skin, I learned that a vaccine existed but was not yet licenced by the FDA. A vaccine that could have prevented the unimaginable suffering of my child and all who knew him.

On June 30, 1988, exactly 1 week after breaking out with chicken pox, Christopher passed away. He died. He was not injured. He did not act differently. He was not crippled. He died. My priceless little boy lay on a cold, steel table swollen beyond recognition, cold and dead, gone from me, gone from life itself.

I cannot hold him, kiss him, see him smile or listen to his laughter as he chases a ball or bullfrog. The chicken pox virus destroyed every organ in his body and it cut pieces from the hearts of everyone who witnessed its devastation.

Vaccines prevent countless deaths each year. Without them the number of valuable human beings we would lose would be staggering. Yes, sadly, some injuries and deaths occur as a result of vaccines, but unfortunately there are risks with every single drug we use. We have and will not ever reach perfection. We must remember that the benefits of our vaccines far outweigh the risks. Especially for those who are ill or immunosuppressed like Christopher was. There are innocent children and adults who come in contact with the public every day who would die if they were exposed to the diseases we can prevent.

If everyone around them is vaccinated, they are also protected. We owe it to them and to ourselves as a Nation to achieve the highest level of safety and protection possible. We must win the war against infectious disease, and vaccines are our most powerful weapons. We cannot win, however, if we do not use them. Leaving any of our population unprotected is like surrendering to a defeatable foe, and we must never surrender. Thank you.

Mr. BURTON. Thank you, Ms. Cole.

[The prepared statement of Ms. Cole follows:]

Government Reform Committee
3 August Vaccine Safety Hearing
2157 Rayburn
House Office Building
Washington, DC 20515

Members of the Congressional Committee for Government Reform

Thank you for allowing me to speak to you today.

On June 30, 1988, I stood by helplessly as chickenpox claimed the life of my oldest of five children. Christopher, developed asthma at the age of eight, and four years later suffered his first and only severe asthma attack. He was treated with all of the normally prescribed drugs, during his hospitalization, including a corticosteroid. (Anti-inflammatory drugs used in asthma, arthritis, allergies, etc.) The corticosteroid lowered his body's immune response. When he got the chickenpox, one week later, he could not fight the disease. As my son lay in a coma, swollen beyond recognition, and hemorrhaging from every area imaginable, I learned that a vaccine existed, but was not yet licensed by the FDA. Christopher died at the age of twelve after varicella destroyed every organ in his young body. My son had been a beautiful, healthy boy, who someday wanted to be a scientist or doctor, but because of the unavailability of the vaccine, we will never know what contributions he might have made to society.

Vaccines prevent countless deaths each year. Without them the number of valuable human beings we'd lose would be staggering. Yes, sadly, some injuries and deaths occur as a result of vaccines, but unfortunately, there are risks with every single drug we use. We must remember that the benefits of our vaccines far outweigh the risks. Especially for those who are ill or immunosuppressed like Christopher was. There are innocent children and adults who come in contact with the public everyday who would die if they were exposed to the diseases we can prevent. If everyone around them is vaccinated, they are also protected. We owe it to them and to ourselves as a nation to achieve the highest level of protection possible. We must win the war against infectious disease, and vaccines are our most powerful weapons. We cannot win, however, if we do not use them. Leaving any of our population unprotected is like surrendering to a defeatable foe. We must never surrender.

Rebecca Cole
North Carolina
1-877-557-5437

Mr. VAN ZANDT. Thank you, Mr. Chairman and committee members. My name is Dr. Keith Van Zandt, and as a practicing family physician I appreciate the opportunity to address this committee regarding vaccines.

I have degrees from Princeton and Wake Forest Universities and completed residency training in family medicine here in Washington at Andrews Air Force Base. Today, however, I am here as a dad. I have five children, two of whom my wife, Dede, and I adopted from Romania. Our youngest, Adriana, was nearly 4-years-old when we adopted her from the orphanage and was found to have chronic active hepatitis B when we performed bloodwork prior to bringing her home. She had contracted this from her mother, who died when Annie was 9 months old from the effects of her liver disease as well as tuberculosis.

We have been very fortunate to have had some excellent medical care for Annie, but her first year with us was an endless procession of liver biopsies, blood draws, and over 150 painful Interferon injections that I gave my new daughter at home. Interferon is a form of chemotherapy for hepatitis B that has many side effects and only a 25 to 40 percent response rate. We know first-hand the pain and family disruption this completely preventable disease can bring.

As a family doctor, I see patients every day whose lives have been significantly improved by the immunizations we now have available. My forbearers in family medicine struggled in the prevaccination era with the ravages of horrible diseases that are now of only historical interest. Preventive immunizations have so changed our world that I am afraid that we no longer remember how horrible some of these diseases were.

My family and I have made multiple trips to Romania to work in the orphanages and unfortunately I have seen the effects of many of these diseases there. I am certainly aware of the potential for adverse reactions to our current vaccines but we must maintain the perspective that these reactions are extremely rare.

My partners and I in Winston-Salem care for over 40,000 patients, and I can honestly say that in over 20 years of practice, we have never seen a serious adverse reaction to any vaccine. I believe that the vast majority of family physicians around the country can say the same. Certainly I do not wish to minimize the suffering and losses of families who have experienced these problems, but we must remember that immunizations remain the most powerful and cost-effective means of preventing disease in the modern era.

Personally, it still sickens me to know that the disease that my daughter has was completely preventable if hepatitis B vaccines had been available to Annie and her mother. Whereas 90 percent of adults who contract hepatitis B get better, 90 percent of children under the age of 1 go on to have chronic disease and 15 to 20 percent of them die prematurely of cirrhosis or liver cancer.

I know first-hand the gut-wrenching feeling of being told your child has a chronic disease that could shorten their life. I know first-hand the worry parents feel when their hepatitis B child falls on the playground and you don't know if her bleeding knee or bloody nose will infect her playmates or teachers. Our kids are all over this country. They play with your kids in preschool. They date

your kids in high school. I know first-hand the concern for my other children's health with a 1 in 20 chance of household spread of hepatitis and the thankfulness I feel that they have had the availability of successful vaccines. I know first-hand the pain a parent feels for their child as they undergo painful shots and procedures for their chronic disease with no guarantee of cure.

I am not the world's leading expert on hepatitis B or the hep B vaccine, but I am an expert on delivering the best medical care I can to my patients in Winston-Salem, NC. I am also not the world's leading expert on parenting children with chronic diseases, but I am the world's best expert on parenting my five children.

I know professionally that immunizations in general have hugely improved the lives of those patients who have entrusted their medical care to me. I know personally that had the hepatitis B vaccine been available to my daughter, her life and mine would have been drastically different. I am also thankful that my other children have been spared Annie's suffering by being successfully vaccinated.

Anecdotes of vaccine reactions are very moving, but they are no substitute for good science. Please allow me to continue to provide the best medical care I can with the best system of vaccinations in the world and allow me to keep my own family safe. Thank you very much.

[The prepared statement of Dr. Van Zandt follows:]

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My name is Keith Van Zandt, and I appreciate the opportunity to address this committee regarding hepatitis B vaccines. I have degrees from Princeton and Wake Forest Universities, and completed residency training in family medicine here in Washington at Andrews AFB. Today, however, I am here as a dad. I have five children, two of whom my wife Dede and I adopted from Romania. Our youngest, Adrianna, was nearly four years old when we adopted her from the orphanage, and was found to have chronic active hepatitis B when we performed blood work prior to bringing her home. She had contracted this from her mother, who died when Annie was nine months old, from the effects of her liver disease as well as tuberculosis. We have been very fortunate to have had some excellent medical care for Annie, but her first year with us was an endless procession of liver biopsies, blood draws and over 150 painful interferon injections I gave to my new daughter at home. We know first hand the pain and family disruption this completely preventable disease can bring.

As a family doctor, I see patients every day whose lives have been significantly improved by the immunizations we now have available. My forebears in family medicine struggled in the pre-vaccination era with the ravages of horrible diseases that are now of only historical interest. Preventive immunizations have so changed our world that I am afraid that we no longer remember how horrible some of these diseases were. I am certainly aware of the potential for adverse reactions to these vaccines, but we must maintain the perspective that these reactions are extremely rare. My partners and I in Winston-Salem care for over 40,000 patients, and I can honestly say that in over 20 years of practice we have never seen a serious adverse reaction to any vaccine. I believe that the vast majority of family physicians around the country can say the same. Certainly, I do not wish to minimize the suffering and losses of families who have experienced these problems, but we must remember that immunizations remain the most powerful and cost effective means of preventing disease in the modern era.

Personally, it still sickens me to know that the disease my daughter has was completely preventable if hepatitis B vaccines had been available to Annie and her mother. I know first hand the gut-wrenching feeling of being told your child has a chronic disease that could shorten their life. I know first hand the worry parents feel when their hepatitis B child falls on the playground, and you don't know if her bleeding knee will infect her playmates or teachers. I know first hand the concern for my other children's health, and the thankfulness I feel that they have had the availability of successful vaccines. I know first hand the pain a parent feels for their child as they undergo painful shots and procedures for their chronic disease.

I am not the world's leading expert on hepatitis B or the hep B vaccine, but I am an expert on delivering the best medical care I can to my patients in Winston-Salem, NC. I am also not the world's leading expert on parenting children with chronic diseases, but I am the world's best expert on parenting my five children. I know professionally that immunizations in general have hugely improved the lives of those patients who have entrusted their medical care to me. I know personally that had the hepatitis B vaccine been available to my daughter, her life and mine would have been drastically different. I am also thankful that my other children have been spared Annie's suffering by being successfully vaccinated.

Thank you very much for your time.

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Mr. BURTON. Thank you, Dr. Van Zandt. I hope that the impression has not been given that anybody on this committee thinks vaccinations aren't important. I think we all agree that they are. The question is, are all of them absolutely necessary and are there things that can be done to make sure that they are necessary?

In your particular case, you adopted a child where they probably didn't have available to them on a regular basis those kinds of vaccines. I mean Romania has had some difficult times and had some very unfortunate situations, but I just talked to a family where, and I won't identify them because the lady did not want anyone to know she has hepatitis B, but she had hepatitis B and she came to the United States and married and her child was born with hepatitis B.

Had she been tested for hepatitis B during her pregnancy, it would have been very clear that the child should get a hepatitis B shot to prevent hepatitis. As I understand it, hepatitis B is spread through blood or from birth through the mother, or from needles, or from sexual contact. That being the case, it seems to me that if there are side effects to hepatitis B shots, as I believe there are because my granddaughter almost died—I think you heard that in my comments—then it seems to me that one of the first lines of defense would be to test every pregnant woman while she is pregnant to see if she has the hepatitis B virus.

Mr. VAN ZANDT. We do that.

Mr. BURTON. Well, this woman was not tested when she was pregnant. The hospital evidently neglected to do that.

If the mother doesn't have hepatitis B, then it may or may not be necessary for that child to have the hepatitis B vaccine and that I think should be something that parents should be aware of, especially if there are side effects. Now this is just my own opinion. I am not a scientist or a doctor, but I have talked to a lot of people who feel the same way I do who do have this expertise.

If you would like to comment, I would be happy to have you——

Mr. VAN ZANDT. If I could respond to that, we have heard earlier today that 40 percent of the cases of hepatitis B there is no identifiable cause, no identifiable risk factor.

Mr. BURTON. About 25 percent I think.

Mr. VAN ZANDT. It varies. I have read different, but nonetheless like I said I will defer to my CDC colleagues on that. The problem is that children with infectious diseases are out there. They often are totally asymptomatic. We don't know that they have these infectious diseases and that puts the population at risk.

We cannot simply target those populations that we think are prone to the disease and only gear our immunizations toward them. We tried that with hepatitis B in the past with adolescents. We tried to simply immunize adolescents. It didn't work.

Mr. BURTON. Let me ask you this question——

Mr. VAN ZANDT. We got dismal immunization rates by doing that and it didn't work and we moved back to the infancy time.

Mr. BURTON. May I ask you a question?

Mr. VAN ZANDT. Sure.

Mr. BURTON. This lady's child died and it is believed by the coroner that it was caused by the hepatitis B shot, because we called

the coroner this week, did we not? We called the coroner and asked him.

My granddaughter, within 12 hours of the hepatitis B shot, wasn't breathing. She was in a hospital, turned blue, and they thought she was going to die. She had to go on oxygen and she did survive, thank goodness.

What do you say to the two of us?

Mr. VAN ZANDT. Certainly I can't speak specifically to the cases. That would be unfair to you and to me. I don't have the details.

What I can say is that the system of vaccinations we have in this country works well. My personal experience is all I can speak to on that. The experience of my partners in Winston-Salem is all I can speak to on that. The reaction rates are rare. We rarely see them. There may be associations between the timing of the shot and diseases that develop. I think we need more data and more information to truly determine whether there is a cause-effect relationship or simply an association between those two and that is a big difference.

Mr. BURTON. Well, I agree with that and I think those are things that the Surgeon General and CDC and the FDA and everybody else ought to get on with as quickly as possible because vaccinations are absolutely necessary. But if vaccinations are causing autism, like in my grandson, or almost killing someone, like my granddaughter, or killing these people's child, then I think that it ought to be found out so that we can make corrections.

Mr. VAN ZANDT. Absolutely.

Mr. BURTON. We agree.

Mr. VAN ZANDT. We are all on the same page. I think that we don't want to throw out the whole system based on that, however.

Mr. BURTON. Ms. Spaith, did your supervisor get those shots?

Ms. SPAITH. No, sir, he didn't.

Mr. BURTON. He did not?

Ms. SPAITH. No, sir, he did not.

Mr. BURTON. Why did he ask you to get those shots?

Ms. SPAITH. Because I travel to Russia to dangerous sites, as he does, and my second level supervisor and other people in the office do.

Mr. BURTON. And they didn't get the shots?

Ms. SPAITH. No, sir, they did not. They said they didn't have time.

Mr. BURTON. So you were the only one and you ended up being the guinea pig?

Ms. SPAITH. Yes, sir.

Mr. BURTON. Let's see. Mrs. Cole, if a child is immunosuppressed, could they be vaccinated?

Ms. COLE. They hold off on that with the live virus vaccines. There are children who can't be vaccinated because of a drug they are on or a disease they have and that is why it is important that the rest of the population be protected so they are not exposed to it.

There could be four or five children in one classroom in a school that haven't been able to be vaccinated because their immune system is down a little, not enough to make them obviously ill, but

down, and anything they are exposed to in that room could really, really harm them and as in my son's case, kill them.

Mr. BURTON. Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman, I regret that I wasn't able to be here to listen to all the oral presentations, but we do have written testimony and I thank all the witnesses for being here, and I know it is not easy to come before Congress and share your personal loss and pain.

Dr. Van Zandt, how has contracting hepatitis B affected your daughter's current health and future health, and will she be more susceptible to diseases of the liver?

Dr. VAN ZANDT. This is unknown at this time. She did respond fairly well to the Interferon shots we gave her. Her viral titers, which is how we measure that, are undetectable at the present time. The problem is we never know. She fell several months ago and split her forehead, like anybody, parents have had children that do that, and with blood all over the floor, my first thought was hepatitis B. Not will she scar, or will we need to clean the rug? It was hepatitis B and who is at risk, and who will be at risk for that. If it had happened at school, without universal precautions being performed, I don't know.

Mr. WAXMAN. Some physicians have stated that hepatitis B is more a disease of sexual behavior and drug needle use and that it is unethical to mandate the vaccine for school children. Do you agree with that sentiment?

Dr. VAN ZANDT. I think those are two mutually exclusive sentences. I believe that it is more likely to be related to sexual patterns and IV drug abuse, but to say that it is morally unethical to vaccinate against it, I don't get the connection on those. Certainly, the higher risk population groups of sexual activity and IV drug abuse do have a higher incidence of hepatitis B.

What I am here to tell us is that our kids are out there with hepatitis B and they may be completely asymptomatic. You don't know it, and they are at risk, or there is a risk of them transmitting the disease. Because of that, I feel that the vaccinations—it is morally unethical not to vaccinate in that sense, to protect the public health.

Mr. WAXMAN. As a family physician, what do you tell your patients about the risk of possible adverse effects of immunizations?

Dr. VAN ZANDT. We use the CDC's vaccine information sheet to get out to every parent. The tough part about that, as many people on this panel will say, is that it has information that may or may not be really relevant and comprehensible to what can happen.

We know there are serious adverse reactions, and to counsel accordingly is appropriate. But it is also very important to counsel the risk of not getting the vaccine and the risk of having an infectious disease, and what that can do to your life.

Mr. WAXMAN. As a scientist, have you heard of any work that would show that there may be a connection between immunizations and autism?

Dr. VAN ZANDT. I am not aware of that, but, again, I am a practicing physician, not a research physician.

Mr. WAXMAN. I just don't know if there is something in the scientific literature. You know, I must say that I hear there is an in-

crease in autism. I hear there is an increase in dyslexia and learning deficiencies. Maybe in the latter it may be more of an ability to discern these problems.

It is frustrating to think that we may be causing all these terrible things happening to our children, and we don't know if it is environmental. Just yesterday, the EPA started to deal with the problems of pesticide residues in foods that we know from the Institute of Medicine adversely affect children more than adults. We don't know what other things we are being subjected to.

Whenever many of us try to fight for environmental protections, we get all the industry groups coming in and saying, oh, it can't be us, we are fine. But you wonder with all the information that comes out, in dribs and drabs sometimes, what we are going to learn later on, whether it is immunization. If it is immunizations, if it is chemicals in our food, if it is toxic substances in the air, in the water, we, as a society, have got to understand what is happening and try to protect people, particularly children.

Mrs. Cole, many parents are not aware that chicken pox can be fatal. How have you been able to educate others about chicken pox and the need for vaccines? Have you taken that on to talk to folks about?

Ms. COLE. I worked more or less as a mom through FDA to get warning labels put on all cortico-steroids about their dangers, potential danger with chicken pox and measles. Chris has been gone for 11 years. I worked for 7½ years through letters and phone campaigns to see the vaccine for chicken pox licensed by the FDA.

I went to FDA twice and spoke before two FDA Advisory Committees about my experience with chicken pox. I listened to what they had to say about the vaccine, and there were many, many articles written about Christopher, because chicken pox being fatal is something not many people ever hear about. Most people think, OK, I can expose my children on purpose and it is better for them, but they don't realize that it can be dangerous.

Yes, I have worked for a long time to try to educate the public as to the facts. It is not just immuno-suppressed children or individuals that can have a problem with chicken pox. From what I understand, and this may have changed, about half of the people that die each year of the varicella virus are not immuno-suppressed, they are healthy, normal people.

Mr. BURTON. Thank you very much.

Mr. WELDON. I have seen that. I had a 21 year old come in. He acquired—actually, he was about 25, acquired it from his child who ended up passing away. So it is a mistaken notion that chicken pox is a harmless disease. Occasionally, it can be fatal.

I want to thank each and every one of you for coming. I guess the question that I would have, and maybe I can start with you, Mr. Rollens, what do you think we should be doing? I have a constituent in my congressional district who believes that his son became autistic in response to the MMR. You provided testimony that you thought in your particular situation it could have been the DPT and the MMR might have made it worse.

We have testimony from the people sitting next to you about the devastating effects of the lack of immunization for some of these diseases. There are epidemiologists who have come into my office

and explained to me the tremendous impact that it could have on our population if there was a large scale rejection of these immunizations on the part of parents, if we were to have outbreaks of these clearly preventable diseases.

I would be very interested to hear comments from the other panelists. What do you recommend we do as policymakers? You know, we are here to pose the tough questions and get the answers. But then after all the talking is done, where do we go from here? Your thoughts?

Mr. ROLLENS. Yes, sir. The first thing that needs to be done is to stop politicizing this issue. There isn't anyone sitting in this room who is in favor of infectious diseases, and everyone is in favor of eradicating infectious diseases. So I think it is an issue that, unfortunately, those sometimes on both sides tend to politicize to make either pro-vaccine or anti-vaccine. I don't think that is the case at all.

I know the parents that I deal with in the world of autism around the country and around the world, all are conscientious parents who want the very best for their children. They don't want their children to pass away from any infectious disease. They want to provide the very best they can for their kids.

What we are asking, and what I am asking particularly from you is that before we deal with bringing new vaccines onto the market, and before we decide to mix such potent chemicals and potent viral and bacterial agents together, that independent safety studies be done about their effects.

And when I say independent, I mean devoid of the public health community's involvement. It is a conflict of interest to have the CDC, the NIH or anyone else who is involved with the promotion of vaccines to be telling us if they are safe or not. Like I said before, it is like asking the oil industry to come in and tell you that there is no relationship between smoking and lung cancer. It is ludicrous to have these people who are in charge of promoting this policy to be telling you if they are safe or not.

We have able immunologists, virologists, and neurologists around this country and around this world who are very able to look at the science of the interactions and the effects that these vaccines have on a certain percentage of the population.

I would also say that when I keep hearing that it is a rare chance occurrence, or this is a rare effect, I am telling you, as honestly as I can, that I have witnessed in the last 6 years alone, since my son was diagnosed, an explosion of autism, and parents are reporting objective reports, nothing besides the parent's observation of what happened to their children, of this strong temporal relationship between the vaccinations that they received, primarily the DPT, hepatitis B, and MMR, to the onset of their child's autism. The numbers are there. The California Department of Developmental Services has reported two reports within the last year on this epidemic of autism in California.

I challenge you again, when you go home next week to your districts, walk the neighborhoods, talk to the parents, they will tell you what is going on.

Mr. BURTON. Thank you. Mr. Rollens, I don't want to belabor this point, but you quoted some statistics from California. I have just

instructed Beth here to contact the Departments of Health in California to get that statistical data.

Mr. ROLLENS. Yes, sir.

Mr. BURTON. But we got an e-mail last night from a doctor in Louisiana who said that she has had reported to her over 600 vaccine-related autism cases. So that is Louisiana, it is not California. Have you talked to anybody in other States? I know that you are very involved in this, and I am very interested in it, too, because of the personal problem we have in our family. Have you talked to people in other States to see how pervasive it is?

Mr. ROLLENS. Yes, I have, and I can speak in volumes to what is happening in California, because I have been very involved in that.

Mr. BURTON. Well, tell me about other States that you are conversant with.

Mr. ROLLENS. Well, this is anecdotal. Once again, there has not been the kind of comprehensive study that was compiled in California in any of the other States. But the U.S. Department of Education has reported increases in every State in reported cases of autism.

What makes the California situation interesting and very significant is that in California we have something called the Lanterman Act, and I am sure Mr. Waxman remembers, in the California legislature, passed in 1969, which is essentially a program that entitles people who are diagnosed with autism, cerebral palsy, mental retardation, and epilepsy to services from the State. In order to qualify for those services, you have to have a diagnosis by the regional centers of our State in order to receive those services.

The report that California came out with last year shows that in the cases of what is known as DSM4-autism, this is full blown autism, not pervasive developmental disorder, or any other autism spectrum disorder, that there was an unexpected huge increase in the numbers of cases coming to the regional centers.

Now, one would say, well, this is an entitlement program, so people are coming for services. That is true. But they don't get those services unless they are diagnosed by a licensed psychologist or a professional person who uses the DSM4 for the criteria to diagnose for autism.

The other issue is that in California we have almost 16,000 children in the Early Start program, this is a program for children ages zero to 3 with developmental delay and language delay, but have yet to receive a diagnosis. When you see development delay and language delay, many people, including myself, feel, and I am sure time will show this, that a number of those children will also be added to the ranks.

The other concern that we have, of course, in California is that in the last 6 months, from January until July of this year, we have added 1,027 new children to our system. On average, six new kids a day, one new child every 4 hours. As you can see from my chart over there, that baseline of 200 new children stayed very steady all the way until the late 1970's, and there was a massive increase that occurred, it broke the 200 new cases a year, and has continued to go up, till today we are adding people at a rate of one child every 4 hours.

Mr. BURTON. Let me ask one more question. There is the chart he is talking about Henry. I don't think you saw that earlier. The other thing I would like to ask, and we have some people from the health agencies here, you implied that there might be a vested interest in them not giving information to the Congress and to the country regarding various vaccines. That is a pretty serious allegation. You said we ought to have independent studies from outside. What makes you say that?

Mr. ROLLENS. Well, first of all,——

Mr. BURTON. I mean do you think they are being influenced by pharmaceutical companies or what is it?

Mr. ROLLENS. The lack of responsiveness to the call that we have made for years now about this growing problem between the relationship between our children being damaged by vaccines and becoming autistic, and no response, or being literally blown off, that it is a rare chance occurrence that your child has become autistic right around the same time as the vaccine, with absolutely no safety studies to back it up.

I want to see from Dr. Satcher and others where the CDC's safety studies are that tell me as a parent, and as a taxpayer, and as a good person, a father who loves his child, that these vaccines will not cause autism or that my child, most importantly, did not become autistic because of the vaccines that he received.

Mr. BURTON. When they come up with a new drug at CDC and FDA, I have talked to them, they say they have to do a double blind study and sometimes more than one before they will attest to the veracity of the particular product. Since they are vaccinating everybody in the country, how do you propose they do a double blind study?

Mr. ROLLENS. Well, sir, I am not a scientist.

Mr. BURTON. No, I am just curious, from your perspective.

Mr. ROLLENS. Yes. I feel that when someone asked me to turn over the most precious thing in my life to them and trust them that my child would be out of harm's way, that the people that are doing the medical procedure, it is their responsibility. It is not my responsibility as a parent to ensure that every vaccine that I give my child, when I have been told that they are safe by the pediatrician, I have been told by society that there is no such thing, essentially, as an adverse effect.

You know, we are all sitting here with this issue on our minds, but how many parents out there really understand what can possibly happen from the documented research that has been done, and documented cases of adverse vaccine reactions?

Mr. BURTON. Thank you very much.

Mr. and Mrs. Nelson, you have come out here and I know you. Let me just ask you, when your child passed away, as I understand it from my daughter, when she talked to you, you called the doctor a number of times telling them of various symptoms, the temperature dropping, wrap her in blankets they said, and so on and so forth, and then, of course, the child, you took her to the hospital and she didn't make it. Can you really quickly tell us what happened, what the initial decision was that was made or what initial analysis was that was made of the death of the child, and what they told you?

Ms. NELSON. In the beginning they told us it would take 2 weeks to get the cause of death back. It was approximately 2 months later we heard from the coroner's office, Dr. Thomas Gill, who told us our daughter died of hepatitis B due to the vaccine. Sixteen weeks later we received the death certificate in the mail stating that she died of natural causes, SIDS. I called to find out how they determined that.

Mr. BURTON. Who told you that she died of SIDS?

Ms. NELSON. Dr. Karl Manders, the coroner of Marion County.

Mr. BURTON. The coroner of Marion County, Dr. Manders. OK.

Ms. NELSON. He stated that he had read over the autopsy documentation and that he signed the death certificate due to the fact that Dr. Gill was asked to resign. They filed the autopsy report the day after the autopsy. They did not wait for the toxicology report to come in, which came in 2 months later.

I asked him why he did not go back and check that over. He told me it was already signed. Then recently I have contacted the coroner's office. They refuse to give me her records. They refuse to give me any notes of Dr. Gill's, and they continue to tell me it was SIDS.

Mr. BURTON. I want those subpoenaed. We will subpoena those records. We will get those records. We will look into that.

Ms. NELSON. And they refused to tell me Dr. Gill's location, where he was or anything like that.

Mr. BURTON. All right.

We talked to the coroner's office and they said it was hepatitis. So, evidently the records do reflect that. So we will check into it.

Ms. NELSON. OK.

Mr. BURTON. Do you have any more questions Mr. Waxman?

Mr. WAXMAN. Yes, Mr. Chairman.

Mr. Rollens, you said that you entrusted the care of your child. People told you there were no such things as adverse reactions, and I think it is a mistake when people are told that there is no risk. As we know, there is some risk.

I know it is frustrating because so many of these people that you are looking at don't see it the way you see it. They don't see the connection. You may be right, they may be wrong.

Mr. ROLLENS. I hope I am wrong, sir.

Mr. WAXMAN. But they are people who are scientists, and they are not making any money out of having vaccines out there, and they are certainly not doing a service to anyone if they are not monitoring whether these vaccines are safe. I just want to point out there is an Advisory Commission on Childhood Vaccines and its membership is made up of public representatives as well, and I hope maybe we can look at that commission with you and it would give a sense of comfort that it is not just people who are professionals at the CDC.

But I have to say that I have always had the highest regard for the people at the CDC, and I think they are trying to do the best job they can, and I don't think they have any ulterior motives.

Mr. Chairman, I know there are people here from the NIH and maybe they could tell us, although it is probably unfair to ask anybody to come up and talk about what research is going on in the area of autism. But if we don't have a response now, I would like

to hold the record open, ask you if you could hold the record open. I want to know what our Government is doing in terms of autism research.

Mr. WELDON. Would the gentleman yield?

Mr. WAXMAN. I find what you have said, Mr. Rollens, and others, very, very sobering and of great concern.

Yes, I yield.

Mr. WELDON. I had CDC and NIH in my office on this issue, and there is really quite a bit of research going on. I have already asked them to provide that for the record.

Mr. WAXMAN. Good.

Mr. WELDON. I will share with you, though, that I think they need to do more, but, in that regard, they will need funding to cover it. I think that I would like to see that ultimately be one of the recommendations that comes out of these hearings is that the Congress of the United States takes initiative and funds more studies on this issue, particularly because I think it is going to be very important to restore public confidence in the system.

Mr. WAXMAN. Well, I certainly agree with you that we have got to spend more money on this research and try to find out what is causing autism and to try to see if we can find a way to prevent it or cure or control it because it is a very painful situation for everybody involved.

I don't want to say that because we don't have the answer to what causes autism that there is a lack of confidence in the system because science doesn't always give us the answer we want right away. We have got to make a commitment to invest in scientific research so that we can find some answers that can be replicated, can be validated and believed in because it has been scientifically established, not believed in because people want to believe in something, because that is not going to lead us to where we want to go.

So I want to join you in saying that perhaps one of the good results of this hearing might be a commitment that all of us will share to increase the research in this particular area.

I have no other questions and I thank all the witnesses. Thank you, Mr. Chairman.

Mr. BURTON. Thank you. I want to thank this panel very, very much, and I think, regardless of what your position is on vaccinations, we all share the heartache that you have gone through. I really feel empathy and sympathy for all of you. Thank you very much for being here.

The next panel is Dr. Kennedy, Dr. Kinsbourne, and Dr. Katz, and I would like for them to come forward at this time, and I apologize to you folks for this panel being so late.

One thing while they are coming up, I would like to say to our friends before you leave from the health agencies, I hope that somebody, if you haven't done this research, if they could look into whether or not all of these vaccinations coming in such a short period of time might cause overload on the immune systems of these children. Maybe the vaccinations, if given over a longer period of time might be less hurtful to the children, and maybe you can give me some information on that.

We heard from the people who just testified that some of them experienced 30 vaccinations by the time their child was 3 or 4

years old. We understand there are 21 different vaccinations they have to get from the time they are born to the time they get into school in many States. I know when we had the old electric system, if you put too much electricity on one fuse, you would blow the fuse, and I know that is an oversimplification of the problem, but it seems to me that might be one of the causal effects of too many vaccines in too short a period of time.

Would you gentlemen please stand?

[Witnesses sworn.]

STATEMENTS OF RONALD C. KENNEDY, PROFESSOR, DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY, UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER; SAMUEL L. KATZ, PROFESSOR EMERITUS, DEPARTMENT OF PEDIATRICS, DUKE UNIVERSITY MEDICAL CENTER; AND MARCEL KINSBOURNE, PEDIATRIC NEUROLOGIST

Mr. BURTON. We will start with you, Dr. Kennedy.

I apologize for it being so late in the day.

Dr. KENNEDY. It's OK. I apologize for putting on these glasses and not being able to see any of the members of the committee anymore.

Mr. BURTON. They will all be informed of your testimony. There are a lot of people paying attention across the country. Thank you.

Dr. KENNEDY. I would like to take this opportunity to thank you for the invitation to speak to this committee regarding issues related to vaccines, public safety, and personal choice. My name is Ronald Kennedy, and I am a professor of microbiology and immunology and obstetrics and gynecology at the University of Oklahoma Health Sciences Center. I am a research scientist and teach medical and graduate students.

My education has taken me from Connecticut, where I was born, to New Jersey, to Hawaii, where I received my master's and doctoral degrees, Houston and San Antonio, TX, and finally Oklahoma City.

My training is in microbiology and immunology and I have been working in the area of vaccinology since 1981, when I first started working on the immune response to hepatitis B surface antigen, the component of the hepatitis B vaccine.

Since that time I have performed basic and applied research as it relates to a variety of viral, bacterial and cancer vaccination strategies. Included in these efforts were studies to develop and/or improved vaccines to hepatitis B virus, the human immunodeficiency virus, HIV, hepatitis C virus, and simian virus 40, among others a virus that been recently associated with cancer in humans.

Because of my expertise in animal models for infectious diseases, particularly non-human primate models, I've also performed a number of collaborative studies with investigators on vaccines for haemophilus influenza type B, group A and group B streptococcus and meningococcus, among others.

As a number of these infectious diseases cause diseases in newborns and infants, I have become aware of the difference between how newborns respond to vaccination when compared to an adult.

I consider myself pro-vaccine. However, growing up in the field of vaccinology as I have, I am aware of a number of issues and considerations that should be brought forth when it comes to vaccines, public safety, and personal choice.

I would like to briefly mention three issues as it relates to the subject of this hearing.

The first is a lack of a mechanism to study the basis for adverse reactions to vaccines.

The second is, how can we improve vaccine safety, particularly when immunizing infants?

The final issue is that certain vaccines are just not appropriate and have not been tested well enough to mandate mass vaccination of infants, and this deals with informed consent and the parents' right to personal choice.

Regarding the lack of a mechanism to study the basis for adverse reactions to vaccines, I along with several colleagues have submitted grant applications to the National Institutes of Health to study the basis and mechanism of adverse reactions seen as a result of the hepatitis B vaccine. We made three attempts.

In each attempt the grant application was not considered for funding. The reasons of the peer review panel were the application was descriptive and a fishing expedition. We had compelling evidence but no direct cause and effect, and limited preliminary data.

As someone who has been funded continuously from the National Institutes of Health since 1984 and who has served on grant review panels for the National Institutes of Health since 1987, I was aware that such comments were a kiss of death. More importantly, I did not disagree with the panel's perception of the grant application. However, it was the nature of the subject matter. Since everyone has a perception that vaccines are completely safe, why would they want to study adverse reactions?

If the National Institutes for Health or Centers for Disease Control and Prevention will not support research by investigators outside their institutions into the basic mechanisms of adverse reactions of vaccines that are presently being used to immunize infants, perhaps the pharmaceutical companies who make the vaccines would fund such work by outside investigators. Honestly, I do not think that the vaccine manufacturers would be interested in supporting efforts that might show that their product is harmful.

I would urge you to provide research funds that are currently unavailable to study serious adverse reactions to vaccination such as those seen with hepatitis B.

My second issue is how can we make vaccines safer, particularly in infants? In my opinion, this requires more substantial testing, a requirement that each lot of vaccine be tested in non-human primate models for safety and comparative potency. Many of the present vaccine products have bypassed non-human primate studies and gone directly from rodent studies into human clinical trials. This was based on cost and comparability issues.

Additionally, other vaccines have shown problems in non-human primate models, and these were ignored and the product went into human clinical trials anyway.

It is important to test vaccines in immunologically similar animals and in an outbred population like us, particularly when ad-

dressing issues like long-term safety and comparable potency of a given vaccine lot.

My final issue relates to whether certain vaccines are appropriate for infant immunization and whether parents should be informed about the risk versus benefit of vaccination. More importantly, the physician who administers that vaccine is probably not aware there are any risks.

Two specific vaccines come to mind, hepatitis A and hepatitis B. I will not go into a long-winded scientific process and simply state that the chance of an infant or child getting either hepatitis A or hepatitis B is close to none or nonexistent. When the potential for exposure does exist, those risk factors are easily identified. Even more disturbing is that hepatitis A causes a self-limiting infection and does not cause chronic disease. It is my opinion that parents should be made aware of the risks and benefits of each vaccine where the chance for infection during infancy is minimal to nonexistent.

Certain vaccines, such as the enhanced and inactivated polio, diphtheria, tetanus, acellular pertussis, and the haemophilus influenza type B conjugate vaccines have significantly reduced infant mortality and morbidity and should be considered for infant immunization. However, other vaccines such as hepatitis B may be more effective when given at a later age rather than at birth. Informed consent for vaccines such as hepatitis A and hepatitis B should be considered and parents allowed to choose based on their perceived risk to benefit from vaccinating their infant.

To further illustrate my points, I would like to discuss adverse reactions and the need to support funding activities. The example I am going to pick is the whole cell pertussis vaccine.

This vaccine started for universal immunization of infants in developing nations in the 1940's. The whole cell pertussis vaccine causes frequent systemic symptoms such as irritability, lethargy, loss of appetite, and fever in 72 hours following immunization in up to 50 percent of subjects. More severe reactions include prolonged inconsolable crying, high pitched fever, screaming, fever above 104.9 degrees Fahrenheit, febrile and afebrile seizures, and shock-like states that can last up to 36 hours. In comparable trials, these adverse effects were more common in DTP recipients than in DT vaccinees. This suggested that the pertussis vaccine caused these reactions.

The public believes that the whole cell pertussis vaccine causes brain swelling and permanent neurologic damage and is widespread. However, scientific epidemiologic data to support a casual relationship are said to be inadequate, and this is simply not true.

Why is this the perception? First, there is no support for basic research into adverse reactions. The data on the casual relationship and inadequate nature to show a cause and effect, a lot of the data comes from the vaccine manufacturers. New and improved vaccines should decrease the adverse reactions, and the acellular vaccine is certainly associated with the lower incidence of these reactions.

Will we ever understand the mechanism of how the whole cell vaccine produced these side effects, and is there any association with neurologic problems? This is unlikely, because this has been

going on for 50 years, and what research really has been done? My question is, why then is the whole cell vaccine still being used?

Regarding the area of informed consent, I would like to quote from Chapter 17 in a textbook entitled Pediatric Infectious Disease, Principle and Practices. The editors are two pediatric infectious disease specialists. The textbook was published in 1995 and it is one that I use to teach medical students. In the area of informed consent, I am quoting directly from the book.

> Vaccines should be administered only after consent has been obtained from the parent, guardian, or in some cases the vaccine recipient. In the United States informed consent should be in writing and include an explanation of the disease to be prevented, the benefits and risks of immunization and the side effects that parents should look for following immunization.

Relative to requirements, again I am quoting from this chapter.

> Every time a public or private health care provider in the United States administers a particular vaccine, it is required to provide a legal representative of a child or any other adult or individual receiving a vaccine a copy of the vaccine informed statement prepared by the CDC. In addition, the names of the patient and parent, the date, site of immunization, dose, manufacturing vaccine lot number, name of person who administers the vaccine, and the place where the vaccine is administered should be recorded. This information is absolutely important if an adverse reaction occurs following immunization.

I think this is part of the problem with the adverse vaccine effects reporting system. Health care providers are not required to obtain the signature of the patient, parent or child's legal representative to acknowledge receipt of the vaccine information statement. This is an absolute must.

I want to thank you for the opportunity to appear before this distinguished committee. I would be happy to answer your questions at the end of the testimony.

Mr. BURTON. Thank you, Dr. Kennedy. I will have some questions in just a minute.

Dr. Katz.

[The prepared statement of Dr. Kennedy follows:]

The University of Oklahoma

Health Sciences Center

DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY

July 29, 1999

Congressman Dan Burton
Chairman,
Committee on Government Reform
United States House of Representatives
2157 Rayburn House Office Building
Washington D.C. 20515-6143

To the members of the Committee on Government Reform:

I would like to take this opportunity to thank you for the invitation to speak to this committee regarding issues related to Vaccines, Public Safety, and Personal Choice. My name is Ronald Kennedy, and I am a Professor of Microbiology and Immunology and Obstetrics and Gynecology at the University of Oklahoma Health Sciences Center. I am a research scientist and teach medical and graduate students. My education has taken me from Connecticut, where I was born, to New Jersey, to Hawaii, where I received my Masters and Doctoral degrees, Houston and San Antonio Texas, and finally Oklahoma City. My training is in Microbiology and Immunology and I have been working in the area of vaccinology since 1983, when I first started working on the immune response to hepatitis B surface antigen, the component of the hepatitis B vaccine. Since that time, I have performed basic and applied research as it relates to a variety of viral, bacterial, and cancer vaccination strategies. Included in these efforts were studies to develop new and/or improve vaccines to hepatitis B virus, the human immunodeficiency virus, hepatitis C virus and simian virus 40, a virus that has been recently associated with cancer in humans. Because of my expertise in animal models for infectious diseases, particularly non-human primate models, I have also performed a number of collaborative studies with investigators on vaccines for *Haemophilus influenzae* type B, group A and group B *streptococcus* and *meningococcus*. As a number of these infectious agents cause diseases in newborns and infants, I have become aware of the differences between how a newborn responds to vaccination when compared to an adult. My research efforts have also focused on non-human primate models to test and evaluate vaccine safety and potency. Studies have included vaccinating pregnant non-human primate mothers and vaccination of the fetus to determine what effects this has on the infant's ability to respond to subsequent vaccination. I have published a number of papers and manuscripts on the subject of vaccines. I also have co-authored two papers in the journal **Scientific American**, one in 1986 and the other in July 1999, on the subject of developing new

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kinds of vaccines. I consider myself pro-vaccine, however, growing up in the field of vaccinology as I have, I am aware of a number of issues and considerations that should be brought forth when it comes to Vaccines, Public Safety and Personal Choice.

I would like to briefly mention three issues as they relate to the subject of this hearing. The first is the lack of a mechanism to study the basis for adverse reactions to vaccines. The second is how can we improve vaccine safety, particularly when immunizing infants. The final issue is that certain vaccines are just not appropriate and have not been tested well enough to mandate mass vaccination of infants and this deals with informed consent and a parent's right to personal choice. Regarding the lack of a mechanism to study the basis for adverse reactions to vaccines, I along with several colleagues have submitted grant applications to the National Institutes of Health to study the basis and mechanism of the adverse reactions seen as the result of the hepatitis B vaccine. We made three attempts and each attempt the grant application was not considered for funding. The reasons of the peer review panel were the application was descriptive and a fishing expedition. We had compelling evidence, but no direct cause and effect, and limited preliminary data. As someone who has been funded continuously from the National Institutes of Health since 1984, and who has served on grant review panels for the National Institutes of Health since 1987, I was aware that such comments were a kiss of death. More importantly, I did not disagree with the panel's perceptions of the grant application. However, it was the nature of the subject matter (e.g. adverse reactions of vaccines) since every one has a perception that vaccines are completely safe, why would one want to study adverse reactions? If the National Institutes of Health, or the Centers for Disease Control and Prevention will not support research into the mechanisms of adverse reactions of vaccines that are presently being used to immunize infants, perhaps the Pharmaceutical Companies who make the vaccines would fund such work by outside investigators. Honestly, I do not think that the vaccine manufacturers would be interested in supporting efforts that might show that their product is harmful. It might cost them a lot of revenues in the short and long term. Regarding the problems with the hepatitis B vaccine, it is my scientific opinion that the adverse reactions being caused by this vaccine are not the result of the preservative (thimersol) or the presence of mercury. In my mind it is the product itself, and the change from the old plasma derived vaccine product to the new recombinant vaccine product. How can one study these problems if one can neither access the product nor procure the funds to support these research activities? I would urge you to help to provide research funds that are currently unavailable to study the serious adverse reactions to vaccination, such as those be seen with hepatitis B.

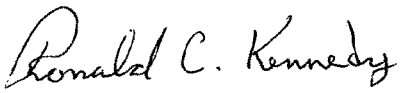
My second issue is how can we make vaccines safer, particularly in infants? In my opinion, this requires more substantial testing - a requirement that each lot of vaccine be tested in non-human primate models for safety and comparative potency. Many of the present vaccine products have bypassed non-human primate studies and gone directly from rodent studies into human clinical trials. This was based on cost and comparability issues. Additionally, other vaccines have shown problems in non-human primate models and these problems where ignored and the product went into human clinical trials anyway. If you are a company making a vaccine, why test in non-human primates if you

are not mandated to do s?o. From a company perspective, it will cost more to do studies appropriate studies in non-human primates and that will mean lower profitability. You may also identify problems that might require modifying the product. This would also cost money and delay the use of the product. It is important to test vaccines in immunologically similar animals and in an outbred population like us. Particularly when addressing issues like safety and the comparable potency of a given vaccine lot.

My final issue relates to whether certain vaccines are appropriate for infant immunization and whether parents should be informed about the risk versus benefit of vaccination. More importantly, the physician who administers that vaccine is probably not aware that there are any risks. I will focus on two vaccines, the hepatitis A and hepatitis B vaccine. I will not go into a long-winded scientific process and simply state that the chance of an infant or child getting either hepatitis A or hepatitis B is close to non-existent. When the potential for exposure does exist, those risk factors are easily identified. Even more disturbing is that hepatitis A causes a self-limiting infection and does not cause chronic disease. It is my opinion that parents should be made aware of the risks and benefits of each vaccine where the chance for infection during infancy is minimal to non-existent. Certain vaccines, such as polio, Diphtheria-Tetanus-acellular pertussis and the *Haemophilus influenzae* type b conjugate vaccines have significantly reduced infant morbidity and mortality and should be mandated. However, other vaccines, such as hepatitis B may be more effective when given at a later age, rather than at birth. Informed consent for certain vaccines, such as hepatitis A and hepatitis B should be considered and the parents allowed to choose based on their perceived risk to benefit from vaccinating their infant.

Thank you for the opportunity to appear before this distinguished committee. I would be happy to answer any of your questions or provide you with any additional information you may request.

Sincerely,



Ronald C. Kennedy, Ph.D., Professor,
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Dr. KATZ. Good evening, Mr. Chairman. I am Dr. Samuel L. Katz, a pediatrician involved in immunization research, development, patient care, teaching, and policy for over 40 years. I have served and continue to serve on a number of national and international committees that study, review, and formulate vaccine research and immunization recommendations.

Also, I am a father and grandfather whose eight grandchildren have all received their recommended childhood immunizations. The deliberations and recommendations that come from committees such as this will eventually affect every child and grandchild in the United States, including my own.

Today I am here representing the American Academy of Pediatrics [AAP], or Academy, and the Infectious Disease Society of America [IDSA].

I want to emphasize and restate three points.

First, our vaccines are highly effective and safe, but the diseases they prevent are still spreading through many other parts of the world.

Second, the system of research and development, of clinical testing, of licensing, of recommendation and monitoring of vaccine use, that system is in place and working well.

Third, there is a need to continue the education of parents and clinicians about diseases they no longer see because these serious diseases have been prevented so effectively by our immunization policies, but they are only a jet plane ride away from our shores.

Immunization is the single intervention that has most dramatically reduced childhood morbidity and mortality in the United States. Immunizations have reduced by almost 99 percent the vaccine-preventable infectious diseases in this country, although once again the causative germs continue to circulate widely elsewhere.

Most young parents cannot appreciate, fortunately, as I do, the horror of polio with iron lungs and crutches; measles with encephalitis; meningitis due to haemophilus influenza B, with death or with crippling or with mental retardation; the deafness, blindness and brain injury that you heard about from Ms. Zitzmann, caused by congenital rubella; tetanus of newborn infants with overwhelming mortality; and a number of the other infectious diseases that we fortunately do not see.

It is true that despite all that vaccines have done to improve the health of individuals and communities in the United States and throughout the world, they are not perfect. However, one simple fact cannot reasonably be disputed—the benefits of immunizations far outweigh any possible risks.

Dr. Satcher pointed out a number of features which I won't reemphasize, but how susceptible unimmunized individuals in a community threaten not just their own well-being, but that of their contacts, whether they are in day care, in school, in various settings where people crowd and gather.

I would just like to remind you of a few anecdotal events. Where were the last big measles outbreaks in older youngsters in this country? In a school for Christian Science college students where there were deaths due to measles because they don't follow immunization. I respect their religious point of view. I only use it as an example.

The last epidemics of polio in this country, where were they? In a boys school in Greenwich, CT, for a religious group who do not practice immunization; among an Amish population in Pennsylvania and several other States because they do not practice immunization.

These are only examples, and there could be many quoted to you. You heard about diphtheria. We've only had one case of diphtheria in this country in the last year. There were over 100,000 in the countries of the former Soviet Union within the last several years. The bacillus of diphtheria hasn't disappeared; we've just protected our population well.

You heard about haemophilus influenza B disease. Over 20,000 cases a year in children under the age of 5, causing meningitis, pneumonia with empyema or other invasive disease. Do you know how many cases there were last year in just the 10-years since we've had that vaccine? 125 cases in contrast to 20,000. Our results are striking and remarkable.

You heard about deaths from varicella. There have been an increasing number of deaths from varicella among children who are not immunized because of the interaction of what you have read about in the newspapers of the "flesh eating" streptococci, the group-A streptococci which superinfect youngsters with varicella and can cause death.

The fact that States have inaugurated requirements for school entry are based on trying to prevent these episodes occurring within their own venues. A recent article, which again I believe Dr. Satcher quoted, in the Journal of the American Medical Association pointed out the 35-fold greater risk of contracting measles among unimmunized individuals as compared to those who had been immunized, and that paper also demonstrated that the disease that occurs more commonly in these exemptors has the ability to initiate and propagate an epidemic in the community at large.

Should we allow our community immunity to wane, we will negate all the progress we have made and allow our communities to be at risk from threats that are easily prevented.

Immunization has a clear community benefit in addition to its benefit to the individual patient. An individual's freedom to ignore a stop sign while driving, to pollute the environment, to drive with his child without a car seat or a seat belt, or to spread disease do not serve the public good ultimately. We do place certain restraints on individual freedom because of our belief in the greater social well-being and the community well-being of certain responsibilities.

Ongoing vaccine safety efforts and continuous monitoring of adverse events, be they alleged, potential, or real, are crucial to our Nation's childhood immunization program. As science and resources allow, we are obligated to continue to improve the effectiveness of these safety monitoring measures.

The Academy and the IDSA have seen allegations that a variety of illnesses may be caused by various vaccines. It's easy to understand how a family with a tragedy can believe that a vaccine caused the sudden unexpected death of a child or the appearance of autism or another illness of unknown cause.

We give these vaccines in the first 2 years of life when all of these disorders have their common onset, so that guilt by temporal

association is very difficult to separate from guilt by causality. The available scientific data have shown, for example, that with increasing use of hepatitis B vaccine there has been a marked diminution in Sudden Infant Death Syndrome [SIDS] in this country. I don't think the two are related. Don't misunderstand me. Why are we seeing less SIDS? Because we are placing babies on their backs instead of their stomach. The same thing has been observed in the United Kingdom, a remarkable reduction in SIDS, but having nothing to do with more or fewer vaccines.

A robust system of checks and balances exists to monitor the safety and effectiveness of our vaccines, a system that we strive continuously to perfect. These efforts are designed to ensure that our recommendations about immunization and procedures reflect the best available science. There can be no doubt the public and private sectors and academia continue to be alert and responsive to vaccine safety needs.

The identification of potential safety issues, rapid review, and broad dissemination of interim guidelines demonstrate that we have an early warning system in place, that has the ability to detect and rapidly respond to new information. We must pay attention to this system to assure that it performs to the best of its ability. When any concern about vaccine safety arises, we have the capacity to evaluate the issue scientifically, to act both rapidly and prudently in the interest of what is best for our children, which is our overriding concern.

The role of parents as well as physicians in vaccine safety is paramount. Physicians must regularly update their knowledge about specific vaccines and their use. Information about the safety and efficacy of vaccines and recommendations relative to their administration continue to develop even after a vaccine is licensed.

As pediatricians we know that families are more likely to have their child immunized if they understand the risks and the benefits of immunizations and the consequence of the diseases they prevent. To ensure that parents and other caregivers take advantage of the benefit of immunizations, particularly for preschool children, the AAP and the IDSA recommend public education efforts on the importance of immunization, and that these continue. The Academy provides a variety of easily read patient educational materials for parents, for guardians, for physicians, for nurses, for whomever is involved in the setting.

Mr. Chairman, I greatly appreciate this opportunity to present this statement and will be pleased to answer any questions that you and your colleagues may have.

Thank you.

Mr. BURTON. Thank you, Dr. Katz.

Dr. Kinsbourne.

[The prepared statement of Dr. Katz follows:]

STATEMENT OF

SAMUEL L. KATZ, MD

PROFESSOR EMERITUS

DEPARTMENT OF PEDIATRICS

DUKE UNIVERSITY MEDICAL CENTER

REPRESENTING THE:

AMERICAN ACADEMY OF PEDIATRICS

AND

INFECTIOUS DISEASE SOC IETY OF AMERICA

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

AUGUST 3, 1999

Good afternoon, Mr. Chairman. I am Dr. Samuel L. Katz, a pediatrician from Duke University in Durham, North Carolina. I am a professor emeritus of pediatrics and have been involved in immunization research and development, patient care, teaching and policy for over 40 years.

During this time, I have served on a number of national and international committees that study, review, and formulate vaccine research and immunization recommendations. These include the Institute of Medicine (IOM), the National Academy of Sciences (NAS), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Vaccine Advisory Committee (NVAC), the Advisory Commission on Childhood Vaccines (ACCV), the National Institutes of Health (NIH) and the World Health Organization (WHO).

I am also a father and grandfather whose eight grandchildren (ages 5 months to 4 years) have all received their recommended childhood immunizations. I fully recognize, as does this Committee, that the deliberations and recommendations that come from Committees such as this, as well as those on which I have served, are not merely interesting discussions but will eventually affect every child and grandchild in the United States -- including my own. We all keep pictures of these children in our mind's eye every day as we care for our children, as we make our decisions and recommendations, and as we monitor the impact that these decisions have on our communities.

Today, I am here representing the American Academy of Pediatrics and the Infectious Diseases Society of America. The American Academy of Pediatrics represents over 55,000 pediatricians. Its mission and guiding interest is to guarantee the health and well-being of the infants, children and adolescents for whom pediatricians have the privilege of caring.

The Infectious Diseases Society of America (IDSA) is the professional society of infectious disease researchers, clinicians, teachers and public health professionals with a membership of over 5000 infectious disease specialists.

Immunization is the single intervention that has most dramatically reduced childhood morbidity and mortality. In our lifetime it has led to longer, healthier and happier lives. No longer do parents live in fear that their children will develop life-threatening paralysis from polio when they are at a swimming pool or the movie theater in the summer. No longer is a child with a fever in a day care center the harbinger of an outbreak of fatal bacterial meningitis with the well-documented chronic debilitating effects of seizures, deafness and mental retardation in up to one-third of the survivors. No longer are respirators standing by as a child, suffocating with the glue-like secretions of whooping cough, is brought to the emergency room late at night with his or her anxious parents trembling in a corner of the waiting room. We have entered a new era thanks to the development and widespread use of modern vaccines. Immunizations have reduced by more than 95 to 99 percent the vaccine- preventable infectious diseases in this country although the causative agents (except for smallpox) persist in epidemic or endemic burdens elsewhere in the world.

Limits of Effectiveness and Safety

We also know that despite all that vaccines have done to improve the health of individuals and communities in the United States and around the world, they are not perfect. However, the benefits of immunizations far outweigh any possible risks.

Our current level of protection is remarkable. It is a function of two things: the performance of the vaccines and their use broadly in the population, the latter largely a function of the increasing importance that most parents and all clinicians place on protecting children from diseases that are easily prevented with vaccines.

We know too well that the level of protection that we have now established in our children and our communities is a fragile one that depends on what we refer to as community or "herd" immunity. From the standpoint of effectiveness, modern childhood vaccines are approximately 90 - 95% effective. What that means is that for every 20 children who are vaccinated one or two may not develop a sufficient immune response. It cannot be assured that these children will be protected from the virus or bacteria should they encounter it at school, at a playground, at a shopping mall, or at their church day care. However, if sufficient numbers of children in a community are immunized, the vaccinated ones protect the unprotected by effectively stopping the chain of transmission in its tracks and drastically lowering the probability that the susceptible child will encounter the bacteria or virus.

As long as the great majority of children receive their vaccines, we will be able to maintain our current level of disease control. However, should the level of community protection drop to the point where the viruses and bacteria travel unimpeded from person-to-person, from school-to-school, and from community-to-community, we instantly return to a past era when epidemics were an accepted part of life. We experienced that just a decade ago [1989-91] with the resurgence of measles. There were 55,622 reported cases mainly in children less than 5 years of age, more than 11,000 hospitalizations and 125 deaths.

Because of the quality of our vaccines and our diligence in carrying out immunization policies, the US is the envy of the world with regard to the control of childhood infectious diseases. I have included a table from a recent edition of the CDC's *MMWR* that shows the power of vaccines and demonstrates quite clearly the full impact of vaccines today, compared with the prevaccination era. (*MMWR*, April 2, 1999).

Balancing Public Health and Safety with Personal Freedom of Choice

Personal freedom of choice must be examined in perspective. As framed in this hearing, on one side of the equation is "insuring a person's freedom" to make decisions while the other is "public health and safety." In this context, personal freedom of choice implies the decision of parents choosing not to immunize their children. Given such a "choice" we must acknowledge that this increases the potential for harm to other children who, for

a variety of reasons, are either not able to be vaccinated (they may be too young or too ill) or who were vaccinated but in whom the vaccine did not provide the expected protection. A recent article in the *Journal of the American Medical Association* (copy attached) found that, on average, those who chose to exempt from immunizations ran a 35 fold greater risk of contracting measles compared to those who had been immunized. *This important paper also demonstrates that disease that occurs more commonly in the exemptors has the ability to initiate and propagate an outbreak in the community at large.*

Compulsory vaccination laws in the United States have repeatedly been upheld as a reasonable exercise of the state's compelling interest even in the absence of an epidemic or even a single case. As the U.S. Supreme Court held in 1905 in the case Jacobson vs. Massachusetts:

> " ...in every well-ordered society charged with the duty of conserving the safety of its members the rights of the individuals in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations as the safety of the general public may demand...the liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good.... (Liberty) is only freedom from restraint under conditions essential to the equal enjoyment of the same right by others."

Understanding and Communicating Risk

Mr. Chairman, we did not get where we are today by accident. In the late 1960s and early 1970s, despite the availability of a safe and effective measles vaccine, we continued to experience regular epidemics of measles. Left to individual choice we were only able to achieve utilization rates of 60 - 70% in most communities. A 60 -70% coverage rate for measles did not and will not provide sufficient "community immunity" to dampen an outbreak. States without school immunizations requirements had incidence rates for measles significantly higher than states with these requirements. Recognizing these data other states, not the federal government, quickly adopted similar requirements. These requirements are supported by the American Academy of Pediatrics. The results are striking. Before we had a measles vaccine an estimated one-half million cases of measles was reported each year. Last year there were 89 cases of measles in the United States with no measles associated deaths. Most counties in the U.S. were free of measles. However, we have learned that nearly all of the cases of measles that did occur in the U.S. were imported from other countries. This would not have been possible without the "school exclusion" statutes that now exist in every state. While we hear dramatic stories of exotic diseases that are just a plane ride away, the importation of vaccine preventable-diseases into a susceptible population is much more frightening. Should we allow our community immunity to wane, we will negate all the progress we have made and allow our communities to be at risk from threats that are easily prevented.

As a parent, grandparent, and physician, I feel great sympathy for those unfortunate few who are harmed as a consequence of immunization. Though we recognize these reactions are rare, virtually every time a pediatrician or clinician advises a patient on the benefits to be derived from vaccines in preventing disease in individuals and in the community and about the risks of those vaccines, he or she acknowledges that there is a very remote chance of an adverse reaction to the vaccine. We know all too well that these rare events are not statistics but are real people – our patients. We also know that our patients, if not protected by immunizations, could easily contract a severe, possibly life-threatening disease that could threaten their well-being and prospects for a healthy future.

While we take risks every day in everything that we do, when it comes to immunization, we also know our vaccines are one of the safest forms of medicine ever developed. Few would argue that vaccines must be held to the highest standards of safety, barring none.

Immunization is not like most other aspects of medial practice as it has a clear community benefit in addition to its benefit to the individual patients. An individual's "freedom" to ignore a stop sign while driving, pollute the environment, or spread disease does not ultimately serve the good of freedom.

Vaccine Adverse Events Reporting System

Ongoing vaccine safety efforts and continuous monitoring of potential adverse events from vaccinations are crucial to our nation's childhood immunization program so that we can make our safe vaccines even safer.

The Vaccine Adverse Events Reporting System (VAERS) was established by the Department of Health and Human Services in 1990 to receive and compile all reports of adverse reactions that may be associated with vaccines. Operated by both the Food and Drug Administration and the Centers for Disease Control and Prevention, reports to VAERS may be made by anyone, including private physicians, state/local public health clinics, other health care professionals, vaccine manufacturers, vaccine recipients, parents or legal guardians. This system collects data about all possible vaccine adverse events and although it is not known how many reactions may go unreported, research has shown that the more serious events are likely to be accounted for. However, the strength of VAERS as a "passive surveillance" system that collects and accepts <u>any and all</u> reports is also its potential weakness since it cannot take into account those serious health problems that may happen around the time of vaccinations – coincidental events – that are <u>not</u> related to vaccines. Children regularly experience conditions such as fevers and seizures regardless of when they are vaccinated.

Temporal Versus Causal Associations

The Academy and IDSA have monitored concerns about hepatitis B virus vaccine including some reports that a variety of illnesses have been caused by the hepatitis B virus vaccine. The scientific evidence does not support hypotheses that hepatitis B virus

vaccines may have caused Sudden Infant Death Syndrome (SIDS), multiple sclerosis, autism or other demyelinating disorders. Although it is easy to understand how a family can believe that a vaccine caused the sudden, unexpected death of a child, the evidence is to the contrary. In fact, the progressive decline in the incidence of SIDS occurred during the introduction of routine hepatitis B virus vaccination for infants and there is no reason to hypothesize that this vaccine increases the risk of SIDS. Additional studies in individual states including Alaska and Hawaii where universal hepatitis B virus vaccination was first introduced in the mid 1980's indicated no increased risk of any serious medical conditions in infants who have received hepatitis B vaccination at birth. Thus the available scientific evidence indicates that there is no relationship between these unfortunate events and the hepatitis B virus vaccination.

We all want explanations for events that come unexpectedly and have no specific identifiable cause. Intense research has been conducted for many years into the cause of SIDS and we are making further advances in our understanding of it. While we sympathize with the parents of children who have died from SIDS, we should not assume that the vaccine necessarily causes events that occur in the hours, days or weeks following vaccination.

Whenever vaccines are administered, there is always the risk that coincidental illnesses, those that are known to occur at various ages, will occur and may be falsely attributed to the vaccine. During the late 1970's and early 1980's there was great concern about the possibility of SIDS being caused by pertussis-containing vaccines. It took several years and multiple carefully conducted studies to disprove this hypothesis. Although there are some cases of SIDS that occurred within two days after the DTP vaccination, the risk of SIDS in vaccinated children is lower than the risk for children who have not received the vaccine. The scientific evidence convincingly demonstrates that the DTP vaccination does not cause SIDS.

The National Vaccine Injury Compensation Program

Mr. Chairman, in the late 1970's until the mid-1980's this country faced a crisis in the availability of vaccines, brought about largely by an increase in litigation. In the 1970's, courts imposed liability on manufacturers of vaccines for failure to warn of side effects even when a vaccine was provided through clinics in a public program. In the early 1980's, allegations of injury from the pertussis component of the DTP vaccine led to the filing of approximately 300 lawsuits against this country's DTP manufacturers. In 1984, one of the three DTP producers stopped producing the vaccine and the others reported increasing difficulty in obtaining insurance and seriously considered withdrawing their DTP vaccines from the marketplace. Shortages of the vaccine occurred in several areas of the country and prices escalated dramatically.

Under the leadership of this Committee's Ranking Minority Member, Representative Waxman, Congress, with broad bipartisan support, enacted the National Childhood Vaccine Injury Compensation Act of 1986, which established a no-fault system of compensation for injuries or deaths reasonably associated with the administration of childhood vaccines. Unique under United States law, the compensation system is

supported by a surcharge on each vaccine covered under the no-fault program. Special Masters within the United States Court of Federal Claims administer it. A statutory Vaccine Injury Table (Table) -- which may be amended by administrative rule -- lists the compensable conditions covered on a per-vaccine basis and the time period after administration of the vaccine that the condition must have occurred in order for compensation to be available. If a person sustained the injury or other condition (or died) under circumstances that "fit" the Table, causation is established and compensation is awarded unless there is a preponderance of the evidence that the condition for which compensation is sought was caused by factors unrelated to the administration of the vaccine. This simplified showing is of enormous benefit to claimants because it requires much less proof than is necessary to succeed in a traditional court case. Opportunity is also provided for compensation for conditions "outside" the Table. In these instances, the claimant must demonstrate that the vaccine caused the injury, rather than rely on the Table to establish causation.

The law provides for the addition of new vaccines to the Vaccine Injury Table upon the occurrence of two events. First, the CDC must recommend to the Secretary of Health and Human Services that the vaccine be routinely administered to children. Second, Congress must enact an excise tax, or surcharge, on the vaccine, to support the compensation system. Once a new vaccine is included in the Table, all vaccine-related injuries (or deaths) that occurred 8 years or less prior to the vaccine's inclusion are covered under the compensation system.

Initially, the no-fault compensation program covered three childhood vaccines: polio, DTP and measles, mumps and rubella. Four vaccines, including the hepatitis B vaccine and the rotavirus vaccine, have been added. To date, over 100 petitions seeking compensation for injuries allegedly resulting from the administration of the hepatitis B vaccine have been filed. The rotavirus vaccine was added to the Vaccine Injury Table effective July 27, 1999.

There can be no doubt that the vaccine injury compensation program is an enormous success for the protection of our children. First, the DTP vaccine remained available to pediatricians and health clinics in the 1980s and this country avoided epidemics of pertussis (whooping cough) that have occurred in other developed nations. After a period of regression, in which several vaccine manufacturers abandoned the marketplace, new childhood vaccines have become available; this has had a direct benefit on the health of children in this country. For example, infants now receive a vaccine to prevent *Hemophilus influenza* type b (Hib) meningitis, one of the leading causes of death and mental retardation. Prior to the licensing of the first Hib vaccine in 1985 approximately 20,000 cases of Hib invasive disease occurred annually in children less then 5-years of age. Today, through the use of the Hib conjugate vaccine (licensed in 1987) this disease is virtually gone but will reappear if we do continue to be vigilant in vaccinating our children against this disease.

Many children have been fairly compensated under the no-fault law for injuries attributable to vaccines. To date 1,400 claims have resulted in compensation of over $1

billion. Awards have ranged from only a few thousand dollars to $8 million. A little over 500 cases remain under review. While there can be legitimate criticism of a process that is much more complicated than its proponents expected, and while there will always be disagreement over the scientific basis for inclusion or exclusion of conditions under the Table, there can be little doubt that the law has protected the public health, stimulated vaccine research and production and provided reasonable compensation to hundreds of children.

Professional and Public Information

Physicians must and do regularly update their knowledge about specific vaccines and their use because information about the safety and efficacy of vaccines and recommendations relative to their administration continue to develop after a vaccine is licensed. Physicians as well as other health care professionals rely on the American Academy of Pediatrics' *Red Book: Report of the Committee on Infectious Diseases,* a definitive resource for the control of infectious diseases in children. In addition to the *Red Book,* statements developed by the American Academy of Pediatrics' Committee on Infectious Diseases and approved by the Academy are published in *Pediatrics,* the Academy's peer-reviewed journal. *The Morbidity and Mortality Weekly Report* (MMWR) of the CDC contains current vaccine Advisory Committee on Immunization Practices (ACIP) recommendations and product specific official package inserts provide physicians with additional information. Moreover, we know that families are more likely to have their child immunized if they understand the comparative benefits and risks of immunizations and the consequences of diseases they prevent. To ensure that parents and other caregivers take advantage of the benefit of immunizations, particularly for preschool children, the American Academy of Pediatrics recommends that public education efforts on the importance of immunizations continue. To that end the American Academy of Pediatrics provides a variety of easy to read patient education materials such as the recently published brochure *Immunizations: What you Need to Know.* This informative brochure covers the reasons why immunizations are so important, as well as the common misconceptions, success rates, and risks.

Conclusion

Mr. Chairman, vaccine safety is not a new issue. Even before this hearing was called, the federal government, state governments, academic institutions, and vaccine manufacturers had been (and will continue to be) involved in a wide range of programs and activities designed specifically to ensure that the vaccines that we provide to children, adolescents and adults are held to the highest standards of safety and efficacy. There exists a robust system of checks and balances that monitors the safety and efficacy of our vaccines. These efforts are designed to assure that our recommendations about immunization practices and procedures reflect the best available science.

In addition, Mr. Chairman, there can be no doubt that the immunization community -- the public and private sectors and academia -- has been alert and responsive to vaccine safety needs. For example, when we recognized the need to improve the safety of the whole cell

pertussis vaccine, we focused our collective efforts to thoroughly investigate, and then license, an acellular pertussis vaccine. The new vaccine, which has largely replaced the earlier generation whole cell pertussis vaccine, has resulted in a significant decrease in actual, as well as reported, adverse events. A similar result has happened with polio vaccine with the adoption of new recommendations that move away from the live virus oral polio vaccine in an effort to further reduce the occurrence of the rare cases of vaccine-associated paralytic poliomyelitis. These two examples illustrate the responsiveness of the entire immunization community when it comes to vaccine safety.

Perhaps more timely, in the past several weeks, two "vaccine safety" issues have emerged involving the aggregate exposure to mercury from a preservative known as thimerosal, and concerns, still unproven, that a new vaccine against rotavirus diarrhea could be causing a bowel problem in some children.

The identification of these potential safety issues, their rapid review and the broad dissemination of interim guidelines to all immunization programs and practitioners, is yet another example that we have an early warning system in place that has the ability to detect and rapidly respond to new information. Of course, like any alarm system, the ideal is to assure that it does not misfire and works efficiently and effectively when it should. We must pay attention to this system to assure that it performs to the best of its ability. We need to do all that we can to assure that when a question of vaccine safety or effectiveness arises we have the capacity to find the answer and act accordingly in the public's interest.

In closing, I welcome the opportunity to speak with you today and I am gratified that members of this Committee are concerned about the safety of our vaccines. As a result of these discussions, I hope that you will become convinced, as I have over my many years in this field, that the vaccines that we give to our children and grandchildren are carefully scrutinized at every step in the process -- from development to production to use in the population. This system, the best in the world, continues to improve as science expands with the clear goal that our vaccines are held to the highest safety standards, and are effectively preventing serious, often life-threatening infections.

Mr. Chairman, I appreciate this opportunity to present this statement will be pleased to answer any questions that you may have.

Vaccines — Continued

TABLE 2. Baseline 20th century annual morbidity and 1998 provisional morbidity from nine diseases with vaccines recommended before 1990 for universal use in children — United States

Disease	Baseline 20th century annual morbidity	1998 Provisional morbidity	% Decrease
Smallpox	48,164*	0	100%
Diphtheria	175,885†	1	100%§
Pertussis	147,271¶	6,279	95.7%
Tetanus	1,314**	34	97.4%
Poliomyelitis (paralytic)	16,316††	0§§	100%
Measles	503,282¶¶	89	100%§
Mumps	152,209***	606	99.6%
Rubella	47,745†††	345	99.3%
Congenital rubella syndrome	*823§§§*	5	*99.4%*
Haemophilus influenzae type b	20,000¶¶¶	54****	99.7%

* Average annual number of cases during 1900–1904 (*1*).
† Average annual number of reported cases during 1920–1922, 3 years before vaccine development.
§ Rounded to nearest tenth.
¶ Average annual number of reported cases during 1922–1925, 4 years before vaccine development.
** Estimated number of cases based on reported number of deaths during 1922–1926 assuming a case-fatality rate of 90%.
†† Average annual number of reported cases during 1951–1954, 4 years before vaccine licensure.
§§ Excludes one cases of vaccine-associated polio reported in 1998.
¶¶ Average annual number of reported cases during 1958–1962, 5 years before vaccine licensure.
*** Number of reported cases in 1968, the first year reporting began and the first year after vaccine licensure.
††† Average annual number of reported cases during 1966–1968, 3 years before vaccine licensure.
§§§ Estimated number of cases based on seroprevalence data in the population and on the risk that women infected during a childbearing year would have a fetus with congenital rubella syndrome (*7*).
¶¶¶ Estimated number of cases from population-based surveillance studies before vaccine licensure in 1985 (*8*).
**** Excludes 71 cases of *Haemophilus influenzae* disease of unknown serotype.

ORIGINAL CONTRIBUTION

Health Consequences of Religious and Philosophical Exemptions From Immunization Laws

Individual and Societal Risk of Measles

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Context All US states require proof of immunization for school entry. Exemptions are generally offered for medical, religious, or philosophical reasons, but the health consequences of claiming such exemptions are poorly documented.

Objectives To quantify the risk of contracting measles among individuals claiming religious and/or philosophical exemptions from immunization (exemptors) compared with vaccinated persons, and to examine the risk that exemptors pose to the nonexempt population.

Design, Setting, and Participants Population-based, retrospective cohort study of data from 1985 through 1992, collected by the Measles Surveillance System of the Centers for Disease Control and Prevention, as well as from annual state immunization program reports on prevalence of exemptors and vaccination coverage. The study group was restricted to individuals aged 5 to 19 years. To empirically determine and quantify community risk, a mathematical model was developed that examines the spread of measles through communities with varying proportions of exemptors and vaccinated children.

Main Outcome Measures Relative risk of contracting measles for exemptors vs vaccinated individuals based on cohort study data. Community risk of contracting measles derived from a mathematical model.

Results On average, exemptors were 35 times more likely to contract measles than were vaccinated persons (95% confidence interval, 34-37). Relative risk varied by age and year. Comparing the incidence among exemptors with that among vaccinated children and adolescents during the years 1985-1992 indicated that the 1989-1991 measles resurgence may have occurred 1 year earlier among exemptors. Mapping of exemptors by county in California indicated that exempt populations tended to be clustered in certain geographic regions. Depending on assumptions of the model about the degree of mixing between exemptors and nonexemptors, an increase or decrease in the number of exemptors would affect the incidence of measles in nonexempt populations. If the number of exemptors doubled, the incidence of measles infection in nonexempt individuals would increase by 5.5%, 18.6%, and 30.8%, respectively, for intergroup mixing ratios of 20%, 40%, and 60%.

Conclusions These data suggest the need for systematic review of vaccine-preventable incidents to examine the effect of exemptors, increased surveillance of the number of exemptors and cases among them, and research to determine the reasons why individuals claim exemptions.

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IMMUNIZATIONS ARE AMONG THE most cost-effective and successful public health interventions. Due to the high contagion, morbidity, and mortality associated with most vaccine-preventable diseases (VPDs), and the safety, effectiveness, and potential financial savings offered by vaccines, all jurisdictions in the United States have introduced and actively enforce laws that require proof of immunization for school entrance.[1-3] Many of these laws were initially written specifically for smallpox and later amended to include other VPDs.[4] Although there are no federal laws mandating immunizations, the US Supreme Court has upheld the constitutionality of state vaccination laws. In 1905, the Court ruled in favor of a Massachusetts law; in 1922, the Court specifically addressed vaccination as a prerequisite for school attendance.[3] These federal rulings have served as precedents for state court rulings.

State immunization laws permit certain exemptions. As of January 1998, all states allow medical exemptions (eg, for individuals who are immunocompromised, have allergic reactions to vac-

See also Patient Page.

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cine constituents, or have moderate or severe illness). To qualify for medical exemptions, parents or guardians must provide a letter or other documentation from a physician. Forty-eight states permit religious exemptions, and 15 states allow philosophical or personal exemptions.[5] Such exemptions are defined differently by each state. Texas requires that individuals claiming religious exemptions be a member of a recognized religious group that opposes all immunizations and submit a letter from a faith leader. By contrast, California offers personal beliefs exemptions, which require only a parental affidavit.

Persons who claim exemptions from immunizations for any reason may be at increased risk of contracting a VPD compared with immunized persons. In addition, persons who claim philosophical and/or religious exemptions (exemptors) may create some risk to the community because unvaccinated or undervaccinated persons may be a source of transmission. In contrast to medical exemptions, which are due to an intrinsic medical condition, religious and philosophical exemptions are voluntary choices. Exemptors also pose a social equity issue.[6] While vaccines cause fewer complications than VPDs, no vaccine is perfectly safe. For most VPDs, "herd immunity," an indirect protection for a community, may be established when a high enough proportion of the population is immunized to interrupt transmission.[3] High immunization levels therefore permit some unvaccinated individuals to reap benefits of immunization without facing risks.[6] The current success of immunization programs in achieving record-high levels of coverage and record-low levels of VPDs results in many parents being unfamiliar with VPDs. As a result, the desire of some parents to claim exemptions for their children may increase when vaccine coverage is high.[7] Since the actual impact of exemptors on disease occurrence has not been well studied, we analyzed risks of exemptors to themselves and to the communities in which they live.

METHODS

Cohort Study

Using a population-based, retrospective cohort study design, we quantified the risk of exemptors compared with vaccinated individuals in contracting measles. We identified measles cases among exemptors and vaccinated individuals from 1985 through 1992, using data derived from the Measles Surveillance System of the Centers for Disease Control and Prevention (CDC), Atlanta, Ga. This system receives weekly reports of confirmed measles cases from 53 reporting areas (50 states, New York City, Chicago, and the District of Columbia). The reports include county, age, whether the case was an international importation, vaccination status, and exemption status if unvaccinated.[8]

We restricted our study to school-aged children and adolescents (aged 5-19 years). We compared the relative risk of contracting measles of exemptors and vaccinated individuals. We estimated the number of exemptors using CDC annual, unpublished State Immunization Reports from 1990 through 1994. These reports provide the "percentage of enrollees with an exemption for 1 or more vaccines." Data submitted in the reports do not distinguish between religious, philosophical, and medical exemptors, so we contacted program managers to discern the types of exemptions. For states not able to identify type of exemptions (n = 34 [68%]), we used the overall percentages reported on state surveys, which include medical exemptions (mean average of medical exemptions in the 16 states for which it was possible to identify type of exemption was 0.16). For 1 state (Delaware), which did not report percentage of individuals claiming exemption for any year, we used the average percentage of exemptors for states that did report these data (0.66%). We applied the (mean) average for each state over these 5 years to the period 1985-1992. California provided county-specific data on the percentage of exemptors, which were used in developing the mathematical model.

We calculated the number of vaccinated individuals by assuming a 98% national vaccination coverage rate for school-aged children and adolescents, based on unpublished CDC school-survey data of yearly coverage by state and antigen. All states reported at least 98% vaccination coverage among school-aged youth for measles in the period 1985-1992. Sociodemographic variables were not available. We used age-specific population data from the Bureau of the Census to extrapolate the percentages into estimated numbers. Thus, we were able to estimate age-specific measles incidence and the relative risk of measles for exemptors compared with vaccinated persons.

Mathematical Model

To quantify the risk of contracting measles in communities that have contact with exemptors, we applied a mathematical model to the data from the cohort study (mathematical model available from the authors on request).[9] The model examines the spread of disease through a population consisting of different strata or groups. In our application, the model consists of 2 groups: school-aged exemptors and nonexemptors. It is assumed that youth within a given group mix randomly, but exemptors are more likely to be in contact with other exemptors, and nonexemptors are more likely to be in contact with other nonexemptors.

The extent to which youth are more likely to make contacts with others from the same group is determined by the intergroup mixing ratio, which may vary between 0 and 1. For example, if the mixing ratio is 0.6, then 60% of the contacts are made with children chosen at random from the entire community (including that child's own group), and the remaining 40% of a child's contacts are made with other children from the same group. When the intergroup mixing ratio is 1, there is random mixing between exemptors and nonexemptors, and when the mixing ratio is 0, there are no contacts between groups.

Another important parameter in the model is the transmission probability, which is the probability that a suscep-

tible child becomes infected from a single infected child. This parameter may vary across communities because it depends on socioeconomic factors such as crowding. We assume that the vaccine reduces the transmission probability to each child by a given fraction, which is the vaccine efficacy. The vaccine efficacy in terms of transmission probabilities is defined as 1 minus the ratio of the transmission probability to a vaccinee and a nonvaccinee when both are exposed to a single infected person.[10] The estimate of this quantity depends on the assumption about the intergroup mixing ratio: for mixing ratios 0.6, 0.4, and 0.2, the estimated efficacy is 0.62, 0.42, and 0.22, respectively.

The vaccine efficacy in the model differs significantly from the traditional definition of vaccine efficacy, which estimates the measles vaccine to be about 90% to 95% efficacious.[1] Traditional vaccine efficacy is based on the overall attack rates for a vaccinee and a nonvaccinee during an outbreak. Efficacy also depends on the length of the epidemic period and on vaccine coverage. Estimation of efficacy also may be biased if vaccination is not random or if a vaccinee and a nonvaccinee do not have the same exposure to the infecting agent. Vaccine efficacy based on transmission probabilities, as in the model, standardizes exposure to a single contact with an infected person, so it does not depend on factors such as the vaccination strategy or coverage.[9] These 2 measures of vaccine efficacy can be quite different, even if there is no bias, especially if mixing is not random.

Our model provides equations that relate the disease attack rate (incidence) during an outbreak to the values of the transmission probabilities and intergroup mixing ratios. These equations are used to estimate the transmission probabilities from the observed attack rates among exemptors and nonexemptors and predict the expected attack rates based on changes in the number of exemptors.

To apply this model, we assumed that the population consists of 1000 communities. The distribution of the transmission probabilities over the communities was determined so that the overall numbers of expected cases in exemptors and nonexemptors were close to the observed frequencies. The ratio of transmission probabilities for exemptors and nonexemptors was also determined from the overall attack rates.

We developed the model to account for the clustering of exemptors as seen in national and California data. Five percent of the communities were assigned a rather high proportion of exemptors (5%); another 5% of the communities had no exemptors; and the proportion of exemptors in the remaining 90% of the communities was constant (0.21%), which was determined such that the overall proportion of exemptors was the same as in the entire population (0.44%).

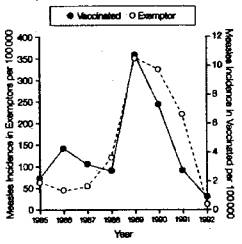
To empirically determine and quantify the impact of changes in the number of exemptors on the number of measles cases among nonexemptors, we explored various changes in the size of the exempt population: 50% decrease in the number of exemptors (ie, these individuals become vaccinated); and 50%, 100%, 200%, and 300% increases in the number of exemptors.

RESULTS

United States measles surveillance data indicate that exemptors were at a statistically significant increased risk of contracting measles vs vaccinated individuals for each age group and in every year (TABLE 1). On average, from 1985 through 1992, for persons aged 5 to 19 years, exemptors were 35 times more likely to contract measles than were vaccinated persons. The relative risk varied greatly by age group and by year, ranging from 4 times the risk of contracting measles for exemptors aged 15 to 19 years compared with vaccinated individuals in 1992, to 170 times the risk in 1988 for those aged 5 to 9 years. Cases among the vaccinated youth were more frequent in the older age categories. Cases among exemptors have a more uniform distribution across age categories (Table 1).

Comparing the incidence among school-aged exemptors with that among school-aged vaccinated children and adolescents during the years 1985 through 1992 indicates that the 1989-1991 measles resurgence may have occurred 1 year earlier among exemptors (FIGURE).

Figure. Timing of Measles Incidence in Exemptions Compared With Vaccinated Youth Aged 5 to 19 Years



Exemptor indicates individuals with religious and/or philosophical exemptions from mandatory school immunization laws; note varying scales between exemptor incidence and vaccinated incidence.

Mapping of exemptors by county was available for California, where school entry laws allow parents to elect personal belief exemptions from mandatory vaccinations for their children. Overall, approximately 0.5% of children enter kindergarten each year with such exemptions, a value that has remained relatively stable over the past 2 decades. However, the frequency of exemptors is not uniform in schools across the state. In 1995, in 84% of California's public and private schools with kindergartens, the proportion of children entering with exemptions was less than 1%. However, in 12% of schools, 1% to 4% of children entered with exemptions, and in 4% of schools, at least 5% of entrants were exempted. The proportion of exemptors is higher in the northern half of the state and is particularly high along the northern foothills of the Sierra Nevada Mountains and in some central and northern coastal areas.

Our mathematical model suggests that changes in the number of exemptors affects measles cases in the nonexempt population (TABLE 2). The mixing ratio largely determines the impact a particu-

lar increase or decrease of exemptors would have on the nonexempt population. For example, if the number of exemptors doubled, then the incidence of measles in the nonexempt population would increase by 5.5%, 18.6%, and 30.8% for intergroup mixing ratios of 20%, 40%, and 60%, respectively. The greater the increase in the number of exemptors, the more effect they have on the nonexempt population.

COMMENT

The control of VPDs by means of immunization requirements necessitates careful balance of individual rights and public good.[3,5] Policymakers must weigh the rights of individuals who wish to claim exemptions from immunizations against VPD risks that endanger the general public. Each US state has permitted some degree of exemptions for medical reasons or for religious and/or philosophical reasons.

Table 1. Relative Risk for Measles Among Individuals With Religious and/or Philosophical Exemptions Compared With Vaccinated Persons, United States, 1985-1992*

Age Groups, y	No. of Exemptor Cases	Exemptor Population	Exemptor Incidence per 100 000	No. of Vaccination Cases	Vaccinated Population	Vaccinated Incidence per 100 000	Relative Risk (95% Confidence Interval)†
				1985			
5-9	26	75 732	34.33	141	16 303 444	0.86	40 (27-61)
10-14	30	75 638	39.66	338	16 652 794	2.03	20 (14-29)
15-19	91	82 670	110.06	610	18 307 902	3.33	33 (27-41)
5-19	**147**	**234 040**	62.81	**1089**	**51 264 140**	2.12	30 (25-35)
				1986			
5-9	40	77 847	51.38	389	16 726 650	2.33	22 (16-31)
10-14	35	73 276	47.76	893	16 112 291	5.54	9 (6-12)
15-19	25	83 194	30.05	874	18 390 824	4.75	6 (4-10)
5-19	**100**	**234 317**	42.68	**2156**	**51 229 765**	4.21	10 (8-12)
				1987			
5-9	41	79 644	51.48	229	17 050 848	1.34	38 (28-54)
10-14	39	73 233	53.25	519	16 017 859	3.24	16 (12-23)
15-19	45	82 801	54.35	853	18 278 945	4.67	12 (9-16)
5-19	**125**	**235 678**	53.04	**1601**	**51 347 652**	3.12	17 (12-20)
				1988			
5-9	121	81 369	148.71	152	17 372 772	0.87	170 (134-216)
10-14	89	74 236	119.89	410	16 135 476	2.54	47 (38-60)
15-19	74	82 013	90.23	804	18 061 600	4.45	20 (16-26)
5-19	**284**	**237 618**	119.52	**1366**	**51 589 848**	2.65	45 (40-51)
				1989			
5-9	267	82 418	323.96	1020	17 526 411	5.82	56 (49-64)
10-14	288	76 125	378.33	1385	16 430 352	8.43	45 (40-51)
15-19	283	80 543	351.37	3119	17 726 632	17.59	20 (18-23)
5-19	**838**	**239 086**	350.50	**5524**	**51 683 395**	10.69	33 (31-35)
				1990			
5-9	287	83 706	342.87	1367	17 664 153	7.74	44 (39-50)
10-14	289	78 787	366.81	1032	16 816 883	6.14	60 (53-68)
15-19	204	79 269	257.35	1388	17 364 915	7.99	32 (28-37)
5-19	**780**	**241 762**	322.63	**3787**	**51 845 751**	7.30	44 (41-48)
				1991			
5-9	230	84 378	272.58	483	17 805 737	2.71	100 (86-118)
10-14	217	81 182	267.30	399	17 273 660	2.31	116 (98-137)
15-19	84	77 406	108.52	527	16 852 854	3.13	35 (28-44)
5-19	**531**	**242 966**	218.55	**1409**	**51 932 251**	2.71	81 (73-89)
				1992			
5-9	9	84 784	10.62	145	17 896 080	0.81	13 (7-27)
10-14	9	83 421	10.79	99	17 682 344	0.56	19 (10-39)
15-19	4	77 682	5.15	214	16 798 768	1.27	4 (2-12)
5-19	**22**	**245 887**	8.95	**458**	**52 377 192**	0.87	10 (7-16)

*Exemptors indicates persons with religious and/or philosophical exemptions from mandatory school immunization laws.
†Average relative risk for persons aged 5 to 19 years (1985-1992) was 35 (95% confidence interval, 34-37).

At low vaccination coverage and exemption levels, exemptors are unlikely to have a significant impact from a public health standpoint. Their impact is essentially a minor increase in the percentage of nonimmune or nonimmunized individuals, the great majority of whom are unvaccinated for other reasons. When vaccination coverage levels are high, herd immunity results in low incidence of VPDs, and reports of vaccine adverse events compared with disease incidence are more visible.[11] For diseases that are transmitted from person to person (and are therefore affected by herd immunity, eg, poliomyelitis, measles, pertussis, rubella, diphtheria, and varicella), individual and societal risk-benefit calculations may diverge.[6] The individual (or parents) wishing to minimize individual risk may decide to avoid vaccination by claiming an exemption, relying on the fact that others are vaccinated to provide protection.

Society's motives in vaccination, however, are to protect both individuals and their neighbors.[6] If a large number of individuals choose exemption, a "tragedy of the commons" may result,[12] with reductions in vaccination coverage and ensuing resurgence of VPDs. In several countries in the 1970s and 1980s, concerns about alleged or suspected adverse effects led to decreases in pertussis immunization resulting in a major resurgence in the incidence of pertussis.[13] Such outbreaks highlight the continued relevance of state vaccination laws as long as VPDs have not been eradicated globally.

The effort to increase availability of philosophical exemptions to vaccinations may reflect this divergence in perceived risk-benefit.[5] Unfortunately, VPDs other than poliomyelitis are unlikely to be eradicated globally in the near future.[14] Consequently, high immunization levels against these VPDs will need to be maintained. Thus, in settings like the United States, where levels of reported VPDs are low and reported adverse events following immunization are relatively prominent,[15] debate over appropriateness of exemptions to mandatory immunizations is likely to continue.

There have been many reports of VPD outbreaks that started primarily in exempt individuals and then spread to vaccinated persons.[5] For example, a 1996 measles outbreak in Utah exemplified the effect that clusters of exemptors can have on the community. Statewide, 118 cases occurred, with 107 in Washington County.[16] Compared with the percentage of exemptors nationally (0.44%), Utah has almost 3 times the national average (1.2%), while Washington County has more than 7 times the national average (3.7%). Of the Washington County cases, 48 (45%) were among exemptors. The outbreak lasted 6 generations. Two (66.7%) of the 3 cases in the first generation were exemptors, as were 17 (53%) of 32 cases in the second generation, and 15 (60%) of 25 cases in the third generation. The substantial percentage of exemptors in this outbreak, as well as the concentration of cases among exemptors in the beginning of the outbreak, suggests that they played a major role in transmission (Rebecca Ward, community health specialist, Utah Immunization Program, oral and written communications, September 1997 through September 1998). Such reports confirm the biological plausibility of outbreaks starting in susceptible, unvaccinated individuals and then spreading to vaccinated children and adolescents who are inadequately protected due to vaccine failure.

While individual outbreaks of measles,[17,18] pertussis,[19] rubella,[20] and poliomyelitis[21,22] in unvaccinated religious communities have been reported, data are lacking to quantify the risk of acquiring a VPD among exemptors vs the general population and the risk that exemptors may pose to the nonexempt public. Our study estimates that from 1985 through 1992, school-aged children and adolescents claiming exemptions in the United States were 35 times more likely to contract measles than vaccinated youth. Surveillance data suggest that increases in VPD incidence among exemptors may be a sentinel effect for a potential outbreak among the general population. We also developed a mathematical model that permits quantification of the risk relationship between exemptor and nonexemptor communities, depending on the relative increase or decrease of exemptors and the degree of mixing between the 2 communities.

We chose to use 1985-1992 measles data for this study because this was the most complete data set to which we had ready access. The data examined in this study include the 1989-1991 measles resurgence, the largest outbreak since 1977. In 1990 alone, 26 672 cases of measles and the largest annual number of measles deaths (n = 89) since 1971 were reported.[23] The resurgence has been attributed to poor coverage rates among children younger than 5 years in urban areas and certain minority groups.[24] We focused on school-aged children and adolescents because approximately 80% of measles cases during these years were among in-

Table 2. Change in Number of Measles Cases Among Vaccinated Youth Due to a Decrease or Increase in the Number of Religious and/or Philosophical Exemptions From Immunization Requirements*

Change in No. of Exemptors	Intergroup Mixing Ratio†		
	60%	40%	20%
50% Decrease	12.3% Less cases	8.7% Less cases	3.1% Less cases
50% Increase	15% More cases	9.5% More cases	3.1% More cases
100% Increase	30.8% More cases	18.6% More cases	5.5% More cases
200% Increase	66.8% More cases	36.9% More cases	10.5% More cases
300% Increase	108.4% More cases	55.7% More cases	15.2% More cases

*Table based on 1985-1992 national measles data for persons aged 5 to 19 years. Exemptors indicates persons with religious and/or philosophical exemptions from mandatory school immunizations laws.
†Indicates the percentage of contacts made randomly in the entire community (including child's own group); the remaining contacts are made with other children from the same group.

dividuals younger than 19 years.[25] Furthermore, exemptions are granted when immunization laws are enforced—usually at day care or school entrance. If not medically exempt, the choice is either to become immunized or become an exemptor. The relative risk between exemptors and vaccinated persons quantifies the consequences of this choice.

We developed a mathematical model based on the known characteristics of exemptors that emerged from the CDC State Immunization Reports and California data. Exemptors tend to cluster within local and state boundaries, thereby increasing the effect that they may have on the rest of the population in comparison with a dispersed pattern. For example, a state may have a relatively low percentage of exemptors overall, while a community in that state may have a substantially higher percentage of exemptors. Our model accounts for this by dividing the population into 1000 communities with varying percentages of exemptors. The mixing ratio accounts for individual choices in social settings. Although there may be a relatively small number of exemptors in the state or county, there could be a significant clustering of exemptors in a given individual's social sphere (eg, school, social organizations, and religious community). It is impossible to quantify a mixing ratio on a national level, but personal preferences in social settings suggest that this fluctuates as accounted for in our model.

Our study findings should be interpreted with the following caveats. Cases of measles among exemptors may have been underreported to the Measles Surveillance System because they are more likely to occur in communities with "alternative" health care beliefs, or overreported because measles vaccination was not recorded in the child's immunization history. Furthermore, there may have been inaccuracies in determining the numbers of exemptors because these data were based on state reports from 1990 through 1994. If there was a substantial change in the percentage of exemptors in any state during these years compared with 1985 through 1989, the earlier estimations may be inaccurate. The number of religious and/or philosophical exemptors may have been overestimated because medical exemptions were included in 34 states for which it was not possible to distinguish between type of exemption.

There are also limitations in the age-specific analysis. Vaccination coverage was estimated using state reports for kindergarten through grade 12. It is possible that immunization coverage was higher for the younger students because the primary point of enforcement is typically at first entry to school and strict enforcement of laws began in the late 1970s.[5] This could account for differences in the age distribution of measles cases among exemptors and vaccinated children. These differences also could be explained by the possibility of waning immunity among vaccinated children or environmental exposure (ie, older children may be more likely to have environmental exposure to measles because of age-related differences in social settings and numbers of contacts). It is also possible that some individuals claimed an exemption for a specific vaccine, but not for other vaccines. If this were the case, the child would be counted in the denominator of the exemptor incidence, despite possible immunization for measles.

Unfortunately, surveillance data prior to 1985 or after 1992 are not available to determine if the earlier increase in incidence among exemptors compared with vaccinated children observed in the Figure has a general sentinel effect or an ecologic aberrance unique to these years. However, such an effect is consistent with the known higher susceptibility rate in exemptors.

Throughout this study, exemptors are defined as individuals claiming religious and/or philosophical exemptions offered by individual states. While this definition is functional for an epidemiologic study, it may not be for policy issues because each state defines exemptions differently. Some states require an unequivocal statement from a religious leader that immunization conflicts with the person's religious belief. This type of requirement for an exemption essentially assesses the strength of conviction of the individual applying for an exemption, similar to Selective Service boards assessing exemptions from military draft. Other states grant exemption based on a form signed by parents, indicating that immunizations are against the individual's personal belief. In these states, efforts may not be made to assess strength of conviction.

Further research is needed to better quantify the magnitude of the risks that exemptors pose to nonexemptors. For example, systematic review of the role of exemptors in facilitating transmission in recent and future VPD outbreaks may be useful. Public health surveillance for VPDs should routinely monitor exemption status among new VPD cases. Methods to help identify potential increases in the number or clustering of exemptors before VPD outbreaks occur may be needed. Having determined that exemptors are a risk factor for contracting a VPD, it is important to discover the underlying reasons why individuals are claiming exemptions. Interventions should be developed and implemented to counter misunderstanding of the relative risks and benefits of immunization at both the individual and societal level.

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REFERENCES

1. Plotkin SA, Mortimer EA, eds. *Vaccines*. 2nd ed. Philadelphia, Pa: WB Saunders Co; 1994.
2. Robbins KB, Brandling-Bennett AD, Hinman AR. Low measles incidence: association with enforcement of school immunization laws. *Am J Public Health*. 1981;71:270-274.
3. *State Immunization Requirements: 1994-95*. Atlanta, Ga: Dept of Health and Human Services, Centers for Disease Control and Prevention; 1996.
4. Jackson CL. State laws on compulsory immunization in the United States. *Public Health Rep*. 1969; 84:787-795.
5. National Vaccine Advisory Committee. Report of the NVAC Working Group on Philosophical Exemptions. In: *Minutes of the National Vaccine Advisory Committee: January 13, 1998*. Atlanta, Ga: National Vaccine Program Office; 1998:1-5.
6. Hershey JC, Asch DA, Thumasathit T, Meszaros J, Waters VV. The roles of altruism, free riding, and bandwagoning in vaccination decisions. *Organizational Behavior Hum Decis Process*. 1994;59:177-187.
7. Fine PE, Clarkson JA. Individual versus public priorities in the determination of optimal vaccination policies. *Am J Epidemiol*. 1986;124:1012-1020.
8. Centers for Disease Control and Prevention. Summary of notifiable diseases, United States, 1996. *MMWR Morb Mortal Wkly Rep*. 1996;45(53):iii-vi.
9. Haber M. Estimation of the population effectiveness of vaccination. *Stat Med*. 1997;16:601-610.
10. Haber M, Longini IM, Halloran ME. Measures of the effects of vaccination in a randomly mixing population. *Int J Epidemiol*. 1991;20:300-310.
11. Chen RT, Rastogi SC, Mullen JR, et al. The Vaccine Adverse Event Reporting System (VAERS). *Vaccine*. 1994;12:542-550.
12. Hardin G. The tragedy of the commons. *Science*. 1968;162:1243-1248.
13. Gangarosa EJ, Galazka A, Wolfe CR, Phillips LM, Miller E, Chen RT. Impact of the anti-vaccine movements on pertussis control: the untold story. *Lancet*. 1998;351:356-361.
14. Centers for Disease Control and Prevention. Progress toward global eradication of poliomyelitis, 1997. *MMWR Morb Mortal Wkly Rep*. 1998;47:414-419.
15. Chen RT, DeStefano F. Vaccine adverse event: causal or coincidental [commentary]? *Lancet*. 1998; 351:611-612.
16. Centers for Disease Control and Prevention. Measles outbreak—southwestern Utah, 1996. *MMWR Morb Mortal Wkly Rep*. 1997;46:766-769.
17. Novotny T, Jennings CE, Doran M. Measles outbreaks in religious groups exempt from immunization laws. *Public Health Rep*. 1988;103:49-54.
18. Sutter RW, Markowitz LE, Bennetch JM, Morris W, Zell WR, Prebud SR. Measles among the Amish: comparative study of measles severity in primary and secondary cases in households. *J Infect Dis*. 1991; 163:12-16.
19. Ettkind P, Lett SM, MacDonald PD, Silva E, Peppe J. Pertussis outbreaks in groups claiming religious exemptions to vaccination. *AJDC*. 1992;146:173-176.
20. Mellinger AK, Cragan JD, Atkinson WL, et al. High incidence of congenital rubella syndrome after a rubella outbreak. *Pediatr Infect Dis J*. 1995;14:573-578.
21. Oostvogel PM, van Wijngaarden JK, van der Avoort HG, et al. Poliomyelitis outbreak in an unvaccinated community in the Netherlands, 1992-93. *Lancet*. 1994;344:665-670.
22. White FM, Lacey BA, Constance PD. An outbreak of pollovirus infection in Alberta: 1978. *Can J Public Health*. 1981;72:119-124. Taken from: *MMWR Morb Mortal Wkly Rep*. 1979;28:345.
23. Centers for Disease Control and Prevention. Measles—United States, 1990. *MMWR Morb Mortal Wkly Rep*. 1991;40:369-372.
24. National Vaccine Advisory Committee. *The Measles Epidemic: The Problems, Barriers and Recommendations*. Washington, DC: National Vaccine Program Office; 1991.
25. Atkinson W, Murphy L, Gantt J, Mayfield M, eds. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. 2nd ed. Atlanta, Ga: Dept of Health and Human Services, Centers for Disease Control and Prevention; 1995.

There's nothing really difficult if you only begin—some people contemplate a task until it looms so big, it seems impossible, but I just begin and it gets done somehow. There would be no coral islands if the first bug sat down and began to wonder how the job was to be done.

—John Shaw Billings (1838-1913)

Dr. KINSBOURNE. Thank you, Mr. Chairman. I am Marcel Kinsbourne. I am a neurologist with a special interest in children, and particularly in learning disability, attention deficit, and in developmental disability such as autism.

I have not had the good fortune of Dr. Katz to have any grandchildren, but all four of my children have been vaccinated. One is healthily present with us in this room today.

I would like to talk to you briefly about serious adverse effects of vaccination. Many are known. In some cases we don't know quite whether there are any, and some we have not yet identified.

Briefly, there are three types of vaccines that may cause three types of adverse reactions.

There are those that cause toxic or poisonous reactions. The whole cell pertussis vaccine is the best example of that. That poison may attack a child's brain within hours or a few days of the vaccination. That one issue has been subjected to adequate epidemiological study, unlike almost all the other issues that I will be mentioning.

A second way of being damaged by vaccine is when the vaccine is a live virus, attenuated virus particles made harmless, except not always so harmless, and occasionally the infection that is protected against in fact happens. Polio is an example of that.

Both bacterial and virus vaccines are apt in susceptible people to generate autoimmune disorders. These are disorders where the immune system of the person defends not only against the vaccine itself, but also, as it were, mistakenly against some crucial component of the person's own body, say the nervous system, causing damage which can be severe.

Incidentally, if there is a relation between the MMR vaccine and autism, this may be a mechanism for it to happen, and I totally agree with Mr. Rollens. There has been no approachingly adequate study of this possibility in this country to my knowledge, and I am unaware of any going on now.

It is easy to say do studies; studies are not easy, not at all straightforward. I would like to mention some reasons why that is.

One reason is that every disorder that a vaccine can cause other causes can also cause. So one has to distinguish the vaccine causation from coincidence. To do that, one has to study epidemiologically. These studies are expensive; they take a long time. Many have not been done. A report of the Institute of Medicine has stressed how often they could not draw conclusions about whether a particular alleged side effect was due to vaccine or not because the epidemiology has not yet been done.

The second point I would like to stress is that indeed some of these are rare complications. To study those, you have to have large populations. Most studies that have been done don't have adequately sized populations to investigate one way or the other whether a rare complication was due to the vaccine or not. That needs to be done.

The third point is that not all vaccine reactions happen immediately, as in pertussis. In the case of viruses and autoimmune disorders they may take weeks; they may take months to emerge. And most safety studies don't last for weeks and months. What we are

left with is passive monitoring which has major weaknesses, which had been alluded to and which we could discuss further.

Yet another problem is that you may have an acute reaction to a vaccine which, however, appears to get better, and the child appears to become normal again. Yet months or years or several years later the child shows cerebral palsy, a learning disability, attention deficit, autism, and the studies have not yet been done to determine whether these were late consequences of those early vaccine reactions or not, and they should be done.

Finally, in my list, and that has been mentioned already by, I think, Dr. Kennedy, vaccine safety tends to be established for individual vaccines, but they are nowadays increasingly often given in combination. That's a new administration, needs new safety studies all on their own, because there is no guarantee that the combined vaccine will only show the adverse effects that each individual constituent shows.

It's my opinion that if studies of the kind I've indicated were done and known to be done and perceived to have been done that this difficulty of balancing the public health against personal choice would be much mitigated.

I would like to briefly add to a point Dr. Kennedy made about informed consent. It is very difficult in a busy pediatric practice for the patient to get access to the doctor or the nurse, to ask proper questions, read the materials, understand them. I would suggest that the information be given to the families well ahead, maybe even when the baby is discharged from the hospital at birth, so they have time to study the materials and ask their questions before they bring the children to the vaccination.

A brief point, sir, has to do with the compensation program. As you very well know, the Congress meant this program to be expeditious, to be generous, and to be non-adversarial. I have extensive experience as a witness in these programs, and I find them not to be any of those things. I have to say that the special masters who are in charge of adjudicating these matters are, in my opinion, highly competent, compassionate, and courteous.

Nonetheless, it is a lucky person who actually gets their case resolved in 2 years, as was mentioned before. I have many cases in my files that have been around for many more years than that, and to my mind the proceedings are nowadays much more like civil litigation in their rigor than they are in any sense not nonadversarial.

It has also been mentioned that in 1995 there was a change in the regulations relative to the most important, often complained of, vaccine, the pertussis vaccine, making compensation for alleged injury by that vaccine virtually impossible to secure. I think that deserves reviewing.

A final point, sir, is I heard mention of what is called a surplus in the moneys available to compensate victims. I am perplexed at this, because I know that there are many children whose cases are still being adjudicated and many more whose petitions have not yet been filed. They will be filed. And I don't know how anybody could tell that the available moneys are too great relative to the needs of those children.

Thank you very much.

[The prepared statement of Dr. Kinsbourne follows:]

Presentation to the Committee on Government Reform
Topic: Vaccines: Finding a Balance between Public Safety and Personal Choice
Marcel Kinsbourne, M.D.
August 3, 1999

The remarks that follow are based upon my training and experience as a pediatric neurologist and my familiarity with the scientific method, as well as my participation as a medical expert in proceedings that evaluate alleged vaccine injury under the terms of the National Vaccine Injury Compensation Act.

Types of Vaccine Injury

Offsetting their undoubted public health benefits, vaccinations incur the risk of a range of adverse side effects, some of which rarely cause long lasting or even permanent impairment of health. Depending upon the nature of the vaccine, major side effects fall into three categories, as follows:

Toxic: Killed bacteria may release toxins as their cell bodies break up. An example is pertussis vaccine, which contains at least one substance that can be poisonous to brain cells. When the toxin injures the brain, this occurs anywhere from a few hours to a few days after the vaccination.

Infectious: A vaccine that consists of attenuated virus particles may cause the very infection that it was intended to prevent. An example is oral polio vaccine. The infection presents after an incubation period of a number of days during which the virus multiplies. The virus may even remain latent in cells of the body for much longer periods of time, and then cause disease.

Autoimmune: The body responds to the vaccine with an immune reaction that attacks its components. Sometimes the immune reaction also attacks a constituent of the body itself, which bears some chemical resemblance to a constituent of the vaccine. Reports of cases in which nerve cells have been attacked have been published for tetanus, influenza and measles vaccines. The "self-attack" is the result of a cascade of biochemical changes which takes at least five days to cause clinically observable disease, and may take at least up to six weeks.

In view of these hazards, safety precautions are called for. This task is not straightforward, for reasons such as the following:

Factors that Complicate Safety Precautions

1. Any disease that can be caused by a vaccine can also be caused by other agents. To help distinguish causation from chance association, epidemiological studies are often required. These studies are typically time-consuming and resource-intensive. Many potential adverse effects of vaccines have not been systematically studied with the

methods of epidemiology. The inventory of side effects of vaccines remains incomplete.

2. Common adverse side effects are likely to be detected during pre-marketing clinical trials. Rare side effects would most likely be overlooked, given the modest number of participants that is customary in clinical trials.

3. Not all adverse effects occur within days or a few weeks of vaccination. Autoimmune disorders may take a month or two to emerge. Virus particles may even remain latent for lengthy periods of months or years, before they begin to trigger diagnosable disease. An example of a combination of vaccines that can cause an autoimmune disorder is MMR (measles-mumps-rubella). Another example may be Hepatitis B vaccine.

4. Even when an injury occurs soon after a vaccination, this may not immediately be noticeable. This applies generally to injuries of the developing nervous system, regardless of the cause. Such neurological syndromes as cerebral palsy and developmental language disorder may come to light months or years after the brain damage was inflicted. The effects of severe injury may take years to show up, for example as learning and attention problems.

5. When several vaccines are given at the same time, they may have adverse effects that none of the individual vaccines have when they are given by themselves. Giving many vaccines at the same time is becoming increasingly prevalent, especially to "captive audiences" like infants. A possible example is measles and mumps vaccines as administered simultaneously in MMR. There is reason to suspect that this combination may cause inflammatory bowel disease and developmental regression into an autistic state in some children in the second year of life.

Post-Marketing Monitoring

The implications of points 1 through 5 are that, at the very least, after vaccines come on the market, they should be monitored comprehensively and for long periods of time. In many instances, particularly for vaccines that have been newly introduced, large-scale prospective epidemiological studies are required. The ongoing passive post-marketing surveillance (VAERS) has shortcomings. Pertussis vaccine illustrates this point.

Whether an adverse event that immediately follows DPT vaccination is reported depends on pediatricians' quite variable levels of awareness of, and index of suspicion for, such events. The ability of agency personnel to evaluate the adverse effects that are drawn to their attention can also be unreliable. It is well known that some lots of pertussis vaccine are associated with a disproportionately high number of notifications of adverse events. These are termed "hot lots". However, the manufacturer is protected by law from disclosing the number of doses that derive from a given lot. Therefore, one lacks the denominator of the function which would reveal whether a given lot appears "hot" because it is more toxic, or because it is the source of more doses. Be that as it may, hot

lots offer the possibility of danger to children. Nonetheless, I have never heard that a hot lot has been ordered withdrawn on the basis of VAERS surveillance.

Since different lots of DPT vaccine vary greatly in the concentration of bacteria per unit volume, and therefore in the amount of potential toxin they contain, even when they are produced by the same manufacturer, research to determine whether hot lots contain relatively high levels of bacteria and toxins would seem important. A chemical/bacteriological study that compares hot lots with standard lots seems indicated.

We anticipate that the newly licensed acellular pertussis vaccine will cause far fewer serious adverse neurological reactions, but we do not yet know this for certain. In any case, many children still receive the whole cell pertussis vaccine, with its cargo of potentially harmful endotoxin.

Studies of vaccine safety could be supported by initiatives of the National Institutes of Health, with specially earmarked funds. Requests for applications for research funding could be issued, and the applications be subjected to the customary NIH peer review process.

Informed Consent

The remote but real risk of serious disease that attends vaccinations must be scrupulously and comprehensively disclosed to the parents of the children that await vaccination. In a busy pediatric practice this is not an easy matter, and not all parents readily understand what some of the risks actually entail. It would be helpful if the CDC were to develop handouts that are both comprehensive and user-friendly, that list possible adverse side effects for each vaccine. These handouts should include information about what health and behavior changes parents should be alert for after the vaccination. I suggest that parents be given copies of such handouts for each vaccine well ahead of the projected date of vaccination, so that they have sufficient time to digest the information, and to ask any questions they might have. This might perhaps even be done before their newborn is discharged from the hospital.

Personal Choice

Immunization programs most effectively serve the public health if most members of the target population participate. Nonetheless, personal choice is a civil liberty that must be respected.

The estimates of risk offered by medical authorities often diverge greatly from those assumed by some members of the community. It may never be possible to reconcile these entirely. However, I believe that almost all parents would favor having their children vaccinated if more research on risk factors had visibly been performed. This includes not only identifying adverse events that might happen, but also detecting any predisposition that children in particular families might have that increase such risks.

A genuine and vigorous effort to identify risk factors would help dissipate the impression that some citizens have formed that vaccine safety is not a high priority. The Institute of Medicine (1997) publication, "Vaccine Safety Forum", presents some promising suggestions for risk factor research, particularly for those effects that arise from autoimmune reactions.

Compensation for Vaccine Injury

Congress has mandated a compensation program to meet the needs of children who were injured by a set of required vaccines. Congress made it clear that this program was to be both generous and expeditious, but in my experience as a medical expert in many such proceedings, I have found that this has not usually been the case. Although the Special Masters who adjudicate the Petitions for Compensation are generally both highly competent and compassionate, the proceedings in numerous cases extend over many years. This foils the intent of Congress that the proceedings be non-adversarial and leaves even those families whose claims are ultimately judged to have merit, unassisted and often in severe financial straits. The financial burden of raising a handicapped child can be severe. It also burdens the law firms that assist Petitioners with expenses that are not met for up to a decade. This has a chilling effect on the participation of attorneys in the Vaccine Injury Compensation Program, and thereby limits the choice of citizens who wish to file petitions. Also, a series of Rule changes as of 1995 has so severely constricted the definition of Table Injury (an injury presumed by the statute to have been caused by the vaccine) in the case of pertussis vaccine (the vaccine that is complained of in the great majority of petitions), that those who nowadays file for compensation must anticipate a lengthy, complex and arduous proceedings with uncertain outcome.

Statute of Limitations

Compensation for injuries due to Hepatitis B vaccine has recently been authorized, retrospective to 1990. The Statute of Limitations for claims in regard to injuries that occurred more than three years ago takes effect this Friday, August 6th. Efforts to publicize this fact appear to have been less than enthusiastic. Unnotified citizens who feel that they or their children were injured by this vaccine between 1990 and 1996 will soon be without remedy. An outcome so clearly counter to the spirit of the National Vaccine Injury Compensation Act might be of interest to the Committee on Government Reform.

Mr. BURTON. Thank you, Dr. Kinsbourne.

Dr. Kennedy, you said you submitted an application to NIH for a research grant on the hepatitis B vaccine; is that correct?

Dr. KENNEDY. Yes. Myself and a number of other colleagues.

Mr. BURTON. You have had grants before? You have done research before?

Dr. KENNEDY. Yes, since 1984. In fact I had the early grants on looking at the immune response to the plasma-derived hepatitis B surface antigen.

Mr. BURTON. Did they give any reason why they turned your grant request down?

Dr. KENNEDY. Yes. Essentially that it was—the term "fishing expedition" means that you have a big juicy worm and you are throwing it out there and hoping that someone will bite on it.

Mr. BURTON. Do you still have a copy of that grant application?

Dr. KENNEDY. Yes. I can provide that.

Mr. BURTON. Can you give me a copy of it?

Dr. KENNEDY. Certainly can.

Mr. BURTON. I would like to have a copy as soon as possible.

Dr. KENNEDY. We did two additional revisions on the grant through the process.

Mr. BURTON. I want to take a close look at it, if I could.

Dr. KENNEDY. OK.

Mr. BURTON. Maybe we will have a hearing on that grant application itself and haul the people in here.

Dr. KENNEDY. I would rather you not. The process of NIH does work, but I think the problem is the understanding of——

Mr. BURTON. Wait just a minute. You say the process does work. How long ago did you submit this grant application?

Dr. KENNEDY. 1997. And how we are supporting our present efforts to address these issues relative to adverse reactions are kind of through private funds.

Mr. BURTON. I don't mean to interrupt you, but my granddaughter almost died. While your grant application sits there, how many other adverse reactions have occurred like that and how many other parents may have lost their child like the lady that was sitting over there? I think something as important as that should get timely review. So I would like to see your application. You let me worry about what to do with it, OK?

Dr. KENNEDY. OK.

Mr. BURTON. Dr. Katz, have you had any kids suffer adverse reactions?

Dr. KATZ. Yes.

Mr. BURTON. What kind?

Dr. KATZ. I've had a youngster whose arm got so swollen it ran from his wrist up to his shoulder. I've had children who have developed what apparently were febrile seizures. That is, they got such high fevers that they had a seizure following a previous immunization.

Mr. BURTON. Do you have any that were autistic?

Dr. KATZ. No. I happen to work in an institution with a neurologist whose life work has been on autism, and he has presented us as well as published in the neurology literature, some as recently

as June 1999, his approach to autism, and it has nothing to do with vaccines.

Mr. BURTON. I'm sure. The question that I would like to ask is the pertussis vaccine that they were talking about a while ago. If you thought that it caused autism in some children, would you give it to your grandchildren?

Dr. KATZ. I think that if I believed it caused autism, I would have severe reservations. I agree with you.

Mr. BURTON. That's all I want to know, because there are a lot of people that believe that it does, and I'm one of them. Do you think that people that feel there is a real risk to their loved ones should give that kind of a vaccination or be required to do it?

Dr. KATZ. I don't believe that you should labor under the burden of saying I really believe this and I don't want my child to be immunized. I think you have to accept the fact, however, that if your child goes to school or to day care, for example, and there is a case of whooping cough in the school, your child would be banned from school because they are not immunized.

Mr. BURTON. Let me ask Dr. Kennedy a question. What did you say was the percentage of reactions to the pertussis vaccine within the first 48 hours?

Dr. KENNEDY. It was within the first 72 hours. Approaching 50 percent.

Mr. BURTON. Fifty percent. Just a second. Fifty percent would have an adverse reaction within the first 72 hours?

Dr. KENNEDY. I will provide you with the documentation that quotes that.

Mr. BURTON. In many cases that is not of long duration.

Dr. KENNEDY. Right. Correct.

Mr. BURTON. It is something that comes and goes.

Do you have any percentages that show the adverse reaction that is of long duration?

Dr. KENNEDY. No, I don't.

Mr. BURTON. So we really don't know. You know that there is an adverse reaction that is pretty substantial within the first 72 hours in half of the cases where they give those shots.

Dr. KATZ. We haven't used that vaccine for several years, Mr. Burton. I think one of the things that I would love to point out to you is that we do improve. We use the acellular vaccine in this country. The British continue to use the vaccine that Dr. Kennedy has described. We haven't used it for several years in this country.

Mr. BURTON. Is the DTP vaccine rather than the DTaP vaccine still being used?

Dr. KATZ. The DTaP vaccine is being used, which has an infinitesimal degree of reactivity compared to the DTP.

Mr. BURTON. The Department is behind you. Is the DTP vaccine still being used in this country?

Mr. EGAN. Yes.

Mr. BURTON. It's still being used in this country. So, Dr. Katz, you are incorrect. It is being used in this country.

Dr. KATZ. If it is, it's in a very small percentage.

Mr. BURTON. It doesn't matter if it's your kid or your grandchild. If they get a DTP vaccine and there is this adverse reaction that Dr. Kennedy is talking about, it's of great concern to people, and

we don't know whether it leads to autism or not, but I have an autistic grandchild, and we've had a number of other people that have seen tremendous problems with autism, and they are still using that vaccine. You said you didn't think they were.

Dr. KATZ. I said they are still using it in the United Kingdom. They don't use acellular pertussis vaccine.

Mr. BURTON. That's the United Kingdom. It's not the United States of America.

Dr. KATZ. The World Health Organization is using it throughout the world. We are the only country with the exception of Japan that made the switch.

Mr. BURTON. I know, but if it's causing adverse reactions that are so severe that they affect people in the first 72 hours, 50 percent of them, it should be something that is clearly looked into, and if there is any indication it may cause autism, it should be really scrutinized.

Let me yield to the doctor here, and I will come back for some more questions in a moment.

Mr. WELDON. Maybe our friends in the back can answer. I thought we withdrew all the DPT, the cellular pertussis in the United States. It is still licensed and it is still sold in the United States; is that correct?

Mr. EGAN. Yes.

Mr. WELDON. The FDA has never ordered that to be withdrawn? Why was it not ordered to be withdrawn considering the higher incidence of side effects? They felt that the side effects were not sufficiently life-threatening to warrant it's withdrawal? Is that the rationale?

For the record, Mr. Chairman, this pertussis issue is something that I followed through the years, and I thought it was completely off the market. That may be something that we may need to address.

If I may just go a little bit further. Dr. Kinsbourne, I really enjoyed your testimony. You seem to get at a lot of the problems. Some of the issues that you brought up I've had conversations with other scientists and some of the folks that have already testified. The real bottom line issue is that there would have to be very significant funding to get at these issues, because it would require some very large studies that would have to be extended over many, many years, correct?

Dr. KINSBOURNE. Yes, sir.

Mr. WELDON. Unless those studies are done, the questions that you were posing are very difficult for us to answer, correct?

Dr. KINSBOURNE. Could not be answered until they are done. So the sooner they are started the sooner they will be answered.

Mr. WELDON. The only other point I would like to make, Mr. Chairman, is that if these studies are done, they may show that the vaccines are much safer than is being alleged by some of the people who have provided testimony. Until they are done, the public discontent that exists among some element in our country is not going to go away, and it would be a mistake for us to just take the face value of some who have testified alluding to the fact that all is well. All may not be well, and the responsibility ultimately is

going to fall to political leaders in this country to make sure that the proper research is done.

I again want to thank you, Mr. Chairman, for holding these hearings.

Mr. BURTON. Thank you, doctor.

Mr. WELDON. Did you want to respond to my comments at all?

Dr. KINSBOURNE. Only to agree wholeheartedly. I think even if the public were to see that the work was being done they would comply more willingly with the mandates.

Mr. WELDON. I will share this with you, Dr. Katz. In politics they say perception is reality. If your opponent buys $500,000 worth of TV ads and says that you cheated on your wife even though you have never cheated on your wife, if the end result is that three out of four voters conclude that you cheated on your wife and therefore they should vote against you and you lose your reelection, that is reality. Even if our vaccines are extremely safe, if the perception is growing out there that the vaccines are not safe and people are starting to refuse their vaccinations, then we've got a problem. The way to address this, though, is we need to better fund the agencies that need to do the research.

Mr. BURTON. I think that is a very good point, doctor.

Who manufactures the DTP vaccine?

Dr. KINSBOURNE. Lederle.

Dr. KENNEDY. Wyeth Lederle Pediatric Vaccines it is now called.

Mr. BURTON. Is that the only one that manufactures that?

Dr. KENNEDY. No. There are a couple others that make the whole cell pertussis. I don't know it off the top of my head.

Dr. KINSBOURNE. Connaught is another company.

Mr. BURTON. Those are both domestic companies here in the United States?

Dr. KINSBOURNE. I think Connaught is largely Canadian.

Dr. KENNEDY. It's Pasteur Merieux Connaught, but they have a manufacturing facility in the United States, in Pennsylvania.

Mr. BURTON. You may not know this. I may have to check into this in a later hearing or something. Do you know if they give any funds or grants or honorariums to anybody over at NIH or CDC?

Dr. KATZ. No.

Mr. BURTON. They do not?

Dr. KATZ. No.

Mr. BURTON. You're sure about that?

Dr. KATZ. I am sure that people at NIH are not allowed to take funds even from universities. If I invite an NIH investigator to give a lecture at Duke, I can't even pay him an honorarium.

Mr. BURTON. According to my assistant here, that isn't the case.

Dr. KATZ. Maybe you could ask Dr. Rabinovich. She works at NIH.

Mr. BURTON. They can accept honorariums, I believe. Can't you?

Dr. KATZ. Regina, do you want to respond?

Mr. BURTON. Aren't you the general counsel?

Dr. RABINOVICH. No. I'm here from the National Institutes of Health. We do receive ethics training, and I've never accepted an honorarium. There may be other situations in which intramural investigators can. We can provide that information for you.

Mr. BURTON. I'd like to have that.

Dr. RABINOVICH. But I do not.

Mr. BURTON. Thank you. I would like to have that information if I could.

I just can't for the life of me fathom why that one vaccine is still on the market and being manufactured and sold here and used in the United States. I just don't understand that.

Can you explain that, Dr. Kennedy?

Dr. KENNEDY. I can maybe address the situation relative to the issue of combination vaccines and why it may still be there. There were studies done where they were combining the DTaP vaccine with the haemophilus influenza type B glyco-conjugate vaccine, and a number of studies, both in non-human primate models and in children, suggested that by combining and then giving it at a single site that you would interfere with the ability to respond to the haemophilus influenza type B [HIB] component, and the interference appeared to be as a result of the acellular components.

They do not know the mechanism. They knew if they took out the acellular component and did a DT/HIB combination, it went fine. If they did the DTaP at one site and then the HIB at the other site, the response was fine. If they did the DTP/HIB, it appeared to be fine from a standpoint of responding to all four of the components.

That could be one of the potential reasons, because some of the first licensed combination vaccines are DTP/HIB, et cetera. It doesn't make sense, but that's——

Mr. BURTON. I'm not sure I comprehend if there is that kind of a reaction in 50 percent of the cases in the first 72 hours why it's on the market. I just do not understand that.

Do you have any reason why that would be the case, why they would keep that on the market and continue to use it?

Dr. KENNEDY. Yes. If people are not complaining, you can make quite a bit of money. What it comes down to the vaccine manufacturers, it's money if the vaccine has already been produced; its already licensed.

Mr. BURTON. I know, but the people sitting behind you are not influenced by these pharmaceutical companies. I'm sure of that. So why would they not insist that it be taken off the market?

Dr. KATZ. This vaccine has been used for 40 years in this country and its record of achievement has been a very successful one. What he is describing as 50 percent is sore arms, sore legs, redness, fever. It's not life-threatening reactions. It is more reactive than the acellular vaccine, which is why most people have switched to the acellular vaccine, but these are not life-threatening reactions that have been shown with the whole cell pertussis to be any more than with any other acellular pertussis.

Mr. BURTON. These are FDA serious events in 1999. How many are in here, 1,500 or more?

Dr. Kennedy, of these 50 percent of the reactions were any of them pretty severe?

Dr. KENNEDY. Yes. Quite a few were more severe, such as the high pitched screaming, the crying, the fever, the shock-like syndrome.

Mr. BURTON. Running around and waving their arms and that sort of thing?

Dr. KENNEDY. Yes, but the percentage I could not find.

Mr. BURTON. I will tell you that is exactly what happened to my grandson. Exactly. He ran around waving his arms, a high pitched scream, waving his arms up and down, and everything else, and he's autistic now.

I'm getting a little emotional about this. I think we will conclude this hearing. But I want to tell you, this isn't the end of it.

We stand adjourned.

[Whereupon at 7:30 p.m., the committee was adjourned.]

[Additional information submitted for the hearing record follows:]

JOHN M. McHUGH
24TH DISTRICT, NEW YORK

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REGULATORY REFORM CAUCUS

August 3, 1999

The Honorable Dan Burton
Chairman
Committee On Government Reform and Oversight
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

I would appreciate your assistance in placing the enclosed materials I received from Geoffrey G. Peterson, Director of Government Affairs and Public Policy for Pasteur Merieux Connaught, in the record for today's hearing "Vaccines: Finding the Balance Between Public Safety and Personal Choice."

While I am not in a position to judge the accuracy of this information, I believe their views and concerns should be available in the formal record in the interest of a full examination of the facts surrounding vaccines.

Thank you for your assistance.

Sincerely yours,

John M. McHugh
Member of Congress

JMM/jmb
Enclosures

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Basic Facts about Vaccines

Q. How do vaccines work?

A. Vaccines are composed of mixtures of complex compounds such as proteins taken from viruses and bacteria — the same microorganisms that cause diseases such as mumps, measles, and polio. During the manufacturing of vaccines, these microorganisms are either killed, weakened, or inactivated, or compounds are derived from them. These altered microorganisms or derived biological materials are then incorporated into a stable formulation that can be safely injected into the human body. When injected, this vaccine acts as a stimulant for the body's immune system. The immune system responds to the vaccine with antibodies, thus protecting the body from future invasions of the microorganism. For example, subsequent exposure to polio virus for a person with the polio antibody in their blood would lead to rapid elimination of the virus and no debilitating disease.

Q. How are vaccines developed and approved?

A. The first step to licensing a new vaccine is safety testing on animals. If the animals' cells are not damaged by the vaccine, the vaccine is then tested on people. Prior to the initiation of human trials, the FDA may bring in an advisory committee to review the proposed studies. These experts are frequently involved throughout the trials and the FDA review. Human clinical trials for vaccines typically include several hundred to several thousand patients. All trials are aimed at evaluating safety and efficacy.

In order to produce a product for use in the U.S., manufacturers must receive a license for the vaccine (a product license) and one for the manufacturing plant (an establishment license). Following licensure by the FDA, manufacturers must submit samples of each vaccine lot, along with the results of the manufacturer's tests of potency, safety and purity, to the agency prior to release. Each lot must be tested because of the sensitivity of vaccines to environmental factors and the possibility of contamination.

Q. Do vaccines cause, rather than prevent, disease?

A. FDA-approved vaccines have greatly decreased the occurrence of mumps, measles, polio, rubella, pertussis, diptheria, tetanus, Hib disease, Hepatitis B, and Varicella (chicken pox). Serious reactions to vaccines are extremely rare, but do occur. Although clinical trials are carefully designed to uncover potential adverse reactions prior to FDA approval, it is impossible to gather all information pre-approval. Side effects that occur in one patient per 100,000 or one million patients would be difficult to detect in a clinical trial, since no trial can possibly include one

million patients. However, the risks of mental retardation, blindness, deafness, or debilitation that occur without vaccines are much greater than the risk posed by vaccines.

Q: Are there any safe, effective alternatives to vaccines for preventing these diseases?

A. Vaccines have been proven over the years to be one of the safest, most effective disease-prevention tools available. Pharmaceutical manufacturers conduct years of clinical trials prior to submitting a new vaccine to the FDA for approval. The granting of FDA approval only occurs after an exhaustive review of the trial results. There is no known "cure" or "prevention" for these diseases that is as safe and effective as vaccines.

Vaccines are largely responsible for eradicating many diseases that were once feared. For example, there were no cases of diphtheria or wild-virus polio reported in the United States in 1995. In less than 30 years, the number of cases of mumps has fallen from 55.5 cases to 0.35 cases per 100,000 people. Since 1950, the number of cases of pertussis (whooping cough) has fallen by 97 percent. Similar, equally large, decreases have occurred for measles and rubella.

Vaccines in development show promise against diseases as diverse as AIDS, ear infections, and sexually transmitted disease.

Q. How effective is the extensive approval and review process required by the FDA prior to release of vaccines to health care provider?

A. Tests done on vaccine lots prior to release include tests for sterility, safety, purity, identity, and potency. Vaccines made from disease-causing organisms must be tested for the presence of living, viable organisms. Acceptable standards of purity must be met for all inactive ingredients used in the vaccine. In the last 10 years, there have been only three vaccine recalls out of thousands of vaccine lots released. One lot was recalled after the FDA detected particulates in the product; another was mislabeled. The third lot was recalled because of potential problems with good manufacturing practices following an FDA inspection of the licensed plant.

Q. What is thimerosal, and what is its danger?

A. Thimerosal is a mercury-containing preservative that has been used in vaccines since the 1940s. Because of its effectiveness in preventing contamination of vaccines by bacteria, thimerosal is the most widely used vaccine preservative — the FDA estimates it is used in more than 30 licensed vaccines and biologics. FDA guidelines govern the inclusion of thimerosal in vaccines, and no vaccine available

in the U.S. contains more than the level approved by the FDA. At very high levels, mercury can cause neurological damage in children. To date, there is no clinical evidence of harm from thimerosal in vaccines. The known dangers of childhood diseases far outweigh the potential harm of small doses of mercury.

Q. Is there an alternative to thimerosal?

A. The vaccine industry is working closely with the FDA to eliminate thimerosal from vaccines whenever possible. However, vaccines are closely regulated by the FDA — any modification to the chemical formula must be approved. New products that do not contain thimerosal will be available as soon as vaccine manufacturers can develop and acquire FDA approval for a thimerosal-free or thimerosal-reduced product. In the meantime, the minimal risks of mercury should not be the cause of children missing scheduled vaccines.

MANUFACTURER PRACTICES AND FDA REGULATION PROMOTE VACCINE SAFETY

The extensive FDA review and approval process for vaccines assures patients of a safe and effective product. Vaccines are potent compounds carefully researched and developed to prevent life-threatening diseases. Vaccine manufacturers and the FDA take very seriously their responsibility to make these products as safe and effective as possible.

Several rounds of clinical trials are completed under FDA guidance in order to assess a vaccine's safety and effectiveness.

- Prior to testing vaccines in humans, the compound is tested in animals to ascertain any severe negative effects.
- After a review of animal results by the company and possibly the FDA, the manufacturer initiates human clinical trials.
- Phase I trials evaluate basic safety and are intended to identify only very serious or common adverse effects.
- Phase II trials include hundreds of patients, and can last from several months to two years. Safety information and preliminary effectiveness information is collected during Phase II.
- Phase III trials occur as long as Phase II has not resulted in severe reactions or a lack of effectiveness. Phase III trials, which measure both safety and efficacy, can include several thousand people.

The safety and efficacy of vaccines must be proven to the FDA and its Vaccine Advisory Committees prior to licensure of the vaccine.

- Once clinical trials demonstrate safety and efficacy, the manufacturer must apply to the FDA for two licenses — one for the vaccine (product license) and one for the manufacturing plant (establishment license).
- The FDA reviews the manufacturer's clinical data and manufacturing protocols that ensure a consistent product, as well as the results of the agency's own confirmatory tests.
- FDA Advisory Committees (groups of non-government vaccine experts) assist in the FDA review. This is just one indicator of the heightened scrutiny given these products pre-approval.

- Prior to licensure of either the product or the facility, the FDA must inspect the plant to ensure that current Good Manufacturing Practices (GMPs) are being utilized in the facility.

FDA oversight of vaccine manufacturing does not end following product approval.

- The FDA requires manufacturers to submit a sample of each vaccine lot to ensure product purity, potency, and safety. The results of manufacturer tests of the lot must be submitted for FDA review at the same time.

- If a problem is suspected, the FDA may choose to test any or all lots submitted by a manufacturer or the lots for a particular product.

- Ongoing studies are voluntarily undertaken by manufacturers in an attempt to identify adverse effects so rare (e.g., one in one million) that they cannot be detected in clinical trials.

- For most approved vaccines, manufacturers, the FDA, and the Centers for Disease Control and Prevention (CDC) rely on the Vaccine Adverse Event Reporting System (VAERS) to identify problems that occur post-marketing.

Prescription medicines, especially vaccines, provide incalculable health benefits in helping people live longer, healthier, and more productive lives.

SAFETY FIRST, LAST AND FOREMOST
The Development of Modern Vaccines in America

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies. PhRMA member companies are developing new and better vaccines, including combination vaccines that incorporate more antigens and reduce the number of doses needed to immunize patients effectively.

Vaccines are among the miracles of modern medicine. Diseases that once hospitalized, disabled or led to the death of thousands of Americans each year — like smallpox and polio — no longer threaten Americans, while others — like diphtheria, measles, mumps, rubella, and *haemophilus influenzae* type B (hib) invasive disease — have been all but eliminated thanks to the preventive power of vaccines. In an era where governments worldwide seek positive solutions to rising health care costs, vaccines are among the proven options: the cost effectiveness of immunization is well established, with the potential to produce many millions of dollars in direct and indirect savings through disease prevention.

Only immunization programs that maintain the public's confidence in vaccines can prevent the potentially devastating recurrence of disease. Thus vaccines must be extraordinarily safe and the risks associated with any vaccine used in our national immunization program must be minimal. For this reason, safety is the most consistent priority in every stage of research, discovery, manufacturing, and distribution of vaccines in the United States. And the continued

improvement and assurance of vaccine safety is as much a research priority for America's vaccine manufacturers as the discovery and development of new vaccines.

RISKS VERSUS BENEFITS

Vaccines are the most heavily regulated, most extensively tested of any product under the jurisdiction of the Food and Drug Administration (FDA) and are as safe as current science can achieve.

Even so, it is important to understand that safety cannot be absolutely guaranteed. As defined by the relevant Code of Federal Regulations, safety is the "relative freedom from harmful effect to the persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time." (21 CFR 600.3 (p))

But given the complex and sophisticated process in place for validating the safety of vaccines licensed in the U.S., severe adverse experiences temporally associated with the administration of a vaccine are extremely rare. Such events are reported to occur at a frequency of less than one per million doses of vaccine administered (National Institutes of Health: *Task Force on Safe Childhood Vaccines*; 1998, pg. 23). To put this number in perspective, if the entire populations of Indianapolis, Fort Wayne and Gary, Indiana, were vaccinated, there would be only one reported adverse experience.

EARLY RESEARCH AND DEVELOPMENT

For America's vaccine companies, safety begins with the high caliber scientists who conduct the research and oversee the development process. A typical curriculum vitae for a

vaccine researcher would include a Ph.D. or M.D, multiple years of post doctoral study; a stint at the National Institutes of Health, a biotech company, or the Centers for Disease Control and Prevention.; and 10 - 20 years of hands-on experience in epidemiology and/or a state-of-the art research setting.

From test tube to syringe, as many as 300 scientists and technicians may be involved in bringing a new vaccine to market. They approach the challenge first on a strictly intellectual basis: what do we know about this disease and its pathology; what do we know from the fields of microbiology, immunology and chemistry that would have implications for developing a vaccine that is the safest, most reproducible, most medically effective way to prevent this disease.

The research and development process begins with the production of small batches of vaccine, which are tested extensively in the laboratory — and in animals, where indicated. The objectives at this stage of testing are to validate the product's immunologic properties (does it work) and uncover any reactogenicity or toxicity (can it harm). Modifications in the vaccine may be made to increase effectiveness and safety. On average, more than 4 - 5 years is invested in this stage of research.

If early laboratory studies appear promising, the manufacturer will apply for permission to begin testing in humans by submitting an application to the FDA under the Investigational New Drug (IND Application process. Integral to the IND process are frequent, and closely monitored, safety check points. Before a trial can begin, for example: 1) the test protocol most be described in detail; 2) all preclinical data must be submitted; 3) an institutional review board (IRB) must certify that there are appropriate safeguards for humans in the trial; 4) the credentials

of trial investigators must be provided; and 5) the new vaccine must pass the same kind of release testing as an already manufactured vaccine.

CLINICAL TRIALS

Once the FDA approves an application, the vaccine moves into **Phase 1 clinical trials.** At this stage, a very small number (20-80) of healthy, immune adult volunteers who are highly informed about any potential risks, are studied to evaluate basic safety and identify any serious or common adverse experiences. These trials last several months. If the safety data collected from this trial indicates no untoward risk, the vaccine can move into **Phase 2 clinical trials.**

For a vaccine intended for pediatric use, Phase 2 trials involve several hundred children and can last several years. Measuring safety and effectiveness — including proper dosing — are the primary objectives at this stage of evaluation. Unless severe reactions or a lack of effectiveness surface during these first two stages, the IND process moves the vaccine into Phase 3 trials, involving several thousand children.

All phases of these clinical trials are closely monitored by the FDA and the manufacturer. As important, the parents of children involved in the trials are fully informed about any potential risks and well educated on daily monitoring of a child who has received the vaccine.

Phase 3 clinical trials not only confirm safety and effectiveness, but test the manufacturer's ability to produce larger quantities of the vaccine in consistently acceptable lots. Information about potential risks to certain individuals, based on sound medical and scientific principles, also is gathered and evaluated at this stage in the vaccines development. Studies are

done as well to establish how the new vaccine would react with others that might be administered concurrently.

At any point along the process of safety and efficacy testing in clinical trials, the FDA may decide to involve a group of outside experts known as an Advisory Committee in the review of data and issues associated with the vaccine.

Although Phase 2 and Phase 3 clinical trials are useful in estimating the incidence of minor, common adverse reactions (such as fever), there are a number of challenges to determine the likelihood of severe, life-threatening events. Assume, for example, that through postmarketing surveillance, a certain severe condition is observed in 1 in 100,000 vaccinated children. The safety issue is whether that condition is a direct result of vaccination, or caused by other stimuli. The sample size needed for a simple, randomized clinical trial to statistically demonstrate the difference between vaccinated and unvaccinated children for this condition would be a logistically prohibitive 9.5 million subjects. (National Institutes of Health: *ibid*; pg. 24)

Such observations turning up in postmarketing surveillance may need to be further studied by case control or other prospective methodology to sort out whether a causal relationship with a vaccine exists.

LICENSURE

Obtaining a license to manufacture and market a vaccine in the U.S. involves several steps beyond successful completion of clinical trials. Not only must the product itself be reviewed and approved by the FDA for safety and efficacy, but the facility in which the vaccine will be made also must be approved.

Of primary concern for plant licensure is the demonstrated ability to manufacture bulk vaccine consistently, repeatedly matching the clinical trial results for safety and efficacy. For the company, this process begins with screening and auditing the vendors that supply the raw materials. The company must prove the ability to consistently meet current Good Manufacturing Practices (cGMPs) — federally mandated regulations which define, in detail, process, control, documentation, testing and facility requirements. In producing bulk vaccine, 10 - 20 percent of the process is the actual manufacturing; the rest of the effort is in testing, retesting, and validation of test results to assure consistent safety and efficacy.

Data required for licensure of a single new vaccine and plant, if stacked, could equal twice the height of the World Trade Center. FDA reviews and evaluates the data, using a panel of internal scientific experts--and outside experts, as needed; conducts its own testing of vaccine lots; reviews and revises the proposed labeling, as appropriate; and completes an inspection of the production facility. If all data are complete and demonstrate that the product is safe and effective, licenses are issued and the company may begin to market the vaccine.

At this point, the FDA may also ask the company to conduct postmarketing or Phase 4 studies and submit them for review. Phase 4 studies might focus on use of a vaccine with other vaccines, or adverse event associations.

SAFETY CHECKS IN THE MARKETPLACE

Once a vaccine is approved for distribution, safety remains a shared responsibility of the company and the FDA. On it's part, the FDA safety-tests lots of vaccine before they can be distributed. All lots must meet test procedures that were approved at the time of product

licensure. Tests include those for bacterial and fungal sterility, general safety, purity and stability. Cell-culture derived vaccines must be tested for disease-causing organisms. All ingredients, including diluents, preservatives, or adjuvants, must meet generally accepted standards of purity.

In the vaccine business, there are no "seconds." Any product that does not meet the prerelease requirements never makes it to any market. **[While a system is in place to recall a lot if problems are reported, to date, no lots have required a recall based on concerns directly related to safety.]** (Partnerships for Prevention: *Congressional Briefing Package*; "What you may have heard about vaccines ... and what you should know." 1997)

At least biannually, FDA investigators inspect production facilities and the Agency periodically reviews and updates GMPs to reflection state-of-the-art technology and science. Any change in the manufacturing process, whether initiated by a company or recommended by the FDA, requires prior approval by the FDA.

For the vaccine manufacturer, given the logistical limitations of clinical trials, information about rare, delayed or population-specific adverse reactions can be gathered only post-license, when the vaccine is more widely used. Post-licensing safety activities include ongoing lot testing and validation, Phase 4 studies, and collection and analysis of reported adverse events.

A SHARED COMMITMENT

America's vaccine companies, along with the FDA and government, share a commitment to the highest measure of safety in our vaccines. And we're always looking for ways to make them safer, based on new medical and scientific information and improved technology. We've

seen the powerful, positive impact that safe and effective vaccines have had on our Nation's health and welfare. Vaccines have changed the experience of childhood for the better for generations of Americans. Our objective is to maintain the trust of generations to come in the interest of continuing this public health success.

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