THE ECONOMIC ASPECTS OF THE PHARMACEUTICAL INDUSTRY IN THE UNITED STATES

HEARING

BEFORE THE

SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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WEDNESDAY, JUNE 25, 2003

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:20 p.m., in room 2247, Rayburn House Office Building, Hon. Dan Burton (chairman of the subcommittee) presiding.

Present: Representatives Burton, Gutknecht, Watson, Sanders, and Allen.

Staff present: Mark Walker, chief of staff; Mindi Walker, professional staff member and clerk; Nick Mutton, press secretary; Brian Fauls and John Rowe, professional staff members; Kelly Lorenz, Rob Rubinstein, Will Drinkwater, and Tiara Wuethrich, staff assistants; Tony Haywood, minority counsel; and Teresa Coufal, minority assistant clerk.

Mr. BURTON. We will go ahead and start the meeting. A quorum being present, the Subcommittee on Human Rights and Wellness will come to order. I ask unanimous consent that all Members and witnesses, written and opening statements be included in the record. Without objection so ordered.

I ask unanimous consent that all articles, exhibits and extraneous or tabular material referred to in the record be included in the record. Without objection, so ordered.

And we have other Members of Congress that may be coming in to attend the hearing who are very interested in this prescription drug issue. So I ask unanimous consent that Congressmen Gutknecht, Duncan and Allen be permitted to serve as members of the subcommittee for today's hearing. Without objection, so ordered.

This is the third in an ongoing series of hearings being held by the subcommittee to examine the problem of high prices charged for prescription drugs here in the United States. In the United States, we pay a higher price on average for prescription drugs than citizens of any other country in the world. And the prices continue to go up and up.

Drug costs have been the fastest growing component of health care expenditures for the past several years, climbing more than 17 percent a year from 1998 to 2001. This double-digit rate of growth is twice the rate of growth for health care costs in general and approximately five times the growth rate of inflation. Thanks to this

astronomical growth in prices, we now have a situation in this country where more than one out of five, 20 percent of Americans are unable to take their drugs as prescribed because they simply cannot afford to buy them.

This figure climbs as high to 40 percent for some groups, including retired, disabled, minority and low income Americans. With an aging population, and 108 million Americans already managing one chronic health condition such as: heart disease, diabetes, asthma or high blood pressure, dependence on prescription drugs will continue to rise dramatically, and it is going to rise even more when the Baby Boomers start reaching senior citizen status.

Unless the high price for prescription drugs is brought down to a more manageable level, we are going to face the very real possibility that more and more Americans will be forced to choose between purchasing their food and buying their prescription drugs.

To me that is completely unacceptable. In a previous hearing on this subject held in April, the subcommittee heard extensive testimony regarding the increasing number of Americans who are going to Canada for their prescription drugs. Why? Because in many cases, the prices charged for a prescription drug in Canada can be half or a quarter of the price charged for the exact same drug that is sold here in the United States. And sometimes it is even less than that.

Just a few examples. Zocor, a commonly prescribed drug to fight high cholesterol, costs $106.84 here in the United States, but only $43.97 in Canada.

Prilosec, a widely prescribed drug to fight stomach disorders, acid reflux disease and others, costs $105.50 in the United States, and $53.51 in Canada. Procardia XL used to treat heart disease costs $110.90 here, whereas in Canada you can buy it for $72.82.

Now, a savings of $38 a month might not seem like a lot to many people. But, it can mean a world of difference to senior citizens living on a fixed income and constantly worrying about how to pay their the next utility bill.

The savings for Americans buying from Canada can be substantial, ranging from 20 to 80 percent. And the U.S. Food and Drug Administration estimates that nearly 1 million Americans already purchase between $500 million and $1 billion worth of prescription drugs from Canada pharmacies every year.

In 2000, Congress overwhelmingly passed, and the President signed into law, legislation that permits U.S. consumers, pharmacists and wholesalers to buy FDA approved drugs, prescription drugs on the international market, including those in Canada.

However, the provisions of the law have never been implemented, even though Congress voted in favor of allowing people to purchase their pharmaceutical products from outside the country. The provisions of the law have never been implemented due to foot-dragging, stonewalling and plain obstructionism from the Secretary of Health and Human Services and the Commissioner of the FDA.

Nevertheless, the number of Americans buying their prescription drugs from Canada and other countries around the world is sure to increase unless the cost of prescription drugs in the United States comes down. As we in the House of Representatives prepare to take up legislation adding a prescription drug benefit to the

Medicare program, which I think we are going to do tomorrow, I would like to say to my colleagues, and everyone who is paying attention to this issue that we face an unprecedented budget disaster if we do not include some mechanism to restrain the high price of prescription drugs in that program.

It has been estimated by the Congressional Budget Office [CBO] and others that it is going to cost about $400 billion over 10 years to implement the prescription drug benefit for seniors. Others have told us it is going to cost much more than that, up to $1.7 trillion over 10 years, and that is a budget buster.

In the 2 years since the study was done by the CBO, in which they said that $1.8 trillion over the next 10 years is possible on prescription drugs, drug prices have gone up 15 to 17 percent a year.

So if CBO were to repeat that study today, the figure wouldn't be $1.8 trillion it would be over $2 trillion. Just yesterday the Wall Street Journal published an op-ed piece authored by two researchers with Texas A&M University. The researchers, Mr. Rettenmaier and Mr. Savings, calculated that at just the present 12 percent annual growth rate of Medicare, the new prescription drug program under discussion in the House of Representatives would add an extra $7.5 trillion in unfunded liability to the Medicare program for all of the years beyond 2013.

That estimate is probably a bit conservative, given that drug prices have been increasing over 15 percent a year. Nevertheless, even if we spent only the budged amount of $400 billion between 2003 and 2013 we still need to find a minimum of $7.5 trillion to keep just the prescription drug component of Medicare functioning in perpetuity. That figure represents almost twice the current debt held by the public, our national debt.

Researchers at the American Enterprise Institute scored the Senate prescription bill at $12 trillion in unfunded liability over perpetuity. Again, the Congressional Budget Office's own estimate is that seniors will need close to $2 trillion in prescription drugs over the next 10 years, not simply $400 billion. That is a $2 trillion expense that the already financially shaky Medicare program is going to have to absorb unless we do something to restrain drug prices.

Bringing prices down by even 30 percent could reduce that $2 trillion price tag by over $600 billion. And that is $600 billion that could extend the life of Medicare to be used to improve our schools, to prepare roads and bridges or bolster our homeland defenses. Over the life of the Medicare program, we could save trillions of dollars.

We owe it to tomorrow's seniors, as well as our kids and grandkids, to give a Medicare prescription drug benefit that is both responsive to seniors needs and fiscally responsible. We owe it to them to do something about the high cost of prescription drugs and not simply pass a financial burden onto our kids and grandkids. I see a lot of young people in the audience. This is something that all of you need to think about, because this is going to be borne by you as you grow older.

Today's hearings will examine the economics between the high prices being forced on American consumers for prescription drugs. In previous hearings, we have heard testimony from the pharma-

ceutical industry arguing that Americans have to pay the highest prices in the world, otherwise research and development of new drugs will come to a screeching halt. This argue is a myth and nothing more than a scare tactic.

The pharmaceutical industry is perhaps the most profitable industry in the world, and by a large margin. Even during the recent economic downturn, the profits of the top 10 drug companies jumped 33 percent, going from $28 billion in 2001 to $37.3 billion in 2002.

On average the drug industry takes in 18½ percent of their income as pure profit, spends 32 percent of their income on advertising to consumers and doctors in order to increase demand for the newest, and consequently the most expensive drugs, and only 12½ percent of the income they derive from high prices, forced on American consumers, actually goes back into research and development.

The numbers seem to speak for themselves, but I will let our distinguished panel of experts explain the contradiction between what the pharmaceutical industry says in public relations statements, and what they say in their annual report to stockholders.

I want to thank Mr. James Love, an economist from Consumer Project on Technology, and Mr. Bill Vaughan, from Families USA, and Mr. Stephen Moore, senior economic fellow at the CATO Institute for being with us this afternoon.

And I also want to thank Dr. Stephen Schondelmeyer, professor of pharmaceutical economics, at the University of Minnesota, and perhaps the Nation's leading expert on the economics of the pharmaceutical industry for rearranging his schedule to remain in Washington and testify before the subcommittee this afternoon. I want to thank you for being here, Doctor.

And finally, I want to thank a true patriot and a true fighter, Congressman Gil Gutknecht for taking time away from meetings and discussions to be here today. He has been involved with this issue for a long time. He has had to withstand the slings and arrows of outrageous fortune by fighting the pharmaceutical companies, and their lobbyists here in Washington.

And Gil, you deserve an arm and a leg as far as compliments are concerned. And also, my colleague Bernie Sanders of Vermont. He has been a real driving force in the House on this issue. And even though we don't agree on a lot of things, Bernie, I really appreciate your hard work on this issue.

And we have a highly distinguished group of people before us here this afternoon, and we are going to hear some creative ideas that we hope the administration and everybody working on this issue will pay attention to. Some of the insights will deal with varied tax credits, tax deductions and research subsidies that the pharmaceutical industry receives from the United States.

I don't want to belabor this, but I think we are all familiar with the Taxol case, which I want to cite, where the National Institutes of Health gave the pharmaceutical industry $484 million worth of research to develop the drug and they—and the health agencies that gave $484 million only got $35 million in royalties from Bristol-Myers Squibb, and Bristol-Myers Squibb made a $9 billion profit while paying only $35 million back to the Federal Government

for all of the research and development money. All of that was total profit.

I am a fiscal conservative who believes in free markets. But I believe we have to do something about those runaway prices, especially since we are going to be passing a prescription drug benefit. I think we have a responsibility to make sure that citizens can get affordable drugs and not be raked over the coals when they have to buy their prescription drugs just to survive.

And as we have said before many times, Bernie, myself and others, it is a shame when seniors go to their pharmacist and they say, this is something I need for my health. How much is it going to cost? And they say, at the pharmacy, it is going to cost you $150. And the person lowers their head and turns around and walks away. And I think, Gil, you said this many times on the floor. And they have to make a choice between paying the rent, buying food, or getting their prescription drugs.

And we can do something about that if we pay attention to what we are doing right now. With that, let me recognize the ranking minority member, Ms. Watson, for an opening statement.

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

Opening Statement
Chairman Dan Burton
Subcommittee on Human Rights and Wellness
Committee on Government Reform
Title: "The Economics of the Pharmaceutical Industry in the U.S."
Date: June 25, 2003

Today's hearing is the third in an ongoing series of hearings being held by the Subcommittee to examine the problem of the high prices charged for prescription drugs here in the United States.

In the United States we pay a higher price on average for prescription drugs than citizens of any other country in the world. And the prices continue to go up and up.

Drug costs have been the fastest growing component of healthcare expenditures for the past several years, climbing more than 17 percent annually from 1998 to 2001.

This double-digit rate of growth is twice the rate of growth for healthcare costs in general, and approximately 5 times the growth rate of inflation.

Thanks to this astronomical growth in prices, we now have a situation in this country where more than 1 in 5 American adults are unable to take their drugs as prescribed because they simply cannot afford to buy them.

This figure climbs as high as 40 percent for some groups, including many retired, disabled, minority, and low-income Americans.

With an aging population and 108 Million Americans already managing one chronic health condition – such as heart disease, diabetes, asthma, or high blood pressure – dependence on prescription drugs will continue to rise dramatically.

Unless the high price for prescription drugs is brought down to a more manageable level, we face the very real possibility that more and more Americans will be forced to choose between purchasing their food and buying their prescription drugs. To me, that is completely unacceptable.

In a previous hearing on this subject held in April, the Subcommittee heard extensive testimony regarding the increasing number of Americans turning to Canada for their prescription drug needs.

Why? Because in many cases, the price charged for a prescription drug in Canada can be half or a quarter of the price charged for that exact same drug that is sold here in the United States.

Just a few examples: 1) Zocor, a commonly prescribed drug to fight high-cholesterol, costs $106.84 here in the U.S., but only $43.97 in Canada; 2) Prilosec, a widely

prescribed drug to fight acid-reflux disease and ulcers, costs $105.50 in the United States, and just $53.51 in Canada.

Procardia XL, used to treat heart disease, costs $110.90 here whereas in Canada you can buy it for $72.82. Now a savings of $38 dollars a month might not seem like a lot to many people, but it can mean a world of difference to a senior citizen living on a fixed income and constantly worrying about how to pay their next utility bill.

The savings for Americans buying from Canada can be substantial, ranging from 20 to 80 percent, and the U.S. Food and Drug Administration estimates that nearly 1 Million American consumers already purchase between $500 Million and $1 Billion dollars worth of prescription drugs from Canadian pharmacies annually.

In 2000, Congress overwhelmingly passed – and the President signed into law – legislation that permits U.S. consumers, pharmacists and wholesalers to purchase FDA-approved prescription drugs on the international market, including those from Canada. However, the provisions of the law have never been implemented due to foot-dragging, stonewalling, and plain obstructionism from the Secretary of Health and Human Services and the Commissioner of the FDA.

Nevertheless, the number of Americans buying their prescription drugs from Canada and other countries around the world is sure to increase unless the cost of prescription drugs in the United States comes down.

As we in the House of Representatives prepare to take up legislation adding a prescription drug benefit to the Medicare program, I would say to my colleagues that we face an unprecedented budget disaster if we do not include some mechanism to restrain the high price of prescription drugs in that program.

The Congressional Budget Office estimated about two years ago that American seniors will spend $1.8 Trillion over the next ten years on prescription drugs. In the two years since that study was done, prescription drug prices have gone up about 15 to17 percent annually. So, if CBO were to repeat that study today I am sure the figure would be well over $2 Trillion dollars.

Just yesterday, the *Wall Street Journal* published an Op-Ed authored by two researchers with Texas A&M University. The researchers, Mr. Rettenmaier and Mr. Savings, calculated that at just the present 12 percent annual growth rate of Medicare, the new prescription drug program under discussion in the House of Representatives would add $7.5 Trillion dollars in unfounded liability to the Medicare program for all years beyond 2013. That estimate is probably a bit conservative given that drug prices have been increasing on average 15 to 17 percent annually.

Nevertheless, even if we spend only the budgeted amount of $400 Billion dollars between 2003 and 2013, we still need to find a minimum of $7.5 Trillion dollars to keep just the

prescription drug component of Medicare functioning in perpetuity. That figure represents almost twice the current debt held by the public.

Researchers at the American Enterprise Institute scored the Senate prescription drug bill at $12 Trillion in unfounded liability over perpetuity.

Again, the Congressional Budget Office's own estimate is that seniors will need close to $2 Trillion dollars in prescription drugs over the next ten years, not simply $400 Billion. That is a $2 Trillion dollar expense that the already financially shaky Medicare program is going to have to absorb – unless we do something today to restrain drug prices.

Bringing prices down by even 30 percent could reduce that $2 Trillion price tag by over $600 Billion. That is $600 Billion that could extend the life of the Medicare program, be used to improve our schools, to repair roads and bridges, or bolster our Homeland defenses. Over the life of the Medicare program we could save Trillions of dollars.

We owe it to tomorrow's seniors as well as today's to give them a Medicare prescription drug benefit that is both responsive to their needs and fiscally responsible. We owe it to them to do something about the high cost of prescription drugs, and not simply to pass the financial burden on to our children and grandchildren.

Today's hearing will examine the economics behind the high prices being forced on American consumers for prescription drugs.

In previous hearings we have heard testimony from the pharmaceutical industry arguing that Americans HAVE TO pay the highest prices in the world otherwise Research and Development, of new drugs will come to a screeching halt.

This argument is a myth and nothing more than a scare tactic. The Pharmaceutical industry is perhaps the most profitable industry in the world, and by a wide margin. Even during the recent economic downturn, the profits of the top 10 drug companies jumped 33 percent, going from $28 Billion in 2001 to $37.3 Billion in 2002

On average, the drug industry takes 18.5 percent of their income as pure profit and spends 32 percent of their income on advertising to consumers and doctors in order to increase demand for the newest and consequently the most expensive drugs. Only 12.5 percent of the income they derive from the high prices forced on American consumers actually goes back into Research and Development.

The numbers seem to speak for themselves, but I'll let our distinguished panel of experts explain the contradiction between what the pharmaceutical industry says in PR statements and what they say in their Annual Reports to stockholders.

I want to thank Mr. James Love, an Economist from the Consumer Project on Technology, Mr. Bill Vaughan from Families USA, and Mr. Stephen Moore, Senior Economic Fellow with the CATO INSTITUTE for being here with us this afternoon. I

also want to thank Dr. Stephen Schondelmeyer, Professor of Pharmaceutical Economics at the University of Minnesota, and perhaps the nation's leading expert on the economics of the pharmaceutical industry for rearranging his schedule to remain in Washington and testify before the Subcommittee this morning. Thank you Dr. Schondelmeyer.

Finally, I would like to thank Congressman Gil Gutknecht, for taking time away from the meetings and discussions he has been involved with regarding the upcoming Medicare debate to be with us this afternoon. Congressman Gutknecht, along with Congressman Bernie Sanders of Vermont, has really been a driving force in the House on the whole issue of the high cost of prescription drugs here in the United States, and we thank him for his time today and his leadership on this issue.

We have a highly distinguished group of people before us this afternoon and I am sure we will hear some creative ideas for solving this very serious problem, as well as some interesting insights into the numerous and varied tax credits, tax deductions, and research subsidizes the pharmaceutical industry receives from the United States.

No doubt we are all familiar with the
Taxol case, where the National Institutes of Health did $484 Million worth of research to develop the drug and received only $35 Million in royalties from Bristol-Myers Squibb, the company contracted to market the drug. Bristol-Myers Squibb on the other hand made a profit of $9 Billion thanks to the work done by Federal scientists on the taxpayer's dime.

I am a fiscally conservative Republican who believes in free markets. I believe that making an honest buck is not a bad thing.

I do not believe in or support government mandated price controls. And I have no desire to stifle innovation or curtail legitimate pharmaceutical Research & Development.

On the other hand, do not believe or support price gouging, and so far as I can see, Americans are being gouged by the pharmaceutical industry to fund enormous corporate profits and CEO's salaries. To me that is not acceptable.

We all need to remember that a prescription drug a patient cannot afford to buy saves no one's life, and that the true measure of any society is how well it treats its weakest citizens.

We have a responsibility to ensure safe and AFFORDABLE prescription drugs for American consumers. And I can assure everyone here this afternoon that this Subcommittee and this Member of Congress takes that responsibility very seriously.

Ms. WATSON. Mr. Chairman, I want to thank you sincerely. And I appreciate the attention that our subcommittee is giving to such an important health topic.

The economics of the pharmaceutical industry in the United States affects so many aspects of our society. Employment, basic research and development, Wall Street markets, and health care delivery are impacted, to just name a few.

Sitting at the top of the list is the quality of life, a concept that we embrace as a people and as a Nation. It is very difficult to create a steadfast rule to govern the quality of life. But the U.S. Government has elected to express the thoughts and ideas of the American public.

Prescription drug prices are just too high. To protect the American quality of life a solution must indeed be found. Mr. Chairman, American biotechnology has advanced with astounding speed. Dependence on prescription drug has risen dramatically. Our population is aging. And over 108 million Americans are managing at least one chronic health condition.

Seniors inherently require a large portion of the perspective drugs that are produced. There is no good reason why the prices of pharmaceuticals are higher in the United States than in any other country in the world.

The Congressional Budget Office [CBO], estimates that seniors will spend $1.8 trillion on prescription drugs in the next 10 years. Seniors that have contributed to American society throughout their lives should not be forced into a food or prescriptive drug dilemma with their retirement dollars. Why are drug prices increasing at approximately 17 percent each year?

Mr. Chairman, Congress is adding Medicare reform at the same time our subcommittee focuses on pharmaceuticals. Seniors want stable and reliable coverage. Seniors would like a reasonable solution to high prescriptive drug costs. I commend your subcommittee's dedication to collect information.

Older Americans want Congress to take the time to thoughtfully craft legislation that affects our quality of life. And that is the process that we are in as we speak.

Mr. Chairman, I yield back my time.

Mr. BURTON. Thank you, Ms. Watson.

Mr. Sanders.

Mr. SANDERS. Thank you, Mr. Chairman. And because of what you said, the outstanding remarks that you made and what Ms. Watson said, there is not a whole lot that I can add. But let me just say a few things.

No. 1, we are coming down to the crunch now. And the key point that you made as I was walking in the door, is that if we do not deal with cost containment, it is going to be an extraordinary burden on an already pressed Federal Government.

So we have to deal with cost containment. There are a number of mechanisms out there that have been discussed for years that we are all familiar with. The idea that in a global economy, why can't people buy safe and affordable drugs in Canada is clearly on the top of many of our minds.

My guess, Mr. Chairman, is if we just did that, which would cost the taxpayers of this country zero, you would have a stronger bene-

fit for senior citizens than the bill we are going to be looking at for $400 billion over a 10-year period.

But, we can do more than that. You talked about the issue of the fact that the Federal Government has poured in tens of billions of dollars into research that have gone into the companies, and after the company develops its product, the taxpayers get nothing, the consumers of this country get no benefits whatsoever.

And the third element of cost containment, in my view, is when you have the Veterans Administration, Medicaid, and all of the folks of Medicare, the Federal Government should be able to negotiate very, very reasonable prices.

But we are coming down to the crunch. And the good news, from a political perspective, and I say this very, very sincerely to you and to Gil Gutknecht and others, is that we are seeing a lot of bipartisanship now. We are seeing progressives, conservatives, people in the middle, Democrats, Republicans, independents, coming together to say we have a major health care crisis. We are not going to tolerate elderly people not being able to get affordable prescription drugs. But we are going to solve this problem without bankrupting America.

That is the challenge that we face. My hope is, let me be very pointed here, is that in a week, I hope—we are going to be dealing with this issue we think on Thursday, Mr. Chairman?

Mr. BURTON. Tomorrow.

Mr. SANDERS. I would hope that we can all stand together and tell the leadership of the U.S. Congress, that we are not going to pass a blank check, that we need cost containment. And if your side does it and our side does it, we can yet pull a rabbit out of the hat.

You have already said, and Ms. Watson has already said much of what I think has to be said. The industry is the most profitable industry in the world. They spend far more on marketing and advertising than they do on research. Do not believe them when they say, oh, all of these profits and these high profits go into research, they are just not accurate.

They pay their CEOs, in some cases exorbitant salaries. C.A. Heimbold, Jr., who is the chairman of Bristol-Myers Squibb, CEO received $150 million in compensation in 2001. One guy, $150 million. And yet elderly cannot afford prescription drugs all over this country.

Mr. Chairman, we have heard right in this subcommittee the Food and Drug Administration, representatives in the industry telling us how unsafe it would be, what a terrible problem it would be to reimport medicine from Canada. That is just absolutely untrue. As you know, Mr. Chairman, I released 2 weeks ago a research memo prepared by the Congressional Research Service.

This study analyzes in detail the Canadian regulatory system for prescription drugs and puts the lie to industry and FDA attempts to paint the Canadian prescription drug market as some kind of provincial backwater. CRS has convinced me that nothing can be further from the truth. The two countries, the USA and Canada, regulate prescription drugs in virtually identical ways from manufacturing and importation to labeling, distribution and sales.

And the bottom line is, Mr. Chairman, as you know, as Mr. Gutknecht knows, after all is said and done, after all of the lies that are out there, when we ask them: Tell us, how many people of the 1 million people who now purchase prescription drugs from Canada have been made ill, have died, the answer was zero. Zero. Not one.

And yet when we talk about the reimportation or the importation of lettuce and tomatoes and vegetables and strawberries, meats, a whole lot of Americans become ill and some die.

What we are taking on, and I want everyone in this room to understand this, is the most powerful lobby in the history of the United States of America. A few weeks ago, the New York Times reported they are prepared to spend a $150 million this year alone, that is just pharma, and not the individual companies. They will go into your district, and they have gone into your district already. They will go into Gil Gutknecht's district, and they will go into any district in this country where Members of Congress are prepared to take them on, whether they are conservative Republicans, progressives, or Democrats.

While we have a lot of respect for the researchers in the industry who do great work, I have contempt for the CEOs of these companies who want to do nothing more than raise prices as high as they can possible get away with. So we are making some progress. And we are going to work together. And I hope that we can defeat them on behalf of the American people.

Thank you again, Mr. Chairman, for your outstanding leadership in this area.

Mr. BURTON. Thank you.

Mr. Allen.

Mr. ALLEN. Mr. Chairman, I just wanted to say thank you for holding this hearing. And I will waive any time I have and turn to the witnesses.

Mr. BURTON. Well, thank you. Well, we have Congressman Gutknecht with us, who has been the leader on this issue for a long time. And I am anxious to hear what we has to say. He met with the head of HHS, Mr. Thompson, Secretary Thompson. Maybe we can enlighten us as to what Mr. Thompson had to say to him at lunch today. Did you buy or did he?

Mr. GUTKNECHT. I actually bought. I have the receipt, Mr. Chairman.

Mr. BURTON. We have to swear you in like everyone else. So would you rise?

[Witness sworn.]

Mr. BURTON. You are recognized, Congressman.

STATEMENT OF HON. GIL GUTKNECHT, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MINNESOTA

Mr. GUTKNECHT. Well, thank you very much, Mr. Chairman. And I want to thank you for all that you have done on this issue. I realize, we all have local politics to deal with. I think particularly in the State of Indiana, I admire what you have done, and I also want to say a very special thank you to Mr. Allen and finally and perhaps, most importantly, to Bernie Sanders, and something that he said earlier that is so important and we need to remind ourselves.

I remind everyone who ever listens. I try to mention this in my special orders. The matter that we are talking about today, what Americans pay relative to the rest of the world for the same drugs, is not a matter of right versus left. It is right versus wrong. And this is simply wrong, to hold American consumers captive to pay the worlds highest prices.

And I have written testimony that I will submit, but I am going to depart from that slightly. I will distribute this to members of the committee, some charts, many of which you have already seen, and we have them up in front, of some of the differences. And different groups have done research for us.

I should go back to the beginning, in terms of how I got involved in this issue. It seems a bit bizarre, but I think then perhaps you will understand why I feel so strongly about this. A number of years ago, probably about 5 years ago, I was invited to a town hall meeting with some seniors. And they're telling me about their trips to Canada to buy prescription drugs.

And to be really honest about it, I said, well that is fine. You know, if you want to go to Canada to buy your drugs, that is OK. I didn't really think much about the issue. And then something that was totally unrelated happened. The price of hogs in the American market dropped from about $37 per hundred weight to about $8 per hundred weight. Now, what does that have to do with prescription drugs?

Well, let me explain. My hog producers began to call me and say, man, can't do you something about this? In fact, they went as far as to say that there were thousands of Canadian hogs coming across the borders every day making our supply demand problem even worse. And they asked, can't you do something at least about all of these Canadian hogs coming in and flooding our markets. So I called the Secretary of Commerce. And I called the Secretary of Agriculture. And I got the same answer.

They said, well, that is called NAFTA, that is free trade. And all of a sudden a light bulb went on above my head, I said wait a second. You mean we have free trade when it comes to pork bellies, but we don't have free trade when it comes to Prilosec. And they said, well, yeah, I guess that is one way to look at it. And I began to realize that American consumers could save billions of dollars.

About that time there was a study done by an HMO in the Twin Cities. And they came back with a conclusion and they sent us a copy of their study that said if they could simply buy their prescription drugs in Canada, and recover half of the savings, not all of the savings based on their research, they could save their subscribers $30 million a year.

Now, to that HMO, that is a lot of money. To those subscribers and those employers who are paying the bill, that is a lot of money. And so I became much more interested in this issue, began to do research. And as some people would say, I moved from being a fan of this issue, to being a fanatic.

Now, Winston Churchill described a fanatic as one who cannot change their mind and will not change the subject. And I literally have almost become a fanatic about this, because, I believe in free markets. I believe that if you look at the history of people, the

wealthiest nations, the wealthiest city states, whether it is Singapore or Venice, have always been the trading nations.

But, this is one of examples where American consumers are held captive. They are held captive by their own government. Worse than that, we have senior citizens, whether it is in Maine, or whether it is in Indiana, or you name the State, but particularly along the borders, whether it is on the northern border or the southern border, we literally have senior citizens today that are being treated like common criminals because they are trying to save some money on their Tamoxifen.

Let me given you an example. Recently, and we hear a lot about Canada. You will see on my charts—I have one chart that just compares American prices with the prices in Munich, Germany. And recently, I and one of my staffers, Brandon Lerch, were over in Germany. I am also the chairman of the Congressional Study Group on Germany. And on our way back we went on a little shopping trip to the local pharmacy at the Munich Airport.

Now, most people know that if you want to get a deal, you probably don't run out to the airport to shop. Usually that is where the piece are the highest. But we went to the Munich Airport Pharmacy, and we were able to buy what we believed to be 10 of the most commonly prescribed drugs in the United States. And you have on the chart what the price was in Munich, Germany and then the comparison here in the United States. The total came—to the drugs in Munich, Germany was $373.30. Here if the United States those same drugs would be $1,039.65. We have the receipts to prove this.

But, let me just call your attention to one drug, because I mean, that alone makes me as a representative of good people who are trying to do the best and provide for their families and be able to afford the drugs that they and their families need to stay healthy, but this is one of the examples that we should all be just outraged about.

This is called Tamoxifen. Tamoxifen is one of the most—it really is a miracle drug. It is one of the greatest drugs I think that we have invented in the last 20 years. Tamoxifen is the most effective drug against women's breast cancer. You know sometimes we say, well, breast cancer only affects women. We need to remind ourselves, it affects everyone in that family. So this is an amazing drug for all Americans.

But, this drug was developed, essentially at the expense of the American taxpayers through the NIH. I think the estimate that we have, is we have invested something like $684 million. We literally, the NIH took this drug through what they call phase 2 trials. So most of the research that mattered was done at the expense of the American taxpayers.

Now, that is bad enough. But what made us even angrier is we bought this package of drugs at the Munich Airport Pharmacy for $59.05, American. Let's just round that off. We bought it for $60. This same drug purchased here in Washington, DC, at a local pharmacy is $360. I can't defend that. No one can defend that. I can't explain that. And it seems to me that we have a responsibility as public policymakers to do something about it.

Now, I don't believe in price controls. But, let me explain what I have learned about how they do business in the European Union. They use what they call parallel trading.

In fact in Germany, you know, we hear sometimes about price controls. Well, there are modified versions of price controls practiced around the world. But, basically in Germany they really don't have price controls. What they allow the German pharmacists to do is go out and purchase their drugs wherever they can get them the cheapest. They call it parallel trading.

As a result, they can go to Spain or another country in the European Union or another supplier, wherever they can get the best price on the same drug. And that is what we ought to demand here in the United States. And that is a safety-oriented version of parallel trading, which they have in Europe today. Our estimates are that you can save enormous amounts of money for American consumers, not just seniors.

Now, as Ms. Watson pointed out, the biggest buyers of prescription drugs are our seniors. They are the ones who once they start, for example, my father takes a drug called Coumadin. Coumadin, incidentally, the more I have learned about this, I feel like the little boy who came in and asked his mother a question. His mother was busy and she said, well go ask your dad.

And the little boy said, well I didn't want to know that much about it. I feel a little bit like that little boy. I am not sure I want to know this much about it. But this drug Coumadin is an interesting story as well. This drug was essentially developed at the University of Wisconsin veterinarian schools. It was developed as a rat poison.

But, the interesting thing is this drug in the United States, this package of drugs sells for $89.95. We bought this drug in Germany for $21. Now, this is the kind of drug that once a person reaches a point in their age and physical condition, they are going to be taking this drug probably for the rest of their life. I am not a doctor, I don't play one here in Congress.

But these are things that I have learned. And I can go through this whole package of drugs and talk about the differences between what we pay in the United States and what Americans pay. But I think best analogy, and what this means in having a captive market, and by keeping Americans held captive by our own FDA, an example would be what happened for many years, and it is starting to relax. But in Japan, if you wanted to get a good steak dinner in Japan, it was over $100, a steak that you can get in Indianapolis or Burlington, Vermont or in Minneapolis, a steak that you can get for $15 or $20 would be over $100 in Japan.

The reason was the Japanese Government literally held Japanese consumers captive. They could only buy Japanese produced beef. There was no international market. That was also true, for example, during the old days of the Soviet Union. The Soviets decided that Soviet teenagers did not need blue jeans. So they didn't manufacture them. So the demand was very high, supply was very limited, and the black market price for a pair of blue jeans in Red Square in Moscow was over $100.

That is what happens when you try to hold markets back and you hold consumers captive. Now, I am not arguing for price con-

trols. I am not arguing that pharmaceutical companies are inherently evil. In fact, I don't even say shame on them, but I do say shame on us. Because ultimately we set the public policy. Ultimately the Food and Drug Administration works for us.

And it is time for us to take control of this matter and require the same kind of parallel marketing that they have in Europe to be implemented here in the United States. And when that happens, our estimate is, and I think this is a conservative estimate, if you look at what the Congressional Budget Office tells us, seniors alone in the United States, over the next 10 years, they are estimating seniors will spend $1.8 trillion on prescription drugs.

Incidentally, I have other experts who believe that estimate is actually low. And if we add a prescription drug benefit to Medicare, that number is actually going to go up. In fact, one expert told me that it could be as high as $3 trillion. But let's use the $1.8 trillion. Under the plan that I think we should implement, we could see prices in the United States drop conservatively by 30 percent. This subcommittee has had testimony from Dr. Winter in Vermont that her patients in Vermont are saving 62 percent by being able to import their prescription drugs from Canada.

If you look at the chart in the back of this page, you will see that our studies and the information that we have been able to get, demonstrates that prices are actually cheaper in the European Union, in Europe, than they are in Canada.

So we believe that it is very likely that we can save at least 30 percent. Now, I am not good in math. But 30 percent of $1.8 trillion is $630 billion. And as the point was made, I believe by Mr. Sanders earlier, that the pharmaceutical industry, the Pharmaceutical Manufacturers Association, is going to spend $150 million lobbying and informing us and the public about their problems and the issues.

Clearly, this is a very small investment when you look at the potential savings of just opening markets, of just providing market access to American consumers. $630 billion to spend $150 million lobbying to keep that from happening, it seems to me probably is a good investment.

So, again, it is not shame on them, it is shame on us. I thank you for having these hearings. I think you have at least given us an opportunity to have a forum where these issues can be honestly discussed. And so I am here at your pleasure, and I would be happy to answer any questions, particular if we want to talk about safety, because that is an issue that a lot of people are concerned about.

With that, Mr. Chairman, I would yield back whatever time I might have left.

[The prepared statement of Hon. Gil Gutknecht follows:]

STATEMENT OF CONGRESSMAN GIL GUTKNECHT
HOUSE COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

HEARING OF JUNE 25, 2003

PANEL ONE

Mr. Chairman, members of the Committee, thank you for offering your colleague the opportunity to testify. Although I have been working on the issue of opening American pharmaceutical markets for over four years, this is the first time I have been invited to testify on the issue.

The United States of America has a captive pharmaceutical market. American consumers, American retailers-pharmacists- and American wholesalers have not been permitted to access pharmaceutical markets abroad. No other product distributed in the United States is subject to such a blanket import ban. As we know, closed markets keep prices artificially high and cause great price disparities with other markets. The captive American pharmaceutical market has logically resulted in outrageously high pharmaceutical prices as compared to the rest of the world.

To rectify these intolerable and unjust circumstances, I have offered H.R. 2427, The Pharmaceutical Market Access Act. Allow me to provide a brief summary of the bill:

Under the Pharmaceutical Market Access Act, the FDA must design and implement a system to grant individuals, pharmacists and wholesalers in America access to FDA-approved drugs from FDA-approved facilities in industrialized nations abroad.

Those countries are limited to: the European Union, Australia, Canada, Iceland, Israel, Japan, Lichtenstein, New Zealand, Norway, Switzerland, and South Africa. Note: Mexico is NOT included.

The Pharmaceutical Market Access Act strengthens America's commitment to maintaining the safest pharmaceutical drug market in the world. This bill requires all prescription drugs produced at home and abroad to use counterfeit-resistant packaging, similar to the technology used by the U.S. Department of the Treasury. If the technology is good enough to secure U.S. currency, it's good enough to secure our pharmaceutical chain-of-custody.

The Pharmaceutical Market Access Act contains language written by the legal team at FDA that requires wholesalers to test each pharmaceutical shipment, unless the packaging uses counterfeit-resistant technology. The FDA's strict language was written

to provide for the safety of imported pharmaceuticals from anywhere in the world.

The Pharmaceutical Market Access Act strictly prohibits anyone from importing pharmaceutical narcotics, such as OxyContin.

The Pharmaceutical Market Access Act requires the FDA to implement this program within 180 days of enactment. This frees Americans from an environment where patients forgo pharmaceutical treatments, at risk to their own health, because their prescriptions are too expensive.

The Pharmaceutical Market Access Act recognizes that unaffordable prescription drugs do nothing to improve the health of American consumers. That is an unsafe situation. The bill amends Section 804 of the Federal Food Drug and Cosmetic Act (21 U.S.C. 381) by striking language which requires the Secretary of Health and Human Services to certify that imported drugs pose "no additional risk" to Americans under a market access regime. By contrast, the Secretaries of HHS and USDA are not required to certify "no additional risk" for fruits and meats—food borne pathogens claim thousands of lives each year in the United States. HHS and the USDA have never suggested banning the importation of food. The Pharmaceutical Market Access Act removes this weak language from pharmaceutical legislation and relies on technology and more aggressive safety testing to provide real protections for Americans.

The American people, Mr. Chairman, understand the injustice of our captive pharmaceutical markets. Small businesses have difficulty hiring new employees because they can't afford to provide health insurance. Seniors are forced to cut pills in half or skip meals. Moms and dads struggle to meet the basic health care needs of their children. Prescription drug prices increase 4-5 times the rate of inflation.

The Administration and Congressional leadership, in an attempt to address some of these concerns, is proposing a prescription drug benefit under Medicare. Later this week, the House will bring the Prescription Drug and Medicare Modernization Act of 2003 to the floor. Unfortunately, this legislation does little to address the driver of rising health care costs: outrageous prescription drug prices.

I hope I'm wrong, but I am afraid the proposed benefit may only make a bad situation worse. With 40 million Baby Boomers set to retire in the next 20 years, a benefit that fails to address the price side will result in staggering deficits or dramatic tax increases – or both. If tax cuts are supposed to stimulate the economy today, what will be the effect of massive tax increases in coming years?

We must at least pass an amendment similar to my Pharmaceutical Market Access Act. Colleagues from across the political spectrum have co-sponsored this common sense measure allowing American consumers to import FDA-approved prescription drugs from FDA-approved facilities in 25 industrialized countries.

No one disputes that Americans pay 30 to 300-percent more for the same prescription drugs as our counterparts around the world. I have no problem helping our friends in sub-

Saharan Africa, but I do have a problem with American consumers subsidizing the starving Swiss.

On a recent trip to Germany, I purchased 10 of the most commonly prescribed drugs from the airport pharmacy in Munich. The total cost of these ten prescription drugs in Munich was $373.30. Those same drugs cost a whopping $1,039.65 in the United States.

These price disparities are not isolated to a few drugs. My 86-year old father takes Coumadin, a commonly prescribed blood thinner. A 30-day supply of Coumadin costs $89.95 in the United States, but only $21.00 in Germany. Tamoxifen, a miracle breast cancer drug that was developed almost entirely with American taxpayer dollars, costs $360.00 in the United States, but only $60.00 in Germany. This, unfortunately, is the rule, not the exception.

According to the Congressional Budget Office, seniors alone will spend $1.8 trillion on prescription drugs over the next ten years. Proponents of the prescription drug benefit claim the cost will not exceed the $400 billion set aside. Does anyone believe we will solve a $1.8 trillion problem with a $400 billion solution?

The history of federal entitlements teaches that costs will escalate. For that matter, considering it is an entitlement and has no fixed budget, does anyone believe it will cost less than $1.8 trillion? In fact, according to Texas A&M's Social Security and Medicare Trustees/Private Enterprise Research Center, the new drug benefit will cost a whopping $7.5 trillion.

What's worse, included in the entitlement are the wealthy. In a time when we are facing record deficits, is it wise to provide a prescription drug benefit for Ross Perot? Providing a generous universal subsidy to retirees regardless of how wealthy, is bad public policy.

We simply cannot afford to pass a prescription drug benefit without considering costs. Without competitive pressure, the giant pharmaceutical companies may well shift savings from any discounts given to Medicare onto the backs of businesses, the underinsured and the uninsured. One way to keep costs in check is to open markets.

Unless House leadership addresses the outrageously high prices of prescription drugs, I may have to vote 'no'. This is a matter of generational fairness for our kids and grandkids. And it's a matter of giving seniors *real* reform that provides *affordable* prescription drugs for all Americans.

Large pharmaceutical manufacturers like GlaxoSmithKline (Glaxo) have long been charging American consumers substantially more, in some cases up to 5 times as much, for their prescription drugs sold in the United States than in Canada and other industrialized countries. American consumers are fed up. They are finding importation to be a viable alternative to paying the outrageous mark-up costs.

To close, allow me to submit the statement of a fellow Minnesotan. Kate Stahl is 84 years-old and wears a name tag which reads, "Kate Stahl, Old Woman".

"Eight years ago, in October of 1995, my husband Jim and I took the first Minnesota Senior Federation bus trip to Winnipeg, Canada. Jim was taking medications for his heart condition and CLPD at the time, and the prices were quickly becoming unaffordable. Although the prospect of a seven-hour trip to Winnipeg was daunting, we found that we could save enough money on his medications to pay for the trip for both of us, and still have enough money left over to make it worthwhile. It turns out that we did so well with Jim's drug prices on that trip that in the spring of 1996 we took the second Minnesota Senior Federation bus trip to Canada.

In the years that followed, a number of Minnesota Senior Federation members and I realized that for many seniors, taking a bus trip to Canada would be both physically and geographically prohibitive. So we developed a program through which seniors could import prescription drugs by traveling to their doctor's office rather than to Canada. In January of this year the Minnesota Senior Federation introduced its Prescription Drug Importation Program, in which participants have been saving an average of 40 to 60% on their drug costs.

Unfortunately, current federal laws regarding drug market access are ambiguous. It is therefore conceivable that an American senior who imports her medications from Canada, because that is the only way she can afford them, could be prosecuted by the federal government. Imagine that!

I'll be making a drug-buying bus trip to Canada in a few weeks. It would be wonderful to have this old lady arrested and put in jail for breaking the law. Just imagine, this frail old lady forced to buy her prescription drugs in Canada because her American government found it more profitable to legislate on behalf of the pharmaceutical industry.

This is why Representative Gutknecht's Pharmaceutical Market Access Act is so crucial to seniors in this country, and to anyone else who struggles with the prices of prescription drugs. I would urge all members of Congress to support this legislation."

Mr. Chairman, Kate Stahl is a patriot like those who dumped tea in Boston harbor, exercising their rights as the "people". When Americans risk arrest by leaving their country to save 30%-1000% on their pharmaceuticals, they are speaking to their representatives. Kate Stahl said, "I would like nothing more than to be put in jail." It is time, Mr. Chairman, we listened.

Mr. BURTON. Thank you, Congressman. One thing that might be interesting for you to illuminate a little bit more on, it doesn't take a great deal of illumination. But, you know, we did pass NAFTA. And that was supposed to make sure that there was free trade between Canada, Mexico and the United States. And you mentioned pork bellies and how American farmers, hog farmers were being hurt by the importation of pork bellies from Canada.

Did you find out anything from the Department of Commerce or our trade people as to why they haven't looked into why the pharmaceutical industry is exempted from the free trade agreement.

Mr. GUTKNECHT. Well, I can't say why, and I am not sure anybody can actually tell us why. Now, we can all surmise why. But they are specifically exempted from the North American Free Trade Agreement.

Mr. BURTON. Our trade Ambassadors and the people couldn't give you any explanation as to why that was the case?

Mr. GUTKNECHT. None that I don't think that they are or I could probably share on the record. We can all surmise. This is a big, big deal. I mean, the differences between Canada and the United States are very profound. But the truth of the matter is, the differences between the United States and the Mexico are even more profound.

Mr. BURTON. Well, I don't have any more questions. I would just like to welcome you to be with us on the panel when we bring our other panelists up here. The one thing that does concern me is that it is so obvious what is wrong here that Americans are bearing a huge amount of the burden for research and development and production, and sale of these advertising for these pharmaceuticals, while the rest of the countries are getting off scott free.

And if the R&D is the problem, and I don't believe that it is. But, if the R&D is the problem, research and development, then why should the United States be carrying the entire burden? It should be spread around the entire world.

With that, Ms. Watson, do you have any questions of Congressman Gutknecht?

Ms. WATSON. I have several. In talking to some of the pharmaceutical reps in my office, I said, if you have the same product, and you sell it in Canada, and you sell it in the United States, and all of the ingredients are identical, why is there a difference? And I was told because of the kind of health care system they have in Canada, that their Department of Health Services negotiate a cap, and that doesn't happen here.

Do you think that we could, with HHS, do the same thing? What would it take, and what kind of clout could we combine to give us such a thing here.

Mr. GUTKNECHT. Well, one of the arguments, Ms. Watson, for the prescription drug benefit package that is being discussed and potentially will be voted on tomorrow night, is that we can use some of that clout to get better prices from the pharmaceutical companies.

And there is some evidence that can happen. But, I also have another chart, and I am sorry I don't know if I brought enough with me. And it is kind of interesting because——

Ms. WATSON. Is that the same one that is there?

Mr. GUTKNECHT. No. I don't have a blow-up of this chart. But let me share with you what it is. It is the cost of the pharmaceuticals for the Federal Employee Benefit Program. And what you find is that, yes, they do get some discounts, but they are not nearly as good as the discounts that Canada and Germany and other countries enjoy.

Let me give you a couple of examples. Under the Federal Employees—again, this is research done for us by the Office of Personnel Management in terms of the price that they actually pay.

But for Blue Cross Blue Shield plan, the cost for Coumadin is $55.31. Now, that is better than the retail price of $64.89, but it is not that big a discount. Glucophage. The shelf price is around $124. They get a discount and they buy it for $90. But to put in contrast what they pay in Europe, that Coumadin can be bought for $15.80 as opposed to $55, and that Glucophage can be purchased for $22 instead of $90.

So the argument that somehow we are going to get these miraculous prices simply by having those buying groups inside of Medicare is a specious argument. The only reason I say that is, the evidence that we have right now with the Federal Employees Benefit Program demonstrates that we are getting a little better prices, but not much better prices.

Ms. WATSON. Last time we had this hearing, we heard that there is a great deal of danger, and we put our patients at risk when they order these through the mail, these pharmaceuticals, these prescription drugs.

Have you been able, in your research, to identify any risk at all, and is there a serious problem?

Mr. GUTKNECHT. Well, I think Mr. Sanders probably answered that question as well as I can. I mean, the FDA has done their own research. And we have had Mr. Hubbard here several times. There is a little bit of bobbing and weaving, but at the end of the day, the bottom line is that they do keep records, they do research. The number of people in the last 10 years that have died as a result of taking a legal imported drug is an easy number to remember, it is a nice round number, it is zero.

And now, if you compare that, for example, again, using the CDC's and the FDA's own records, we know that approximately 5,000 Americans every single year die of some food-borne pathogen. Now, we know that, for example, in fruits and vegetables, according to the FDA's own studies, approximately 2 percent of the fruits and vegetables coming into the United States every day, and every day we import thousands of tons of food.

I was surprised to learn myself that last year we imported 318,000 tons of plantains, for example. The amount of orange juice that we bring into this country every day is staggering. So the bottom line is, you are much more likely to get sick and ultimately die from eating raspberries from Guatemala, than you are from taking Coumadin that you may import from Munich, Germany.

Ms. WATSON. Back in the early 1980's when—in California, the University of California, we identified the virus that caused HIV/AIDS. The pharmaceuticals that were developed, and one of the responses I get from the companies is that they need to have these high costs on their drugs because of the research, the R&D.

And so over the years, we negotiated as a Department of Health and Human Services the price, because we had various programs throughout the State of California that would give this drug out to people who are identified.

And over the years, it got cheaper and cheaper. They said to us, that let us recoup what we put into R&D, and we will make it cheaper. Well, this was a brand new discovery of a condition. And they then did the research, and the prices did come down. I can't understand now why drugs like Coumadin and so on are still high here in this country, because the R&D was done decades ago.

Mr. GUTKNECHT. Well, incidentally, and the Coumadin was developed—the research was actually done by the veterinarian school at the University of Wisconsin. So—there really weren't that many—I don't think the expenses of developing that drug were all that high.

Ms. WATSON. So I don't know the truth in all of this. But I do understand that after September 11, one of the few companies—industries that made profits were the drug companies. And big time profits. Because during that time you were taking something to go to sleep, to wake up, to ease your headache, to ease your pain, etc.

And I don't know where it is that we can really believe that there is a reason for these kinds of prices in the United States. Can you help us think through that?

Mr. GUTKNECHT. Well, I can only say this: I think most corporations price their products at what they believe the market will bear. I mean, there is something that you know does not—it is not something most companies want to talk about, but it is a fact. Whether it is Microsoft or General Motors, whatever. One of the interesting things, and part of the reason that I got interested in this issue, is when people try to mislead me, I become even more curious.

And one of the answers I originally got when I asked, well, why are the prices so much different? They said it is the currency rates. Well, I am looking here at the back of this—and this a book I recommend to anybody. It is called the Big Fix. It is by Catherine Greider. On the back of the going it has the prices. It says, $14 United States, $22 Canada. So there is a difference. But it is more expensive in Canada.

And, it is on virtually every other product, it is the reverse of what they tell us. And so the more I learned about this, in fact, even the whole story of price controls, and it is very difficult to unravel this, but even the story of price controls is somewhat misleading, the story that we received from the companies and their representatives. Not every country has these very complicated price controls as we are sometimes told.

And the other thing we have been told is that somehow, well if they don't participate, they are going to take their patents away. Well, that may be the bluff by some countries. But, if they are a signator to any kind of world trade agreements, they ultimately have to abide by the patent laws that are pretty much internationally accepted in all industrialized countries. So I would only say that take everything that you hear from some of sources with a bit of a grain of salt.

Mr. BURTON. Mr. Sanders.

Mr. SANDERS. Thank you, Mr. Chairman. And thanks very much for your testimony, Mr. Gutknecht. Let me jump, and I am in agreement with virtually everything that you said, and applaud you for your years of hard work on this issue.

Let me be practical for the moment. I don't know if you want to, the chairman asked you a little while ago about Mr. Thompson, if you wanted to talk about that. We have got a vote coming up, we think maybe tomorrow night, as early as tomorrow night, and one of the things is the likelihood of us getting a reimportation provision in there.

What is your views on the Cochran amendment? Which, I have a feeling, may be similar to mine, and maybe talk a little bit about the reimportation legislation that passed a few years ago, and that we constantly hear from spokespeople of the industry, that we were told by both Thompson and Shalala that it was unsafe. All right. So I wanted to be more practical. Where we are now in terms of reimportation? What does the administration have to say? Where are we going?

Mr. GUTKNECHT. I would be a bit uncomfortable speaking on behalf of Secretary Thompson. I can say it was a very constructive meeting.

And I came away from the meeting feeling as if Secretary Thompson understands this issue better than we might think. But I will say this: From my perspective, I think to a certain degree, the Secretary is being held captive himself by some of the bureaucracy and the experts inside the FDA.

And so at some point, we as the policymakers, and in fact, he did agree with this statement. They work for us and not the other way around. It seems to me that we are going to have to continue to apply pressure to get the FDA to do what most of us at least believe is the right thing to do, in fact, what most consumers believe is the right thing to do.

In terms of what will happen in the next 24 to 36 hours, I don't know. I mean, I honestly don't know. But I do believe that facts are stubborn things. And I do believe that ultimately we are going to win this issue. I mean, ultimately, Americans are going to get access to world class drugs at world market prices. Will we do it in the next 36 hours? I don't know.

Now, I have learned in this business, and I was in the State legislature. And I will say this: I was the equivalent of the whip in the Republican Caucus in the State House of Representatives. We never had a closed rule. When we had an important issue, we brought it up, we debated it, we offered as many amendments as we wanted. The only rule there was no one could speak twice until everone had a chance to speak once.

But, sometimes the debates would go on for 10, 12, 14, hours. My own—I believe this down in my bones. And regardless of party, regardless of anything else, I think if you are going to take up an issue as important as putting a prescription drug benefit as part of Medicare, perhaps the single most important change in Federal entitlements in 40 years, it seems to me we have an obligation to each other, to have a thorough debate, to at least allow some amendments.

And so I would hope that by tomorrow, people will realize that this is far too important to try to debate and decide in 2 hours with no amendments on the House floor. But, what will happen? I do not know. I cannot speak for anyone else. I am not speaking for any group, just as an American.

Mr. SANDERS. Well, thank you for your comments on that. And I would just say that, as has been the case in the past, if we had a clean opportunity to bring up a decent amendment as we certainly could put together, I think we would win overwhelmingly.

I think you would get strong Republican support, probably overwhelming Democratic support, and that frustrates me very much. I would just remind the committee that even a couple of years ago, you talk about the bureaucracy, and I will talk about the powerful special interests. I don't know how many people know this.

But during the campaign, when George Bush was asked, what is your view about the right of Americans to get medicine from Canada? His initial response is, sounds good to me. Why not? What is the problem? That was his initial response. His response changed over the years. People got to him.

So I think that we have an issue that the vast majority of the people in this country support us on. I think a clean vote would allow Members of Congress to show their support for it.

So we have to stay vigilant. I just worry about the power of an industry which can thwart what the American people, what Members of Congress want. Thank you very much, Gil.

Mr. GUTKNECHT. Mr. Sanders, if I can just say this. I can't speak for anyone else. I don't know what is going to happen in the next 36 hours. But I can promise you this. This issue and my voice are not going to go silent. We are going to continue to press this as long as it takes, because this is an issue whose time has come.

And whether it happens in this bill, whether it happens in a discharge petition, whether it happens in some other form, sooner or later, we are going to get an opportunity to express what I believe is the will of the vast majority of Americans, and when that moment happens, we will begin to change the course of this debate.

Mr. SANDERS. I will probably see you in the Rules Committee.

Mr. BURTON. Thank you, Mr. Sanders. Let me just comment before we go to Mr. Allen. I hope you are right, that this is an issue that we can continue to fight if we don't prevail tomorrow night.

But, once that genie is out of the bottle, I am very concerned that the prices are going to be—that the cost to the U.S. taxpayer is going to be so high, and it is going to go up so fast, and the dependency of so many seniors on the program is going to be so great, that it is going to be awfully hard to do something about it. I hope you are right, and I hope we can do something about it.

Mr. Allen.

Mr. ALLEN. Thank you, Mr. Chairman. I will be very brief. I just wanted to get your reaction, Mr. Gutknecht, to one point. You talked about fees. You talked about what people pay for prescription drugs, the prices charged on a wholesale basis, I take it under—or a retail basis under the Federal Employees Health Benefits Plan.

Mr. GUTKNECHT. Well, that is what Blue Cross Blue Shield actually pays for those drugs.

Mr. ALLEN. Is that in Minnesota?

Mr. GUTKNECHT. No. I think that is for Federal employees nationwide.

Mr. ALLEN. We ought to check this. My understanding has been, that the different companies, different insurance companies negotiate on their own. For example, I have been told that the Blues negotiate separately. Aetna may negotiate with Pfizer or Merck individually on behalf of their beneficiaries. But that the Blues negotiate separately. They don't combine when they go ahead.

And in Maine, there is so many misconceptions about the Federal Employees Health Benefits Plan. In Maine, people are running around saying Federal employees have all of these choices. Well, it depends on which State you live in. In Maine, we have one choice, we don't have multiple choices at all for people like me or any other Federal employees, we just have one plan, it is a Blue Cross Anthem Plan.

But I think that what I suspect that we would find, unless I am wrong, that because they negotiate separately, they don't even know what, you know what one Blue Cross plan doesn't know what another Blue Cross plan is actually getting for a price. And if we had more transparency, if we had more understanding. So many things are priced in the public market. And anyone in the public knows what price is being paid by someone else. This isn't true in the prescription drug market, and it seems to me it would be—more transparency would be desirable.

If you would like to comment on it, I would be glad to hear your thoughts.

Mr. GUTKNECHT. I could not agree with you more. In fact, you are going to have Dr. Steve Schondelmeyer who has been one of my mentors on this whole issue, who is going to testify later. And perhaps he brought with him a chart that he has shown to me. And it is amazing. You take the drug Cipro, which we all learned a lot about after the anthrax scare.

And I think his numbers, and he is much more of an expert than I am. But the price on Cipro, the wholesale price on Cipro can range from over $11 per tablet, down to, I think, 19 cents. OK. That is inside the United States. But, in terms of transparency, here is an interesting example.

When we were doing some research earlier we wanted to find out what the VA was paying for some of these drugs. And so we made an inquiry to the Veterans Administration to find out if, in fact, they are getting good prices relative to the rest of the world.

They have written into their contracts that they cannot share, and will not share, the prices that they pay for the drugs, even with Members of the U.S. Congress.

Mr. BURTON. Really?

Mr. GUTKNECHT. Really. And so that is part of the problem, is you never really know what the prices are here in the United States. And you are absolutely correct. Blue Cross Blue Shield of Vermont may not know what Blue Cross Blue Shield of Maine is doing.

But, I think this applies to all of the Federal employees. But I can't be certain. As I say, the source for us was the Office of Personnel Management.

Mr. ALLEN. So you think that is an average probably?

Mr. GUTKNECHT. I think that is probably the average. But the point really is, you are dealing with a big group, whether it is off a nickel or a dime, you are still 40 to 50 percent higher than you can buy those same drugs for by walking in off the street in Europe.

Mr. ALLEN. Mr. Chairman, thank you.

Mr. BURTON. Thank you, Mr. Allen.

Before you go, I just have one more comment, I hope you can join us up here to question the next panel. You mean to tell me the VA, that is under the control of the U.S. Congress as one of the bureaucracies of the executive branch cannot tell us the cost of the pharmaceuticals they are buying because of a contract they signed with the pharmaceutical companies?

Mr. GUTKNECHT. That is what I am told. We were told that very directly.

Mr. BURTON. I would like for the staff to check on that. Because I think that is ridiculous. There ought not to be anything, unless it is a top secret black secret issue where national security is concerned.

Mr. GUTKNECHT. I reminded the people over there that I have a security clearance as a Member of Congress, that they could share this. And, you know, I would even be willing to, I would be willing to promise that I wouldn't share the information. But we ought to, as policymakers ought to know if we really are getting the kind of deals that some people claim, because if you look at it, the last study I saw as a member of the Budget Committee, I did find out that I think several years ago, 2 years ago, the estimate was that VA and other Federal agencies would buy approximately $5 billion worth of prescription drugs.

You take a number and, you know, if there were additional savings that could be made, even 30 percent, you know, that is $1½ billion. And I haven't been away from Minnesota so long that, $1½ billion is still an awful lot of money.

Mr. BURTON. We will see if they can keep that from us.

Mr. GUTKNECHT. And Mr. Chairman, if I could. Pardon me. My staff just handed me. Just as another interesting side-bar to this, the NIH will not release their total investment in pharmaceutical development to Members of Congress.

Mr. BURTON. Are you talking about R&D?

Mr. GUTKNECHT. Yeah.

Mr. BURTON. Well, that is baloney.

Ms. WATSON. Question, Mr. Chairman. Can we require an audit?

Mr. GUTKNECHT. Well, that is an excellent question as well. And I think one of the things that I would like to see, and we have been pretty busy on other issues here over the last several weeks and some of us have been doing a lot of special orders and other things on this issue, trying to see if we can't move the ball forward. But I think now, if we have a little more time to catch our breath, one of the things I would like to see perhaps this subcommittee and I would be happy to participate with that is lay out the parameters to have the General Accounting Office, do some audits, and ask some tough questions, and begin to at least get to the bottom of what, exactly, do the taxpayers pay for, whether it is the cost of

the drugs or the amount of research and development. And ultimately, I believe that the taxpayers are entitled to some rate of return on their investment, which is why I am a co-sponsor of a bill with Representative Rob Emanuel from Illinois who was, as you know, an investment banker, and said that we ought to get at least a 10 percent rate of return. Some of the stories we have seen is, right now, where we do have royalty agreements on some of these drugs, the return is something like 0.38 percent. And you can actually do better than that in your checkbook today. So not a very good rate of return.

Ms. WATSON. Once you do the R&D, the manufacturing of the drug costs just pennies. You have these huge vats, and what is the cost of a little tiny drug? I was just talking to my staff person who had to take Cipro after September 11, and I was asking him; he said they received them free. So that meant that the Department bought up millions of dollars worth of drugs. Now, we ought to be able to understand the cost to all of this. We are the policymakers—and I am preaching to the choir, but I have to make this point because I am very emotional about it. We are the policymakers, and we have to do and appropriate in the budget. We ought to know what we are dealing with. And I still can't understand why prices for the same product are different in Canada than here, but I do know there is a cap. But these are the questions we need to raise, Mr. Chairman.

Mr. BURTON. I think having a GAO investigation, and also talking to people on the Appropriations Committee and find out why they appropriate money for an agency like the VA, and we can't see, as Members of Congress who vote for that appropriation, we can't see where they are spending it and how much they are spending money for.

Mr. GUTKNECHT. I will say this, though, Mr. Chairman. We do have access. And this is where we are beginning to unpeel this, unravel the layers of this onion, if you will. And we are getting closer and closer to some interesting things. There is a program called the 304B Program that allows disproportionate share hospitals access to drugs at incredibly low prices. And that is an area where, you know, literally this subcommittee could spend, you could have a hearing every 2 weeks for the next 3 years to begin to understand this. But this is where, ultimately, I think you will find the lowest drug prices in the United States.

But the fascinating thing is, the huge disparity between the 304B prices and what the retail price is. And in these average wholesale prices, some of these companies have 10 or 11 different categories. Once again, you will have a very good expert in Dr. Steve Schondelmeyer who can explain this technically much better than I ever could.

Mr. BURTON. Well, we probably ought to bring the next panel up. And I hope you will join us questioning these people.

Mr. James Love, Mr. Stephen Moore, Dr. Stephen Schondelmeyer, and Mr. Bill Vaughan, would you come up and be sworn, please. We appreciate your patience. I know you have been sitting there for a long time. I hope you didn't get saddle sores.

[Witnesses sworn.]

Mr. BURTON. We will start with you, Mr. Love. We'll go right down the line. We are going to have a lot of questions for you, in all probability, so we would like for you, if you can, to keep your comments to 5 or 6 minutes or 7 minutes. And then anything else that you think needs to be given, we can put into the record.

STATEMENTS OF JAMES LOVE, ECONOMIST, CENTER FOR THE STUDY OF RESPONSIVE LAW, WASHINGTON, DC; DR. STEPHEN SCHONDELMEYER, PROFESSOR OF PHARMACEUTICAL ECONOMICS, UNIVERSITY OF MINNESOTA; WILLIAM VAUGHN, DIRECTOR, GOVERNMENT AFFAIRS, FAMILIES USA, WASHINGTON, DC; AND STEPHEN MOORE, SENIOR ECONOMIC FELLOW, CATO INSTITUTE, WASHINGTON, DC

Mr. LOVE. Thank you very much. My name is James Love. I work for a group called the Consumer Project on Technology. It is a Washington, DC, nonprofit organization. I've done a lot of work on pharmaceutical drugs beginning in about 1991, when I was asked by Congressman Ron Widen to look at the contract between the National Institutes of Health and Bristol-Myers Squibb for the commercialization of Taxol, a cancer drug you referred to earlier.

I do most of my work in the last 7 or 8 years internationally, and my first—I am not going to read my statement but just bring up some things that are in response to the comments that have been made in my 6 minutes.

In 1997, I submitted testimony in South Africa to the South African Parliament Committee on Health on the Issue of Parallel Trade. South Africa, at the time, was interested in doing what Europe does, which was described very eloquently by Representative Gutknecht. They wanted to buy in the world market. There was a very inefficient mechanism for distributing drugs in South Africa. Prices were priced for the—basically for the white population, the wealthier people in the country, and the new government was trying to find market-based solutions to increase the cost. And that's where I first discussed this issue with Representative Bernie Sanders back then, because the United States was putting a lot of trade pressure on South Africa not to use this mechanism of parallel trade. And there was, in fact, a rather extensive Federal Government policy to prevent parallel trade across the board all over the world and to have prices really set country by country, to have market segmentation country by country. And so I have been interested in this parallel trade issue for some time.

It has been our position that—and the position of most consumer groups that free trade in the area of consumer goods has a lot of benefits for consumers, and that—but we recognize in the area of medicine that there is an issue between poor countries, like countries in Africa, Latin America, and Asia, and countries in Europe, the United States, Canada, Japan, and areas like that.

So one recommendation that we focused on very closely is we'd like to see liberalized parallel trade in pharmaceutical drugs for the higher-income countries between each other, but not between the rich countries and the poorer countries. And the definition we have focused on has been the World Bank definition of high-income countries, which includes not only Canada but Japan, the European countries, Australia, New Zealand, lots of different countries.

I think I wouldn't want to rely only on parallel trade from Canada, if I was doing this, because Canada is a small country, we are a big market. I think the way to think about this is really to think about the larger community of high-income countries. But I also think you have to send an important signal globally, which is that are not going to try and exploit low prices that are sort of, you know, the idea of putting products in the market in poor countries, the lower prices, because there is a difference between a country that has a per capita income of $500 or $1,000 per year and one that has $30,000 per capita income. So that is one point I want to make, is that I think that it shouldn't just be between here and Canada; it should really be between high-income countries, of which we pay far more than other countries do.

Second, in my testimony I wanted to call attention to a couple of things. One is that the recent circuit court opinion in Jazz Photo versus International Trade Commission, which was a case involving cameras, appeared to us to overturn the First Sale Doctrine on patents, which was a new development. And we believe that if you want to exploit parallel trade in pharmaceuticals, you will have to overturn or fix this decision in the Jazz Photo decision. I am not a lawyer, but I would recommend that your committee staff look at the Jazz Photo decision to ensure that you are not—that you don't sort of achieve the goal of passing the regulatory measure in the Congress and find out that there is a First Sale Doctrine issue out there that has to be addressed. The Jazz Photo issue received almost no publicity whatsoever. And we did contact a number of congressional staff about it at the time, but I think it was too complicated and esoteric for most people to understand what this idea of the First Sale Doctrine means to international trade, but it is important as it relates to pharmaceuticals.

Second, I wanted to mention that in the WTO/Trips Agreement, there is a provision that says that countries can choose their own national policy in the First Sale Doctrine. It is Article 6 of the WTO Agreement on Patent Rights and Other Intellectual Property Agreements, the Trips Agreement. The problem is, that it says that you can't—it has been interpreted by many legal experts to say that you can't discriminate on that policy among countries based upon income. And we believe this is a problem that should and could be easily fixed, and we have actually raised both of these issues and other very similar issues with both the European Commission Trade Officials and with the U.S. Trade Representative in the State Department, and asked them to support a solution in the trade system that allows us to liberalize trade among the wealthy countries, while basically barring the parallel trade of medicines from poor countries to rich countries.

I wanted to make a mention on this question of the R&D. All the time I worked on pharmaceutical drugs and all the cases, in every single case, every abuse, every problem, every pricing, every access issue, the defense is always about research and development. That is always basically it. And if you haven't had it, if you work in this issue a long time, you would know that. That is always what it comes down to.

So one issue is that there needs to be far better transparency. If you look at the tough study where they come up with this num-

ber of $802 million, it is a case that they assigned about a half a billion dollars toward the cost of clinical trials. Now, clinical trials is not some sort of mumbo jumbo magic thing that nobody can figure out what they cost. There is a competitive industry of people who do clinical trials, and the FDA has data on the number of patients in clinical trials. And someone that can do a little bit of grade school arithmetic and do a little math, you can count the number of patients that are in clinical trials, you can pick up the phone and find out what it costs to do clinical trials from the competitive sector which does this, and you can do a reality check on the half billion dollar number.

Now, when we talked to Joe DiMasi and his coauthors, we asked him for two numbers. One, what is the average number of patients in the clinical trials of your study? And, No. 2, what is the per patient cost of clinical trials? And they won't give us those two numbers. Now, there is just no reason. Because if you have those two numbers, then the reasonableness can be very easily verified, because if they don't map in to observable data, then there is a problem. I would just like to mention that.

No. 2. There is a lot of IRS data on R&D, because companies get tax credits related to R&D. So the IRS, for example, in 1999, reported that U.S. R&D based on world sales was 7 percent of turnover. And if you adjust that for the fact that the companies do some R&D overseas, it comes in at under 9 percent of turnover for 1999, the last year we had data. And that was about roughly half of a comparable number out of the PhRMA Survey in terms of the percentage of the sales that was being reinvested in R&D. So, there is enough evidence on the record, as well as from the Orphan Drug Tax Credit, which relates to clinical trials that calls into question some of the popularly held numbers about the R&D. And it's I think outrageous that there is as much reliance on one person, Joe DiMasi, for the cost of drug development, who works consistently for the drug companies in producing information, and no effort whatsoever even to rely on the government's own data, including, for example, what the NIH, has mentioned of problems in getting data out of them, spends on the clinical trials which it performs at taxpayer expense which are routinely not very public.

I will add that, in a recent FOIA case, the National Institutes of Health filled out an affidavit where they said the royalty rates on government-funded inventions is a secret, and they will not disclose it on an FOIA request. Now, can you imagine if I was to get an exclusive right to a government drug worth billions of dollars, take the money, and hire hundreds of lobbyists to lobby the Congress for whatever cause I wanted to do, and someone asked me: Where are you getting all the money to do all this activity? And I'd say, well, I have a license to a government, you know, patent, and it's worth billions of dollars, and we have a lot of resources. And they would say, well, how much are you paying for that patent? And I'd say, I am sorry, it is a secret. I mean, it's not competitive, I didn't really win it in any sort of contest other than a beauty contest. But that is essentially the way we license drugs.

The other thing is that for quite a few drugs the U.S. Government actually has a royalty-free license. The U.S. Government has a royalty license in d4T, a drug for AIDS which you can buy for

less than $50 a year outside the United States, which costs almost $4,000 a year. It was invented at Yale on a government grant. And you can tomorrow buy this from generic suppliers and the U.S. Government could on its royalty-free rights to the patent. The same thing is true with ddl, ddC, Nevirapine and T–20. And those are just drugs for AIDS.

We have asked the OMB a couple of months ago, we asked Mitch Daniels, before he left OMB, if he would write a letter to the Department of Health and Human Services and the Veterans Administration, asking them how much money they would save by exercising the rights they have never used in government-funded drugs.

The last thing I wanted to mention, because I am sure I have exceeded my 6 minutes here, is that we think we are on a treadmill that is going the wrong direction as far as the trade agreement. The U.S. Trade Representative is trying to now solve the unequal pricing thing by making everyone else pay higher prices. So we now regulate innovative products in Korea by, we have a reference pricing system administered by the United States on Korean drugs. We require Korea to pay the average of what they call the A7 prices on innovative drugs. That is U.S. Government regulation of Korean drug prices. We are trying to force Australia to raise prices on drugs, New Zealand, Canada, quite a few other countries.

Now, one of the problems is, is that we are spending now about 2 percent of GDP, about $200 billion a year. If you were to eliminate patent protection altogether, you would easily save $150 billion a year in the U.S. market. Now, what do you get for that $150 billion? You'd probably about, based on the IRS data, roughly about $20 billion a year of R&D financed.

Now, if that's the case, if companies are, in fact, financing about 10 percent of their turnover as the IRS indicates in development of new products, that is an expensive way to fund R&D. Plus, if you look at the FDA data, they say that two-thirds of the new products developed in the last 3 years are no better than existing therapy. So even if you are getting 10 percent of the turnover back in new products, you probably only care about half of that.

The question is, for the next 20 years, can you continue a system where you are getting back maybe a dime or a nickel on the dollar for R&D as we approach 2 percent of GDP and start heading toward 3 percent of GDP? I mean, how far can this go?

So what we think the change should be is to make the trade agreement focus on the percent of GDP which each country has to support for R&D. That is a rule that works better for an African country, for European, for Canada. It is sort of more of an equal rational basis, and give the countries flexibility in how you get there. If you want to follow these new open-source development models, if you want to do high prices, if you want to research mandates, public funding, we don't really care. We want R&D. But we have to think and examine and think newly about new business models for funding R&D, because, ultimately, we are buying R&D when we pay these high prices, but we are not doing a very good job of being a consumer of the R&D purchases.

And I was just at a meeting today at the World Bank. The World Bank is going to schedule a meeting in the fall. Well, it's the recommendation anyhow on different business methods, business

models for funding R&D. And the thinking that people have now is you want to separate the marketing after a product is developed from when the R&D—the initial development. And the goal is to create—this is kind of high tech and far out, and I'm probably ruining my whole performance here by being too far off the reservation.

But what we are trying to say is that the original sin is to finance R&D out of a 20-year marketing monopoly. I mean, you give a company a 20-year monopoly on a drug for cancer, well, what do you think they are going to price it at? I mean, they know what it means to somebody when they have cancer. You give somebody a 20-year monopoly on a drug for heart disease, well, of course, they are going to price it pretty high. That is basically nature following its own course.

If you were to find a different way to fund R&D, even a competitive, entrepreneurial private-sector business-driven thing, you could easily double what the competitive R&D sector makes, the biotech sector, all the guys that actually do the real innovation, and still come out way ahead and have prices priced fairly to people when they actually enter the market.

The marketing process is the cancer on the drug, the system. You can have a very efficient system of distribution, you can have a very efficient system of innovation. But when you tie the two together and finance R&D with that 20-year marketing monopoly, you have a gazillion problems.

Thank you very much.

Mr. BURTON. Thank you, Mr. Love.

[The prepared statement of Mr. Love follows:]

Statement of James Love
The Economics of the Pharmaceutical Market in the United States
James Love
July 25, 2003

Introduction

There was a time when pharmaceutical costs were a fairly minor part of national health care expenditures, and not a great burden on patients and public and private insurers. Those days are gone. In the past two years national expenditures on pharmaceutical drugs increased by 31 percent, and total outlays are now approaching about 2 percent of GDP. Globally, US consumers represent nearly half of the world market for pharmaceutical drugs, spending far more per capita than most countries, including those with similar incomes.

The prices for drugs have soared, and investors are pushing firms to charge ever-higher rollout prices. Conditions that recently were treated for $2.50 per day now see prices for new drugs at more than $4 per day. For severe illnesses, prices can be much higher. Each class of anti-retroviral drugs has been priced higher than the previous class. The new HIV drug T-20 is priced at $20,000 per year for a single drug. An AIDS patient needs at least three. T-20 by itself is priced nearly twice has high as a three drug cocktail based upon d4T+3TC+Neverapine. Gleevic, a new drug for Leukemia, is priced at more than $160 per day. Ceredase was introduced in the market at a price of more than $.5 million for the first year of treatment. .

How high will prices go, and how much can we afford, and why do US consumers pay more than everyone else for medicines? Today I will briefly examine the basic characteristics of the pharmaceutical market, mention that typical measures that could be undertaken to obtain better prices, and finally to suggest it is time to consider a new trade framework that would permit every country to take measures to protect consumers, while ensuring we continue to support high levels of R&D to development new medical inventions.

The Economics of the Pharmaceutical Market

What are the most important features of the pharmaceutical market?

1. Products have high fixed costs of R&D, but often low marginal costs of production.
2. Most new products are protected by strong intellectual property protection, granting long marketing monopolies.
3. Innovation is decentralized and highly competitive. Big pharma typically acquires its technology from smaller firms or non-profit research institutions.
4. Marketing is expensive, requires large fixed costs, and is dominated by handful of large firms.

5. There is considerable evidence that firms can avoid price competition even when there is competition within a therapeutic class. A good example of this is the market for anti-retroviral drugs, where prices for each mature class of drugs used in a HAART regime are quite similar (within the three classes of nucleoside, non-nucleoside and protease inhibitors).
6. Firms engage in much non-price competition, and spend enormous energy and resources to influence physicians, and bias the evidenced base for prescribing.
7. There is a very inefficient private R&D agenda, which can be explained by well-known problems in the markets for innovation. Firms have incentives to invest too much in "me-too" products, and too few incentives to invest in truly innovative products.
8. The patent system is costly to administer, prone to many errors, and is subject to abuse and frequently used to achieve anticompetitive ends.
9. There are huge benefits from extending monopolies, and firms will invest huge efforts and resources to do so. A 2 year extension of a top selling drug can now be worth more than $15 billion, and with incentives like that, there is little wonder we observe astonishingly energetic efforts to not only game the rules, but to constantly change the rules.

The need for more transparency of drug development costs

There is considerable controversy over the costs of new drug development. The latest industry-supported, published estimate for R&D of a "big pharma" new drug pegs the cost at $802 million (DiMasi, et al, 2003), more than three times the estimate the same authors published a little more than a decade ago. In contrast, the Global Alliance for TB Drug Development October 2001 report, *The Economics of TB Drug Development,* estimates that a new TB drug can be discovered and developed for $115 to $240 million, including the costs of failures. For some classes of drugs, costs appear to be even lower. The easiest figures to verify are those associated with the costs of clinical trials. DiMasi and colleagues claim nearly $300 million for the risk-adjusted costs of clinical trials, before capital costs and a half billion after capital costs. The TB Alliance figures are far less. For some products the costs associated with clinical trials may be fairly small. For example, the US Internal Revenue Service (IRS) reports that expenditures on pre-approval clinical trials are a little more than $10 million per approved Orphan product.[1] (But even the smaller costs of Orphan Drug development has increased significantly in the past ten years.) Interestingly, the IRS reports lower outlays for R&D on new products than is reported by the annual PhRMA survey, a fact rarely mentioned by analysis who tend to rely almost entirely on PhRMA's own surveys and experts for data on these issues, ignoring independent data even when it is available.

We have attempted to reconcile some of the conflicting data regarding costs by asking DiMasi and his co-authors to provide two simple numbers. In the DiMasi et al. study, what are:

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[1] James Love, "What do US IRS tax returns tell us about R&D investments? Van ontwikkelen tot slikken, Pharma Selecta congres.

1. the average number of patients in clinical trials, and
2. the average cost per patient in the trials?

If we have these two numbers (which have not been provided) we can better evaluate the reasonableness of their claims regarding costs.

With regard to R&D costs, our own analysis of IRS data suggests that firms invest less than 10 percent of turnover on development of new products.[2]

Understanding better the actual costs of the R&D process is important, but it is also important to understand the character of investment flows, and to evaluate the productivity of those investments.

Despite increased public and private investment in R&D, the number of new chemical entities approved by the U.S. Food and Drug Administration has not changed markedly, and many of the newer products only offer marginal improvements over existing therapies. Over the past three years, the US FDA determined that two thirds of new chemical entities were did *not* represent a significant improvement compared to existing marketed products for the treatment, diagnosis, or prevention of a disease.

Table 1
USA FDA NME APPROVALS
2000 to 2002

	2000	2001	2002	Total
Priority	9	7	7	23
Standard	18	17	10	45
Total	27	24	17	68
% Priority	33%	29%	41%	34%

Source: FDA Center for Drug Evaluation and Research.

It should be emphasized that that firms spend much more on marketing and distribution than is spent on R&D, and this is a consequence of the patent system, which finances R&D in part by providing firms a long marketing monopoly. Tim Hubbard has illustrated the consequences of this system in this simple demand curve analysis.

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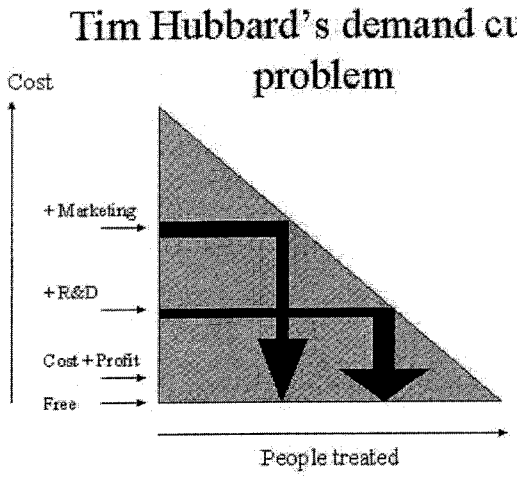
[2] James Love, "What do US IRS tax returns tell us about R&D investments? Van ontwikkelen tot slikken, Pharma Selecta congres.



What to do about high prices

The fundamental problem is that while we depend upon a mixture of public and private financing for drug development, we nearly always end up with a private monopoly marketing the product. Left to their own devices, firms seek to maximize profits, and that means, charging what the market will bear. Government in nearly every developed economy use their buying power to bargain or to set prices for medicines. If you don't do that, you have to take an inventory of the areas where you can make markets more competitive. Remember, competition is your friend. Monopoly leads to high prices. This is not a profound statement, but it is important.

Parallel Trade

This hearing is largely about parallel trade in pharmaceuticals, and it should look at the issue much broader than jus the North American market. Our own view is that parallel trade is a good thing for US consumers, and it should be expanded to Europe and other developed economies. But we do not think that parallel trade or referencing pricing should extend to poor countries. We recommend that parallel trade extend to countries that meet the World Bank classification for high-income countries.

There are two legal issues should receive more attention in the parallel trade debate.

1. First, the committee should study the *Jazz Photo Corporation v. International Trade Commission* court decision to determine if the court has eliminated the first sale doctrine for patented products.

2. Second, determine if Article 6 of the WTO/TRIPS agreement permits applying the first sale doctrine selectively to only countries of similar incomes.

Eliminate or reform wasteful non-patent *Sui Generis* IP rights

Many of the barriers to competition are created by the US Congress, and they include an ever expanding number of extensions of patents and regulatory barriers to entry. It would be a nice start to take an inventory of those barriers to competition, and ask two simple questions:

1. How much do they cost in terms of higher US prices, and
2. What do we get back in terms of R&D?

Better Management of Publicly Funded Inventions

We have asked OMB to ask the DHHS and the Veterans Administration why the US government has failed to ever take advantage of the existing US government rights to use patents funded by the federal government to acquire generic medicines in cases where the government pays for the medicines. There are many drugs in this category, including for example, d4T, and HIV drug that sells for less than $50 per year outside the USA, and nearly $4,000 per year in the United States. The US government has a royalty-free right in the patent on the new $20,000 HIV drug T-20. The federal government has rights in many patents, but never uses them to buy generic drugs.

New Trade Framework for funding R&D

The TRIPS accord and hundreds of bilateral and regional trade agreements focus on patent and other intellectual property rights, but none of them deal directly with the important issue of R&D. US consumers pay for about half of the private sector funded R&D, but also probably 80 percent of the global expenditures on publicly funded R&D, nearly $100 per capita.

What makes far more sense for the trade framework is to require countries to fund a certain amount of the GDP for health care R&D, say 10 to 15 basis points on GDP. This would allow countries more flexibility in meeting trade obligations, but still deal efficiently with free rider problem.

If this was done, we could look at the larger issue. If the cost of the patent system for the pharmaceutical sector is now greater than $200 billion per year, and we are only

financing about $20 billion in R&D on new products (based upon IRS data, and excluding R&D funded by foreign consumers), then it may be too inefficient. It is costing us at least $150 billion per year to have patents, and we are only getting back about $20 billion in R&D, and most of that on products that are not particularly innovative. When the prices of medicines were much lower and we were spending less than 1 percent of GDP on medicines, such inefficiency might have been acceptable. It will clearly not be acceptable in the future. We need to look at new business models for funding R&D, and in particular, we need a business model that separates the market for development of new productions from the post market entry life of a product. It makes more sense to impose obligations on insurers to funding R&D through annual lump sum fees, invested in competitive R&D enterprises, but have post development products be priced closer to marginal costs. You could easily double private sector R&D spending, while making sure that seniors and others could buy every product as a generic. No realistic cost benefit analysis could justify the status quo, which is why it has been defended as dogma, rather than on pragmatic grounds..

Mr. BURTON. Mr. Moore.

Mr. MOORE. Thank you, Congressman, for inviting me to testify. In keeping with the truth and testimony requirement, I would simply say that neither I, nor the CATO Institute, receives any government funding, nor are we seeking any.

When I was putting together my testimony the other day, I realized that I sort of—when I was writing this testimony, that I sounded like a shell for the drug industry. And I just wanted to also tell you that I receive no money from the drug industry; although the CATO Institute gets some, we get very little, although we would like to get more.

The first paragraph of the testimony that I put together has been, unfortunately, proven true by this testimony—by this hearing. I should say that I am really profoundly demoralized by just about everything that I have heard so far today in this testimony, because, you know, the lesson we learn—I'm an economist, and the one thing that we know is that when it comes to the medical industry, we throw out every principle of good economics that we know works in every other industry. And its this paradox about why we throw out all of those principles that we know work in every other sector. And so when it comes to health care, you know, what are we talking about doing? We are talking about price controls. Well, we know from history that price controls have never worked. We are talking about creating this huge new, expensive open-ended entitlement sometime maybe even later this week in the House of Representatives. We know that's what's bankrupted our country and created these huge deficits on our grandchildren. We know that free markets work and command and control systems don't. And yet everything that—every direction that this hearing is headed in is toward these dysfunctional policies.

Let me just make a couple of provocative statements in response, and I will just put my testimony in the record, if I could, and say—and this is maybe the most provocative thing of all: Prescription drugs are not expensive. They are cheap.

Now, I know probably everybody's in this room's jaw drops when I say that. But when you look at the drugs that we pay for and the incredible technological boom that we have seen in this industry, even drawing from your own testimony, Mr. Chairman, where you list these various drugs and how much they cost and how much you can get them for in Canada. And I was thinking, my God, just think back 30 years ago and we said, my God, you can get an ulcer drug that can relieve you from the pain and suffering from ulcers for $105. People would say, my God, that is incredible, or heart disease. Most of these drugs that you are talking about on this list deal with heart disease, they are in the hundred dollar range. Its a miracle. It's a miracle that you can get these drugs today that didn't even exist 40 years ago for $100.

Now, let me just give you one sort of personal example. My sister has a child who has epilepsy. Epilepsy is unfortunately one of these diseases that we don't have good drugs for yet, although sometime in the next 10 to 20 years those drugs will be developed. If you told my sister that we had a new drug for epilepsy for her 4-year-old and it cost $10,000, she would say this is the greatest bargain that she could ever imagine. She would pay that $10,000. She would

pay $50,000 for that drug. And so we have to remember that the prices that we are paying for these incredible life-saving drugs are cheap, not expensive.

The third thing I would say is that it is a good thing, it is not a bad thing, that our drug industry is so profitable. Next week, I am going to be testifying before another committee about why the steel industry is not so profitable or why we are losing money in the telecommunications industry. This is an industry that we should be celebrating that is making so much money. And, in fact, that is good for the workers in the industry, it is good for all of us who are shareholders in the drug industry. So, again, it is sort of this upside down thinking that somehow because the drug industry is making a lot of money, that's a bad thing. It's a very good thing, and, in fact, one of the reasons, unfortunately, that this industry has to spend $150 lobbying every year, unfortunately, is because this industry is almost under daily assault from Congress trying to deplete its profits, I think, very unfairly.

A fourth point that I would like to make is that government has caused the high-price spiral in health care. We know this. You know, everybody—and, again, I'm an economist. I talk a lot to investment groups. And when I talk to investor groups, they are always talking about the fear of deflation. You have all heard about, you know, the specter of inflation out there on the economy. And I always tell people, you know what? There's two industries where deflation is not a problem right now. And you probably know what those two industries are: Health care and education. And what is it about these two industries that cause spiraling cost increases, not the virtuous cycle of lower prices? And the answer to that, of course, is government. Government plays this very pervasive presence in the industry which causes prices to rise.

Now, this is not just speculation on my part, it's not just free market theory. If you look at some of the graphs I provided in my testimony, Congressmen, you will see, for example, that it wasn't until Medicare and Medicaid were created that we saw the very rapid rises in the cost of health care. Prior to Medicare and Medicaid, which was the big infusion of government interference in health care, prices in health care did not rise faster than other industries. Once we had this heavy presence of government in the industry, costs of health care exploded. So right you have health care costs rising at two to three to four times the rate of inflation of other goods and services.

Now, I say that because it points out the real idiocy of the idea of saying, well, gee, if we have the government now get heavily involved in the area of drugs and we impose price controls, that somehow that's going to stop higher prices. In fact, we know from the past that government interference is what causes the higher prices in health care.

The fifth and last point is that you have all said that you are not for—well, most of you have said you are not for price controls. But in truth you are. You are just using different terms. For example, when you, Congressman Gutknecht, were talking about parallel pricing, parallel pricing is price control, it's just a fancier term of describing it. If Canada has a price control—and of course Canada does have price control on drugs. And then we say, well, we are not

going to impose price controls here, we are just going to go let people buy drugs in Canada, we are simply piggybacking off of their price control system. So it's a de facto price control system that you're talking about.

So, we shouldn't mince words. What we are all talking about is imposing price controls on the industry.

And my final point is—because I see my time is up—is that price controls, I think, would be a total catastrophe. A lot of what has been talked about, I think, so far in this hearing is really what I would describe as free lunch economics. And the one thing that Milton Friedman has taught me over the years is there is no such thing as a free lunch.

Look, if you create this new prescription drug benefit, you are going to see exploding costs on the backs of taxpayers. There is no question about that. And the only way you could possibly prevent that would be to do something to control—to cap the price of drugs. If you do that, you are talking about price controls.

Now, what is the impact of price controls? If you take—price controls mean that companies in the industry are going to make less profits. And if companies make less profits—and this is where I think I would disagree with just about everybody in this room—there is just no argument in my mind that the venture capitalists who put up the funds for these exciting life-saving new drugs of the future will not invest as much. And that will lead to the delay of all of these exciting new drugs that are going to come on the line in the next 25 or 30 years. And if that happens, you will be doing a profound disservice to future generations because these drugs have such a wonderful opportunity of making life on Earth better.

Thank you.

Mr. BURTON. Mr. Moore, I'm sure we are going to have a lot of questions for you.

[The prepared statement of Mr. Moore follows:]

Testimony by

Stephen Moore

Senior Fellow in Economics at the Cato Institute

Before the U.S. House of Representatives

Government Reform Committee

Subcommittee on Human Rights and Wellness

On

The Economics of the Pharmaceutical Industry

June 25, 2003

Thank you Chairman Burton for the opportunity to testify on the pharmaceutical industry in the United States. In keeping with the Truth in Testimony law, I wish to declare that neither the Cato Institute nor I receive any government funds, nor are we seeking any.

Why is it that when it comes to medical care in this country, policy makers in Washington almost always completely abandon sound economic principles that we know work to create wealth and improved services in every other sector of the economy? What exactly is it about the health care industry that causes normally level headed thinkers to devise crackpot solutions to the crises that it invariably turns out, government itself created?

Think about it for a moment. In every other sector of the economy we understand basic economic realities that have fostered our wonderfully prosperous society. We understand that free market mechanisms work better than government command and control solutions. We understand that maximizing consumer choice and competition creates better services and drives down costs. We understand that wage and price controls never produce desired results and create shortages.

What is especially disheartening is that we continue to devise dysfunctional legislative policies that hinder an industry that has—despite government interference—been the greatest saver of life in the history of civilization. Yes, of course, much of the progress in medicine over the past fifty years has been a result of public health measures and government investment in drugs and vaccines through agencies like the National Institute of Health. But we must also recognize that most of the progress in medical breakthroughs have been a result of private investment and the capitalistic entrepreneurial spirit which is in the noble pursuit of progress and profits. (I hope all of this does not seem to be patronizing or simplistic, but there are many policy makers in Washington who actually think that profit is a bad thing when it comes to medicine and that seniors should not have to pay the market price for the drugs they want and benefit from.)

Here's one recent example of the supremacy of our private biotechnology industry. T the race to map, decode, and sequence the 100,000 genes in the human body (the human genome project) was won by a private bio-tech firm, Celera Genomics Group, despite the fact that the government supplied billions of dollars to the NIH for this purpose. This would be like a private space industry company getting a manned rocket to the moon before NASA.

It is no accident that virtually all of the breakthrough medicines and vaccines of the past two decades have come not primarily from government investment, but from private biotechnology firms that are financed through risk capital funding. This is an industry with some 1,200 companies and some 100,000 workers. U.S. firms have won the race against foreign firms in almost every one of the top 20 breakthrough new wonder drugs of the past fifteen years.

Let me repeat again the truly preposterous claim that is made over and over again that the U.S. drug industry is not just one of America's most profitable industries, but that it is too profitable. But how can this be a problem? It is profitable precisely because it makes products that people want—in some cases want desperately. Its inventions are arguably the most valuable to society. We would only have a serious problem if the situation were reversed: that the drug industry has no profits.

Now I should note here that I get no money from the drug industry, and that the Cato Institute, gets some, but not a lot. I am a huge fan of this industry simply because I benefit from its products. We all do. In fact, let's reflect for a moment on the last century of biomedical progress: in 1900 the death rate from infectious diseases was 700 per 100,000 Americans. Today, the death rate from infectious diseases is 50 per 100,000. We have been so spoiled by the amazing life saving inventions of the bio-medical industry that we don't even think about the diseases anymore that just a century ago killed millions upon millions of Americans. Back then the leading cause of death were pneumonia, influenza, tuberculosis, bronchitis, and other awful diseases like small pox, whooping cough, and polio.

More recently, consider the progress that the medical industry has made in the two leading killers today: heart disease and cancer. The survival rate from cancer is now twice as high as it was in 1960. The age adjusted death rate from heart disease is now about one-third what it was as recently as 1950.

All of this is to say that the drug industry in the United States doesn't just build a better mousetrap. This is an industry that lays golden eggs. It is now developing a new generation of exciting cures and miracle treatments for dreaded killers: cancer, heart disease, Lou Gehrig's disease, altzheimers, AIDs, multiple sclerosis, arthritis, and on and on. This industry is dedicated to unlocking the biological explanation for these and scores of other diseases that cause pain, suffering, debilitation and death.

New wonder drugs, when they are first introduced on the market are almost always tremendously expensive—just like cellular phones and video recorders were when they first hit the consumer market. But who would argue that the price for new drugs is not worth paying? A recent Washington Post story relates how new arthritis treatments are literally enabling people who have been crippled by this disease to magically rise and walk away from their wheel chairs. What price would an arthritis sufferer pay for such a treatment? Perhaps everything they have. For all the wringing of hands about the expensive costs of drug treatments, the real wonder is not how costly these treatments are, but relative to their value to those who are cured or at least relieved from pain by them, how cheap they are. We should never forget the great wisdom of Emerson who said that "the first wealth is health."

As we speak, Congress is debating a comprehensive prescription drug benefit for seniors. My advice is stop and make a long reflection on the implications of what you are doing. We ought to be very careful—no, Congress ought to have close to 100%

certainty--that any policy changes we make that impact the drug industry, nurture it, rather than interfere with its life saving potential.

Herein lies the tradeoff that Congress seems to want to make. Almost everyone understands that to give seniors all the new drugs they want at a subsidized price could well bankrupt the nation. We can't afford to give every senior every new drug, because these drugs are expensive, anymore than Uncle Sam can build a swimming pool in every American's back yard. So we are confronted with a dilemma. If we are to subsidize drug purchases for seniors, either we let taxpayers shoulder the weighty financial burden through much, much higher taxes (after all, there is no such thing as a free lunch, someone has to pay), or we pretend there is a free lunch by imposing price controls on the drug industry and take the money out of their profits.

Those are really the only two viable options given the current proposals for Medicare prescription drug benefits. Both are very bad options.

If we demand that taxpayers shoulder the cost, we are creating a fiscal blackhole that future generations may never find a way out of. We should recognize a few fiscal realities about the prescription drug benefit plan:

1. The history of Medicare is that the predicted costs always far exceed the predicted costs. When Medicare was launched in 1965 the program was expected to cost $15 billion in 1992. Instead it cost $90 billion. The program was six times more expensive than anticipated. Same with Medicaid. And the same would almost certainly true of a Medicare prescription drug benefit.
2. The unfunded liability of Medicare is $12.9 billion and of Social Security $11 billion. The expected unfunded liability of prescription drugs over 75 years is expected to to be $3 to $7 billion. To put this into context. The value of all the assets of the Fortune 500 companies is less than $5 trillion. When you are in a hole, stop digging. The prescription drug benefit will drill us further into financial bankruptcy at a time when we should be reining in entitlements—especially those for seniors. According to David Walker, the head of the U.S. General Accounting Office, "Absent changes in the Medicare and Social Security programs, sometime during the 2040s, government would do nothing but mail checks to the elderly and health care providers."
3. The prescription drug benefit will almost certainly cause drug prices to rise absent price controls. Medicare and Medicaid were what created the stampeding inflation in health care. In the 15 years prior to Medicare and Medicaid, health costs grew at 3.4% per year. But since 1966, health care costs have run ahead at 7 percent per year and at almost twice the level of overall inflation. We can expect drug prices to rise in a similar runaway pattern if the government gets in that business too.
4. As life expectancy rises, the cost of drug benefits to seniors will grow very rapidly as we pay to keep Americans alive in their last years of life. In just the next eight years the Health Care Financing Administration predicts that spending on prescription drugs will rise from $100 billion today to $250 billion in 2009.

Can the next generation of Americans afford the tax burden that would be required to pay for these new prescription drug benefits? The National Center for Policy Analysis says that to pay for existing promised Medicare and Social Security benefits Americans will be forced to pay a payroll tax of not 15% but 25% by 2025. Add to that a prescription drug benefit and that payroll tax could easily rise to nearly 30% of the worker paycheck. We will see a tax revolt in America that would make the Boston Tea Party seem like a day at the park before our children fork over those hefty taxes.

There is a cartoon in a recent newspaper that summarizes the story well. A senior is pushing a baby carriage through a drug store check out counter and the cashier says: "That will be $54 for your prescription." The grandfather turns to the infant in the baby buggy and says: "Pay up." Let us not mince words. What we have here under consideration is simply a very cynical version of fiscal child abuse.

Congress should reject it.

But this brings us to the alternative form of paying for prescription drug benefits. Take it out of the hide of the industry. This is the most dangerous and unwise course of action available—and yet a course that Congress is very likely to travel.

When government intervenes in an industry as it would do on a massive scale with a new prescription drug benefit, it almost in all cases correspondingly enacted new regulations and controls of that sector of the economy. The only option that Congress would have to constrain costs of pharmaceutical drugs if the new Medicare drug plan is enacted, would be to impose controls on the prices that companies can charge. The government would soon become the single payer for drugs, which gives the Health care Finance Administration virtual unlimited monopsony power.

The temptation to limit prices for profitable drug companies could be politically irresistible. This is especially true given the overcharged rhetoric in Washington attacking drug companies for what Senator Hillary Clinton of New York has called an industry that charges "excessive profits at the hands of our seniors." Moreover, almost all other countries impose price controls on U.S. drugs, so that the price in Canada for prescription drugs is often less than half what is charged in the domestic market.

Why not impose similar controls here and save the government and consumers money? The answer is that most of the rest of the world has become a free rider on the backs of the drug industry. That foreign countries impose price controls and limits drug company profits lowers drug research and development incentives. These country's behavior thus makes sick people sicker in the long run by depriving them of new wonder drugs that would be brought to market earlier in the absence of price controls.

If the U.S. were to follow suit, the results for our health care system could be catastrophic. The U.S. as by far the largest market for new drugs, now shoulders the burden of providing fair profits for the industry. If the U.S. were to impose price controls

as Canada does, we would see a marked reduction and delay in the introduction of new drugs. There is no getting around this political reality.

For those Americans who actually suffer from debilitating diseases, the harm to society of delaying even for a few years new drug patents for heart disease, cancer, and the like is substantially greater than the short term benefit of lower prices. Moreover, in the long term, miracle drugs are the cheapest way to treat disease, so that price controls probably lose money for the government in the long term.

The bottom line is this: Congress needs to keep our drug industry innovative, profitable, and competitive to the point of being globally dominant. Any step that Congress takes to weaken this industry not only impairs one of America's genuinely competitive cutting edge industries—one that reduces our balance of trade deficit by billions of dollars and employs hundreds of thousands of high paid American workers—but also retards the basic health of this and future generations of Americans.

I would end by quoting from a Washington Post new story from June 24th, which underscores the continuing dynamism and contributions of the bio-medical industry:

"Last October a researcher named Patrick Iversen, whoworks at a bio-tech firm in Corvalis, Oregon, pulled genetic information about a virus off the internet and started designing a drug to attack it. He tapped into computers in Bethesda to be sure his drug wouldn't be likely to cause side effects. Satisfied, a week later he had developed some vials of a white powder."

"If all goes according to plan, a doctor nurse will draw some of that drug into a needle later this year, perhaps in a hospital in mosquito plagued Cleveland, Ohio, and inject it into a person with West Nile Fever. The West Nile Virus drug has been developed with the help because he relied on something called antisense technology, which is the specialty of his company, AVI BioPharma Inc, a money losing biotechnology firm in Portland."

Competing drug companies say they are finally close to making antisense drugs work. If they are right, the blistering pace of Iversen's West Niles drug might be a harbinger of the future. In the rosiest scenario of this long-range future, antisense will be like the medical ward aboard the Starship Enterprise, the space vessel from "Star Trek," where the doctor isolates the dread germ that's turning the crew into goo, whips up a perfectly tailored antidote in minutes and sends everyone back to work."

"It's the magic bullet," says Alan Gewirtz, a hematologist at the University of Pennsylvania, who has worked on this technology for a decade. If the approach were to work reliably, "you could kill bacteria, you kill viruses, you could keep joints from being inflamed, eyesight from growing dim, blood vessels from getting too thick and closing off."

These are the golden eggs that I mentioned earlier in my testimony, that are laid by the bio-tech industry. It is the exciting future of the bio-technology industry that is within our grasp. For the sake of our children and out children's children, we should race to get there and we should be willing to pay almost any price to do so. If the U.S. pharmaceutical industry makes tens or even hundreds of billions of dollars getting us to this near-disease free future, all the better.

Mr. BURTON. Mr. Vaughan.

Mr. VAUGHAN. Thank you, Mr. Chairman. And thank you for inviting Families USA to testify.

I think in the last year we got a $100,000 grant from HRSA for some work on presumptive enrollment of children in SCHP.

We get no drug money, and we want no drug money, and we tend to lobby for an America in which every family would have $50,000 to be able to spend on drugs. But until that happy day occurs, we try to work for better drug prices, and we do seek ways to encourage research.

We have issued numerous reports over the past decades on the pharmaceutical industry. Our next report will be out on July 7th. And the doctor here is helping us with the data. It's going to be on the 50 prescription drugs most used by seniors, and we don't have the final hard numbers yet, but I think you won't be shocked that those prices are going up much higher, much higher than CPI. And it once again shows why so many seniors are crying for help.

Your hearing, sir, is extremely timely, because it is absolutely certain that Congress will be back visiting this issue time and time again. And the question will always be coming up, can we get a better price for the pills we buy without killing the golden goose of research? And Families USA thinks we can.

Why do Americans pay higher retail prices than Canadians and Europeans? Page 2 of our written testimony goes into that at some length. But, basically, everything in the health sector is higher in the United States. It's not just drugs that we are a bad buyer on. And the solution won't be easy until we really change our approach in a number of areas. But in the meantime, it's not surprising that societies that do control their prices better than we do have caused the drug companies to charge our citizens more. We are in a sense paying for their successes.

So, what can we do immediately? In the Medicare Prescription Drug Bill that is going to conference, you can make some major short-term savings, we think. One, we believe the best way to get a better price is to use the clout of large buyers. Just like Wal-Mart gets a better price from suppliers than smaller companies, so can Medicare, Medicaid, and the VA. I think you should all be very proud of the price our veterans are getting. And, through the conference, we hope that you will try to support Medicare through its contractors, not directly, but through its contractors being an aggressive buyer.

Second, we hope the House Medicare conferees will accept the Gregg-Schumer Generic Amendment that was approved 94 to 1 in the Senate. This bill is estimated to save Americans about $60 billion over the next decade. We have all seen documentation of the abuses of the brand name companies blocking the generics getting to market. FDA has issued some regs that are a little bit better than current practice, but not nearly as strong as Gregg-Schumer, and we hope the conferees would take that.

Third, we very strongly support Congressman Allen's and the bill you have cosponsored, sir, H.R. 2356 that would really do some decent, good research on the comparative effectiveness of drugs. We shouldn't have to be buying me two products. We ought to know which one's good and go for that one. And, congratulations. I see

the Post endorsed that this morning, that approach. We hope it can be added to the Medicare bill.

Fourth, there is at long, long last a chance to end the average wholesale price, really, loophole or abuse that's been occurring out there. We urge the conferees to take the AWP solution that CBO says is the best; the two Chambers have very different approaches. We urge you not to forget that some of the worst AWP abuse occurs in the kidney disease program. And please don't leave them out of that reform.

And finally, and not least, we hope the House will support free trade in pharmaceuticals with Canada and other nations with good quality control such as your bill, sir.

What can be done in the long run to get better prices without price controls was the committee's letter to me. And we understand the reluctance to talk about price controls, because the pharmaceutical industry has done really a brilliant job of saying that if you even frown at them, their profits will disappear, and they are not going to cure death, and that you are going to kill your constituents. And that is very hard for any elected official to deal with. And we would urge you to reverse that argument, that the American pharmaceutical industry with these incredible profits, with these unprecedented profits, doesn't do enough research. That every time they spend money on some of those lobbyists over there that your staff has put up, that's a dollar not being spent on research; that every time they spend more on advertising and overhead than they do on their R&D, they should be ashamed. And you should push back on this because no other industry when their profits are down says, oh my gosh, we are going to hold our breath, not invent a new product, and it's just terrible. This is not the way businesses work in the rest of our economy.

On the last page and a half of our testimony, we walk through a variety of ways that you might get some cost containment without, we think, price controls and that would actually use Medicare's buying power to try to create new product. We suggest some ways to recoup some of the investment that the public has put into the R&D. There is old ideas like the old Renegotiation Board from World War II and the Korean War that recaptured excess profits that were partly supported by the government. And we would urge you to consider some possible long-term contract negotiations where we will get a better price and are guaranteed to buy your product for a long period of time.

So there are ways to jujitsu or end run this, if you question us, we won't do any more research. And we congratulate you on taking on this tough issue, and wish you good luck.

And before I quit, sir. On the exchange of information, I have heard—and I don't think it's changed—that within CMS, Medicare and Medicaid, the Medicaid best price number cannot be told to the people in Medicare when they pay on Part B, outpatient drugs. So, within a single agency of HHS, they can't talk to each other. So you can add that to your list of information requests.

Thank you very much.

[The prepared statement of Mr. Vaughan follows:]

Statement of Families USA
by William Vaughan
Before the Subcommittee on Human Rights and Wellness
Committee on Government Reform
U.S. House of Representatives
June 25, 2003

Mr. Chairman, Members of the Committee:

Thank you for inviting Families USA to testify on the important issue of "The Economics of the Pharmaceutical Industry in the United States."

Families USA is a national non-profit health consumer advocacy organization. It has issued numerous reports over the past decade on drug pricing, the need for more generics and collusive practices in the industry. Since 1999, we've released reports on the rate of inflation in the 50 prescription drugs most commonly used by seniors. Our next report is due about July 7th, but I regret that we don't have the new data ready yet.
It appears that the numbers will show that the growth in the cost of prescriptions used by Medicare seniors and people with disabilities continues to far exceed the growth in the Consumer Price Index. It will once again show why so many seniors are crying for help: we have the highest retail pharmaceutical prices in the world, and those prices keep rising faster than inflation.

Your hearing is extremely timely. We are pleased that Congress appears to be about to pass a major Medicare prescription drug bill. But during the next decade, CBO predicts Medicare beneficiaries will use about $1.84 trillion worth of prescriptions. With a budget limit of $400 billion, there is no way that Congress can provide as much help as people want or need. It is absolutely certain that Congress will be asked to revisit the issue of pharmaceuticals—repeatedly.

Because of the gaps—or donut holes—in both Chambers' bills, Medicare beneficiaries will be exposed to significant out-of-pocket costs at a time of illness. They will want a better Medicare benefit, and they will want drug price moderation. The Medicare program will need to get the best price for pharmaceuticals if it is to have any hope of expanding the benefit—or avoiding financial crisis.

With deficits facing us, it will be hard to fill in the gaps in the new law, and the question will come up repeatedly, can we get a better price for the pharmaceuticals we buy, without killing the Golden Goose of pharmaceutical research?

Families USA thinks we can.

On the Subcommittee's question: Why do Americans pay higher retail prices than residents of Canada and Europe? An excellent question. Former Oregon Governor Kitzhaber was quoted as saying, in effect, that the Medicare prescription drug debate is

kind of a distraction: the real debate should be on why the price of prescriptions is so high!

Reasons for differences between U.S. and OECD prices

There are a many reasons for the difference between us and other societies. But basically, everything in the world of health is more expensive in the United States than other advanced industrial societies. Americans spend about 60 percent more than the OECD median nation for hospitals and doctors. Yet, we get fewer services, fewer doctor visits, and fewer days in the hospitals, and we generally do not get better outcomes. We have a lot of high tech equipment compared to other societies, but some countries are even ahead of us in things like CAT and MRI scanners.[1] And again, for 4 points of our GDP---about $400 billion per year---we do not get much additional value in health outcomes over other nations, yet we still have 41 million uninsured on any one day. Families USA recently reported that in a two-year period, nearly one out of three of us below age 65 had a period of un-insurance. And as the Institute of Medicine reported last week, having those many people uninsured probably costs our economy between $65 and $130 billion per year. It also costs us about 18,000 premature deaths per year—or about 2 to 3 unnecessary deaths during the time it will take to hold this hearing.[2]

The data on this U.S.-OECD split is clear in the work of Johns Hopkins' Gerard Anderson. Other research by Princeton Economics Professor Uwe Reinhardt seems to show that the phenomena of high U.S. costs but fewer U.S. health care services is largely due to the reimbursment/salary structure (plus unusually high overhead and paperwork costs) in the U.S. health sector versus that of other OECD nations.

It is harder to control costs in the United States, because our health care system (or I should say non-system) is so much more fractured than the foreign systems. Other societies tend to have a universal-coverage, social-insurance system. Think of controlling health costs as a balloon. In foreign systems, it is possible to inflate or deflate the 'cost balloon' without huge distortions. In the United States, if one payer squeezes too hard on part of the cost balloon, it just causes bulges and distortions in other parts. Providers won't serve the tough buyer. Or they shift costs to others, just like we shift costs for caring for the uninsured onto those who have insurance and onto Medicare. Managed care found this out a couple of years ago, when it squeezed so hard it caused a backlash. In our diverse system, no payer can get too far out of line with others in trying to lower costs, or the providers won't play—and thus it is much harder to control costs.

Similar to the cost shifts within our system, in the area of prescription drug costs, it makes sense that foreign cost controls result in higher prices in our uncontrolled market. We are paying for the success of others in giving their consumers a better deal.

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[1] Gerard Anderson, Uwe E. Reinhardt, Peter S. Hussey, and Varduhi Petrosyan, "It's the Prices, Stupid: Why the United States Is So Different From Other Countries," Health Affairs, Vol 22, No. 3, May/June 2003.

[2] Institute of Medicine, Hidden Costs, Value Lost, Uninsurance in America, June, 2003.

Families USA believes that the solution to all this would be to have everyone under one insurance umbrella and cost control system. But that is a discussion for another day.

What can be done in the short run to help get better prices?

In the Medicare Prescription drug bill that appears to be about to go to Conference, you can make some major savings.

Families USA believes that the best way to get a much better price from the giant multinational pharmaceutical companies is to use the clout of large buyers. Just like WalMart gets a better price from suppliers than smaller companies, so can Medicare, Medicaid, and the VA get a better price if they are allowed to be aggressive buyers.[3] At every step in the Conference Committee process, Congress should choose to help Medicare, through its contractors, be an aggressive bulk buyer. For example, before 2006, if a discount card is offered to Medicare beneficiaries, it should be administered by just one or two winning contractors. Multiple vendors negotiating prices independently will not get deep discounts. With too many vendors, beneficiaries are likely to be no better off than they are now with a CVS card or an AARP card. By allowing a large buyer to use the clout of Medicare's purchasing power, Congress can truly help beneficiaries.

Congress allows the VA to negotiate and is proud of the low-cost pharmaceuticals available to our nation's veterans. Congress has allowed Medicaid to get the best price. Surely the nation's 41 million retirees and people with disabilities deserve a similar best price.

On the issue of best price, we note that throughout these Medicare bills, there are provisions that exempt the prices that are negotiated from being counted for purposes of the Medicaid best price. At the rate we are going, Medicaid may soon have one of the worst prices! We urge the Congress to consider what these exceptions will mean for Medicaid. If Congress really wanted to get a good price for the public, it would combine Medicare and Medicaid and the VA's purchasing power to truly get one BEST price.

Families USA hopes the House Medicare Prescription drug conferees will accept the Gregg-Schumer-McCain-Kennedy generic drug amendment that was approved 94-1 by the Senate last Thursday. This bill is estimated to save Americans about $60 billion over the next decade, about $20 billion of which will accrue to public programs.

Generics not only cost less, but they decline in price rapidly. Over the past few years, many hearings and government reports, including one last summer from the FTC, have documented the abuses the brand drug industry has employed to keep generics at bay. The need for reform is clear.

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[3] We commend to the Subcommittee the article in the Washington Post Outlook section of June 22, 2003, by Marc Siegel, "This Doesn't Have to Be the Price We Pay," in which he points out that an aggressive Medicare purchaser would be able to get a much better price than lots of smaller buyers.

The FDA has just finalized a regulation to address some of the brand company abuses. However, the FDA regulations do not go far enough, and in some cases continue the delay in generic entry. Specifically, the FDA regulations fail to give enough market certainty to generic manufacturers by not requiring brand manufacturers to initiate patent infringement lawsuits within any specified period. This uncertainty may cause some generic manufacturers to delay market entry. The regulations also still allow generic companies to "sit on" the 180-day exclusivity period, leaving the door open for brand/generic manufacturer deals that keep all generics off the market. Patents were never intended to give innovators never-ending exclusivity that would stifle innovation—but that is what has happened, and that is why Congress should include the Senate Gregg-Schumer amendment in the final Medicare bill.

--Medicare should be able to decide whether or not to pay for a drug that is just a me-too drug. We support H.R. 2356, by Rep. Allen and by you, Chairman Burton, which would require NIH to conduct research on the comparative effectiveness and cost-effectiveness of prescription drugs that account for high levels of use by individuals in federally funded health programs. We hope that your approach to intelligent purchasing by Medicare could be added to the Medicare Prescription drug bill.

--There is a chance to end the Average Wholesale Price abuse, in which companies have actually used the AWP spread to encourage doctors to use less effective but more profitable drugs—surely a form of malpractice. Families USA urges you to urge the Conferees to take the AWP reform approach that CBO says will achieve the most savings. The Senate bill reduces the AWP to 95% and then 85%. We believe that drug prices are often much lower than 85% of AWP, and that the House's effort to develop a competitive bidding type of distribution system will probably save more money and stretch the Medicare dollar. Some of the worst AWP abuses have occurred in the end stage renal disease (ESRD) program, where dialysis centers make most of their profit outside of the dialysis composite rate. The abuse is so large that one wonders if patients' are not being given much more medicine than they need. The Senate appears to lock in the current inflated ESRD AWPs, but exempts EPO from any future lock-in. Hundreds of millions could be saved in this sector, and EPO—which is garnering its manufacturer about $1 billion a year in profit from Medicare—should not be exempt.[4]

--We also hope the House will support the Senate amendment for what is basically free trade in pharmaceuticals with Canada and, hopefully, other nations with good quality control standards. Yesterday Rep. Gutknecht and Emanuel introduced a similar bill, and we hope the House will consider it. A great deal is made over the fact that the re-imported drugs may come back adulterated or sabotaged. As a consumer advocacy group, we hope the FDA will spend as much time worrying about someone adulterating tank loads of Molson's or quarts of Canadian maple syrup as they do worrying about trade in pharmaceuticals.

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[4] See the HHS Inspector General's 2003 Red Book (Cost-Saver Handbook), for further description of these items and the billions of dollars in savings that are possible.

What can be done in the long run to get better prices without, as the Committee's letter said, "price controls"?

We understand the reluctance to talk about "price controls," because the pharmaceutical industry has mastered the art of saying that anything that impacts their record (highest-of any-industrial-sector) profits will cause them to stop all research. If you question them, you will be guilty of not saving your constituents from terrible diseases. That charge is very hard for a Member of Congress to deal with.

Families USA urges you to reverse this rhetoric. The United States Pharmaceutical industry does not do enough research. With these incredible, year-after-year record profits, they should be doing more research. They should be ashamed at how little research they are doing. They are passing up the chance to cure cancer, and Alzheimer's, and AIDS every time their sales and advertising and profit targets exceeds their R&D budget. They are failing American society every time they spend money on a me-too drug instead of a breakthrough drug. Members of Congress should push back at the industry and its front groups and demand more life-saving, life-enhancing research.

Following are some ideas on how to get more research out of this profitable industry without price controls:

--Stop the advertising. It is frequently inaccurate or doesn't give adequate weight to the adverse reactions. It clearly drives demand and even over-utilization. An important, blockbuster, life-saving drug doesn't need to be advertised. What we are seeing is billions of potential research dollars wasted on the advertising of me-too pills. We should copy the European Union and not allow it.

--There should be a surtax on pharmaceutical industry profits when their overhead, advertising, sales, and profits exceed their R&D budgets. The money from such a tax should be dedicated to NIH pharmaceutical research and development or to helping the public pay for needed pharmaceuticals. Of course, no company would need to pay the tax: all they have to do is reduce overhead and increase research.

--Use Medicare/Medicaid's buying power to force more research. Under this proposal, Congress could estimate what Medicare and/or Medicaid will spend on pharmaceuticals in the coming year. For example, in 2006, let us say it will be $40 billion. Then Congress could set a rate of inflation, say CPI or WPI, and let us say that is 5 percent.[5] Then in 2007, Medicare/Medicaid should spend 105 percent of $40 billion of $42 billion. But if in 2007 spending is higher than $42 billion, then in the next year (2008) the rate of growth would be reduced to 'recover' the amount of overspending in 2007. But the key to driving the companies to spend more on research would be to take the reduction out of OLD product, and not out of recent NEW, breakthrough drug prices. The FDA—or the NIH in Chairman Burton's bill HR 2356---could determine what was an important breakthrough drug. The pharmaceutical companies would know that if they want to sell into the huge Medicare/Medicaid market, they will face gradually lower prices on their

[5] In this example, we assume no growth in population served.

older products, but if they can bring a new breakthrough drug to market, they can charge anything they want. The company that makes the most new, important drugs will have the most profits.

--Do a better job of recovering the public's investment in pharmaceutical research and rededicate that money to research or to programs that help citizens buy the new medicines. A soon-to-be-published book by Merrill Goozner, entitled The $800 Million Pill, documents how almost every major drug breakthrough of our lifetime has come from the research base funded by the government and its taxpayers, yet the companies get almost all the profits and the taxpayer gets little on their investment.[6] Congress could establish a board, like the World War II-Korean War-Cold War Renegotiation Board, that would look at how much the taxpayer contributed to the development of particular drugs and recover the investment over time. The old Renegotiation Board collected hundreds of millions from defense contractors over three and a half decades. It basically audited the books of weapons contractors who had undertaken difficult and novel defense projects and determined whether they had made a fair profit or a windfall profit. If the profits were excessive, the public recouped some of its defense dollars. A similar board is worth considering in the pharmaceutical sector, since so much of the investment comes from the publicly-financed research base.

--When a breakthrough drug enters the market that may be largely paid for by Medicare (e.g., an Alzheimer's drug), it is worth considering a system of negotiations on price. Something similar to this almost happened with the introduction of EPO, a drug mostly paid for by Medicare to lower anemia in kidney disease patients (a program largely financed by Medicare and Medicaid). An effort was made to get a low price on EPO in exchange for a commitment for years of purchases, regardless of other new drugs coming on the market. The deal never happened, but the jawboning appears to have obtained for Medicare a lower price. The drug's manufacturer makes huge profits from Medicare, but in the past has complained that its U.S. price is lower than its price in other nations. If accurate, that is one of the few cases where U.S. citizens may be paying less for a drug than the citizens of other nations. Whether a lower-price/long-term-commitment-to-purchase arrangement could work for both government and manufacturers is worth exploring.

Thank you again for inviting us to testify. Good luck on what will be a most difficult and important task.

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[6] For just one example, see the Wall Street Journal on June 9, 2003, and the article (based on a GAO report) entitled, "U.S. Recovers only $35 Million of $183 Million Spent on Taxol. NIH Says It Lacked Power to Pressure Bristol-Myers for Better Licensing Terms." Taxol, of course, is the best-selling cancer drug in history, with sales of $9 billion.

Families USA received $100,000 from HHS HSRA for work on presumptive eligibility in the State-Children's Health Insurance Program.

William Vaughan worked for various Members of the U.S. House of Representatives Ways and Means Committee between 1965 and 2001. He served on the Health Subcommittee for 16 years, the last five years as Minority Staff Director. In 2003, he was hired as Director, Government Relations, Families USA.

Mr. BURTON. Thank you, Mr. Vaughan.

Mr. Schondelmeyer.

Mr. SCHONDELMEYER. Good afternoon, Mr. Chairman, and committee members, especially my Congressman from Minnesota, Mr. Gutknecht. Thank you for your kind words earlier.

I was asked rather last minute to come testify, and I did rearrange the schedule, and am glad that I was able to be here. I will submit a statement after today. I did provide you with a set of charts that show some data and information that I will try to highlight today.

First of all, let me remind us that the Center for Medicare and Medicaid Services Office of the Actuary estimates that we spent about $161 billion on prescription drugs last year. I see that number often quoted. And that is about 10 percent plus or minus of our total national health care expenditures. And I see a lot of people quote this number. And while I believe the estimate by the Office of the Actuary to be a very reasonable and accurate estimate, most people don't understand what it's estimating and misuse the information. They claim that's the total amount we spend on prescription drugs in America every year. Not true. What CMS and the Office of Actuary say that number represents is the amount spent on retail or outpatient prescription drugs every year. That number doesn't include the amount spent on drugs in the hospital, the drugs paid for in the hospital or in the hospital sector of their estimates. And they estimate that very well. Drugs paid for or used in physicians offices, for example, under Medicare Part B would show up in clinics or physicians office expenditures, drugs that are paid for by the military would show up in a different sector of the Federal national health expenditure estimates.

I attempted to do an estimate, accrued estimate of how much we totally spend on drugs every year in the United States, and instead of being $161 billion last year, I would estimate it to be more in the order of about $280 billion. So instead of being approximately 10 plus or minus percent of our national health expenditures, it's really about 18 percent of our national health expenditures, a much larger number. And I have worked with, been in discussions with folks at the Office of the Actuary about my development of these numbers, and they don't disagree at all that—again, they accurately estimated what they claim to estimate, but most people in literature and in testimony and in many other places misuse or misquote that number.

I raise that to start with to say that there are a lot of misperceptions and misunderstandings in this, what we call a pharmaceutical marketplace. I believe in free markets also. And I believe in economics, but I think pharmaceuticals is a marketplace that has structural barriers and structural problems that don't allow a free market to work in a normal way that we would expect. In fact, a couple of years ago, two American economists, two or three American economists got the Nobel Prize in economics for describing what we call asymmetric markets. They focused on the market for lemons, which is another euphemism for used cars. But I would argue they could have just as easily done their analysis on the market for pharmaceuticals, because it's a very asymmetric market.

What do we mean by an asymmetric market? It means that the seller has a whole lot of information and the buyers have virtually none. And the way we have structured our market, just from your discussion earlier, every transaction price level that occurs tries to hide and keep their price away from buyers in the marketplace. And everything I remember from economics says that price information helps the market work better. And our goal is to achieve a reasonable price in the marketplace and an equilibrium price that balances the interest of all parties in the marketplace. I don't see that happening. I would disagree with my colleague Mr. Moore that disaster will come if the government takes some actions to try to regulate the market. Not necessarily price control, but just to make the market work more like an economic market. I would argue that disaster is already occurring, has been occurring for more than a decade in this marketplace where we have people who can't get medicines that they need and they are trying to give price feedback to the pharmaceutical industry.

Why do we have people going to Canada to buy drugs at a lower price? Because they are concerned about the high price of drugs, and they are trying to make a market work, but the marketplace and the structure of the market won't allow it to work.

So, I would argue that we need to understand, pharmaceuticals are different. I think pharmaceuticals are—I agree with you on one point: Pharmaceuticals are absolutely essential to us as a society. Every citizen has used, will use, or should use prescription drugs in their lifetime. When I go talk to audiences, I ask, is there anybody here who has never been sick a day in their life? And nobody with a straight face can raise their hand. And I ask, is there anybody here who has never taken a prescription drug in your life? Occasionally, I will have somebody raise their hand who for personal reasons may not have ever used a prescription drug. But I would argue, there is no one in our society, America, or the world, who doesn't need or won't during their lifetime, need a prescription drug and the valuable drugs that we do have available. But most people have difficulty obtaining them because of the cost.

I would argue even Allen Homer, the CEO for PhRMA, has acknowledged this. He in a statement in the pink sheet back in November 2002 commented that pharmaceuticals are viewed as a necessity. Patients cannot object to what they view as high prices by just restraining from purchasing the product. If I was that epileptic patient that we talked about earlier and let's say one of you was a diabetic patient, and I found out that your drug was cheaper than mine, I couldn't go start buying your drug to treat my epilepsy because it was cheaper. So we have to view the economics of this marketplace for pharmaceuticals not in terms of the industry and concentration of one drug company versus another, but in terms of concentration in a given disease state. Only within epilepsy can you talk about the concentration of the market. Only within diabetes can you talk about the concentration of the market. Any study that argues that this industry is not concentrated based on industry-wide statistics I would argue has no real validity in terms of actual consumer behavior because there is no cross elasticity between diabetic drugs and epileptic drugs as far as I know.

Let me give you some examples of price increases and changes. And I would comment, again, with all due respect to the comments that have been made previously even by some of the committee members, we often misspeak and say that prescription drug prices have gone up 16 and 17 percent in the last several years. That is not accurate. Prescription expenditures went up 16 or 17 percent. Prices though have gone up, about a third of that is—a lot of that is utilization. And the industry reminds us of that and that's true. But they argue that prices are a small part of that. Well, let me tell you how small of a part prices are of that.

First of all, I looked at some major drugs, some of the most prescribed drugs in the country and their price in January 2003 versus January the previous year.

Let's start with Celebrex, a drug to treat pain of arthritis. It went up 6.9 percent. And I would remind you in the last year—this is the first of your charts. It went up 6.9 percent. I would remind you that the Consumer Price Index, less energy, last year went up about 1.8 percent. So, you know, with price increases like that, it's enough to cause you pain rather than to solve your pain.

Second, cholesterol drugs are in the news a lot lately, on TV ads a lot lately. Zocor and Pravachol both went up about 10 to 11 percent. That's 10 or 11 percent on a 1-year change in price of 10 or 11 percent. Now, do you think most of your constituents had a 10 percent increase in income last year? Did you have a 10 percent increase in income last year?

Mr. BURTON. You must be joking.

Mr. SCHONDELMEYER. I am, yes. That means this takes a bigger bite out of the wallet of those paying for these drugs.

Let's look at diabetes. Humulin, insulin went up 10.2 percent. Glucotrol XL, an oral antidiabetic went up 12.7 percent. But let's look over at the other—these are some, but they're—like they say on TV, but wait, there are more. Claritin went up 21.1 percent last year; 21 percent increase. Now, it went over-the-counter in December, and that may help a little bit with the price, although it hasn't totally. But then beyond that is Ultram, another drug to treat pain of arthritis, it went up 24.9 percent last year. Why?

And, finally, Axid, a drug to treat ulcers, went up 26.3 percent and that's enough to give you ulcers.

Why do we see these dramatic price increases? I work with a group in Pennsylvania, the Pace Program, one of the oldest and probably best run programs to provide prescription drugs for elderly in the United States. A fellow name Tom Sneddon runs that program and has done so for more than 15 years. And every year I get from him the top 50 drugs prescribed for the elderly in Pennsylvania, and I calculate then a weighted average price increase of those top 50 drugs used by the elderly. And this is figure seven in the charts that you have before you.

What we found was in the year 2000, those top 50 drugs went up 2.5 percent in price. And this is price, not expenditure increase. In 2001, they went up 5.4 percent. In 2002, they went up 7.2 percent. And last year, between last year and January of this year, they went up about 6 percent.

Now, let me put those numbers in a different perspective, and that's really on figure. I calculated the price increase of these drugs

used by the elderly as a ratio compared to the Consumer Price Index, less energy. And what we see in 2000, the price increase was about 1.2 times the overall CPI, less energy. In 2001, it was double. The price of drugs for the elderly was double the price increase of the CPI. In 2002, it was 2.8 times. And last year it went up 3.4 times the overall inflation index.

Again, what's going on in this industry? Have the costs to the pharmaceutical industry gone up that much? No. I don't think so. I think it's taking advantage of the price they can charge in the market, and also the industry recognizing maybe we are about to pass coverage of prescription drugs under Medicare, and let's get all the price increases we can now, before the government starts paying for them all because it's likely to cut my prices. We saw this phenomenon back when the Medicaid Rebate Law was passed, and I think this pattern is a part of that explanation. So we see an industry preparing for what they think might come in the next 24 to 48 hours or 2 to 3 weeks or whenever you get around to it.

And I encourage, I think we need to deal with the issue of coverage of prescription drugs for the Nation's elderly in the United States. I am not at all arguing we should not do that, but we do need to be careful how we do it.

I think it is also useful to look at prescription drugs and the prices that we pay, and the cost per day of therapy for drug for the elderly for brand-name drugs from this Pennsylvania program was $4.10 per day of therapy. That's figure 5 of the charts I gave you. The average generic cost is only 98 cents per day of therapy, a difference of four to one. And yet we find the private marketplace, the PBMs and the mail-order plans that are supposedly going to bring us more value and save us more money and the Medicare program have the lowest generic use rates. The highest generic use rates come among the elderly who pay cash out of pocket and among the Medicaid program. But when you look at the private, third-party insurers, they don't have as high of a generic-fill rate as our Medicaid program or the cash-pay customers do. And when you look at mail-order, they have the lowest generic-fill rate and generic-dispensing rate of any sector in the pharmaceutical distribution marketplace.

Why do we see strange behaviors like this? I would argue it's in part because of what I would call reverse perverse economics. Again, I believe in economics, and they work. But if we understand them, we can see why we have some strange anomalies in the pharmaceutical marketplace. We have had at least three pharmaceutical companies come to settlements with the Department of Justice agreeing to pricing issues with the government and the Medicare program. TAP Pharmaceuticals, Bayer pharmaceuticals, and then most recently was the settlement that was just announced in the last week or two, Astrazeneca. And in each of these cases, this was a case where the drug companies had figured out that, if I charge a higher price and give the same or greater discount, the doctor makes more money when they prescribe higher-priced drugs. And so when doctors make more money when they prescribe higher-priced drugs, which drug do you think gets prescribed more often, the lower-cost drug or the higher-cost drugs? The higher-cost drug. That is a reverse perverse economic market.

We need to fix reverse perverse economic markets, and we need not to create another one in the design of the Medicare outpatient prescription drug benefit, however it's structured. We need to be very careful not to create that problem all over again.

All of this then gets back to prices in the United States versus other countries and Canada in particular and reimportation. I find it amusing the dialog that has gone on about how dangerous it would be to have reimportation of American-made drugs back from Canada, the same drugs made by the same pharmaceutical company in Puerto Rico shipped up to Canada and then we can't bring them back. First of all, there is—I think I brought with me. The industry has sponsored and there is a group called Reconnaissance International. It has written a book on protecting medicines and pharmaceuticals. It's all about counterfeits throughout the world and issues on counterfeits. And one of the points they make in here is that in the pharmaceutical or in the marketplace—I don't see it right in front of me. Let me paraphrase it. Basically, higher prices are what create the opportunity for counterfeits. That we only have counterfeits when there are either high prices or high-priced differentials between two markets. When that occurs, then we have an opportunity for counterfeit. So it's the higher prices, stupid, that are creating the opportunity for counterfeits, not reimportation. And, in fact, we have counterfeits that we have been told by the industry already exist in the U.S. marketplace even with the FDA's assurances that we are safe and they are already in the U.S. market. I'm not aware of any of the counterfeits that have occurred in the U.S. market coming through channels through Canada. They come from Belize, they have come from Mexico, they come from other places, but I am not aware of any from Canada. I haven't seen any publicly reported that way. So I have to ask, you know, what are we doing? And particularly, I would ask the FDA, explain exactly what level of safety it is that you are requiring before you will sign off on reimports from Canada. I would argue if the FDA required the same level of safety in approving the new drugs they evaluate every year, that they're holding Canada reimports to, we wouldn't ever approve any new drugs. There is much more risk by the drugs approved by FDA each year than there is from allowing reimports from Canada. Now, I am not saying don't approve new drugs. I think we have to as a society and you have to as policymakers and FDA has to, as administrators of that policy, make risk/benefit decisions. They need to do so wisely and informedly. But from all that I see, the evidence, the information in the marketplace, reimports from Canada have far less risk than approval of almost any new drug I saw approved last year. So, let's put in perspective the risks and benefits that we are creating.

With that, I thank you for your time and attention. I am sure we all would welcome questions.

Mr. BURTON. Wow.

Mr. Moore, you have a little old lady who is 85 years old. She lives in Minnesota. She has to buy Tomoxofin or some other cancer drug. She knows if she drives 50 miles across the Canadian border, she can buy it for one-fourth of what it costs in the United States. Why shouldn't she?

Mr. MOORE. Well, I mean, the problem is that if everyone does that, you know, you are going to drive down the—you are to dramatically drive down the profitability of the industry. When you drive down—this is the whole point I was making, that there is no free lunch here. If we, basically, piggyback off the Canadian price control system, you will, basically, drive down dramatically the profits of the industry. The venture capital industry, and the people that I work with are in the venture capital industry, they aren't going to invest. And I don't care how many people tell me that if you take the profit out of the industry, they are still going to invest.

Mr. BURTON. No. We've had people from the industry before the committee, and they admit that they make a profit in Canada. The profit is much smaller than they make in the United States but, yes, they make a profit. I have a friend that I play golf with, he has a number of problems, diabetes and high blood pressure and I think some heart trouble. He was paying $1,300 for a 30 or 60-day supply of all the drugs he needed, which was a lot. He bought a 90-day supply for one-third the cost. So he got 50 percent more, as far as days covered, for a heck of a lot less. The companies are making a profit in Canada. They told us that. Why shouldn't he buy his products in Canada?

Mr. MOORE. Well, it's sort of like saying, I mean, to think of an analogy. Think of the way that, let's say, airlines price. You know, where they have first class and then they have people who buy tickets at full price and tickets that, you know, if you buy them 6 months in advance and you go over a Saturday night and so on, you can buy the ticket round-trip from here to Chicago for $149. And you say, well, why can't everybody get the ticket for $149? I mean, that's sort of, you know, what you are saying. And I think what's going on here is very much of a sort of cross subsidy time of system.

So what I am saying, though, is we just have to get around this idea that by imposing price controls—and by the way, Mr. Chairman, I am such a big fan of yours. And if I've sounded, you know, at all belligerent about this, it's just because I like, Congresswoman Watson, feel very passionately about this issue.

Mr. BURTON. Well, let me interrupt you just to say that Milton Friedman is one of my heros, and I am one of the right-wingers in the Congress.

Mr. MOORE. I know you are. That's why I am so disappointed that you are so wrong-headed on this particular issue.

Mr. BURTON. Well, you are disappointed that I am so wrong-headed——

Mr. MOORE. On this issue, because you are right on everything else. But price controls—you know, when I first worked for Reagan, you know, people forget. The first—very first thing Reagan did when he was elected President, on the very first day, do you know what it was?

Mr. BURTON. Got rid of price control.

Mr. MOORE. He lifted price controls on energy and natural gas. And, boom, the energy crisis was over. So why do we keep thinking that price controls are the solution?

Mr. BURTON. Well, I think the problem is—and I am going to let Dr. Schondelmeyer respond to this because he is antsy over there, I can see him squirming around in his seat. You are comparing eggs with grapefruits. While I'm for the free enterprise system and the free markets, I don't think that people should be raped and get—because a company that controls a certain product can rip off the people because that's the only product they can get to survive. You know, my wife died of cancer a year ago, and she had to have some of these drugs that are very, very important that are under patent. They could have charged $20,000 for those, and if I could afford it, I would have bought them. But at the same time, those same pharmaceutical products could be purchased in Europe and Canada and elsewhere for a lot less. And people who are terminally ill or who may be terminally ill, they shouldn't be denied those products simply because they live in the United States and can't afford them.

Mr. MOORE. And my point is that if we have it your way, those lifesaving products might not exist. And that's what I really find very troubling about—not that they might not exist, but that you are going to delay the introduction of them. And if you do that, that does a lot of damage. I mean, when Dr. Schondelmeyer said that—you know, with all due respect, that there is something different about the prescription drug benefit than other industries, you know, it's this sort of, I believe in free markets, but with all due respect, Doctor, I've heard that about every single industry that has an interest in Washington. We are different; it's the agriculture industry that's different or the steel industries that's different or the automobile industry that's different. And it's not actually what's causing the very price increases that you have talked about with respect to drugs and medical prices has precisely been the third-party payer system that the government's set up.

Mr. BURTON. Let me interrupt you just to say, you are not for the prescription drug bill?

Mr. MOORE. No.

Mr. BURTON. And you were not for Medicare.

Mr. MOORE. I think Medicare has really screwed up the health care system.

Mr. BURTON. And you weren't for Medicaid.

Mr. MOORE. Right.

Mr. BURTON. OK. I want to tell you a story. When I was a State senator in 1969, and I know I look a lot younger, but when I was a State senator in 1969, the Federal Government came into Indiana and said, "if you don't take Medicaid, we are going to withdraw $2.5 million in Federal highway funds."

We had at that time a township trustee system that worked very well. If a person was indigent and needed medical care, they would go to the township trustee. He would say, tell me what your problem is, and he would take money out of the township trustee fund and he would pay for their medical bills. Costs were much less. When my kids were born, $24.50 a day for a semiprivate room. So, you know, prices were a lot less.

I went to the floor of the senate and I said, "Hey, we ought to tell them to take this $2.5 million and put it someplace where the

sun doesn't shine, because it is going to cost 10 times that much if we take Medicaid."

Mr. MOORE. And you were right.

Mr. BURTON. Do you know how much Medicaid costs in Indiana today?

Mr. MOORE. It is bankrupting the State.

Mr. BURTON. $1 billion. I was so far off, it wasn't funny. So I agree with you. I agree with you. But when you are talking about prescription drug companies that are subsidized in large part by the Federal Government, they manufacture a product that people depend on for life, and they charge an exorbitant price in the United States because they say they want to make up for their R&D here, while they are selling it for a very small profit someplace else, where they say they are not making up for R&D, then I just think that is wrong.

If they can prove to me that they have to have that money for R&D, then it ought to be spread over everybody, not just the United States of America.

Mr. Schondelmeyer, you have heard some of this. Do you want to make some comments on what Mr. Moore said? Don't hit each other.

Mr. SCHONDELMEYER. I will try to keep my comments focused here. First of all, I would comment while R&D may be necessary to bring new medicines to the market, it is not sufficient to bring them to the market or bring to patients in a way that treats them and they get better.

One phrase I often like to use is the phrase that a drug that one cannot afford is neither safe nor effective. It doesn't matter how it was discovered, it doesn't matter how much was spent on clinical trials or how much the government looked at it and evaluated it. If I can't afford the drug sitting on the shelf in that pharmacy, I am not going to get better, and my epilepsy won't get better.

And we have a society where we have a lot of people who can't afford drugs they need. Something is broken in the overall economy, and we need to find ways to fix that.

I am open to any—market mechanisms, price control mechanisms. I am open to any mechanism you can show me that will solve that, but I haven't seen either of them solve it yet. We haven't made much progress; in fact, we have kind of backtracked some.

Next I would like to comment that not all of the new drugs that are—the companies that make application to the FDA to have a new drug brought on the market each year, a third to a half, and in some cases more than a half of those drugs weren't ever discovered by the company that applies for the new drug application. They were discovered by another company, a company in Japan or Europe, or by a university researcher or by NIH research, and the drug company just buys the license, like we saw Bristol-Myers do with Taxol.

Mr. MOORE. So what?

Mr. SCHONDELMEYER. Well, they didn't discover them. The drug company didn't spend the money on the R&D.

Mr. MOORE. And the company that did pay for the R&D was the company——

Mr. BURTON. Let's let Mr. Schondelmeyer proceed.

Mr. SCHONDELMEYER. Well, but that story gets told. For example, we heard about AIDS drugs. A colleague of mine at the University of Minnesota, Dr. Robert Vince, discovered Ziotin, a new AIDS therapy. He discovered this drug back in 1986–1987. The university licensed the patent out to, at the time, Burroughs Wellcome. Burroughs Wellcome examined it, kind of sat on it, had a couple of other AIDS drugs in the pipeline. Then they were bought out by GlaxoSmithKline. GlaxoSmithKline had some other AIDS drugs, and they sat on it.

This drug then, they didn't really develop it until the mid to late nineties. And then when they did develop it and applied to FDA, FDA approved it in 4 months. So this wasn't the government that delayed bringing this product to the market. It wasn't the university's research that delayed bringing it to the market. It was the drug companies sitting on it for a decade before they brought it to the marketplace, because they had other AIDS drugs and they wanted to play them out first.

Then, GlaxoSmithKline had the audacity, when they were ready to come to market, to send a letter to the university, "By the way, we are going to make this product in England and we don't believe we owe you any royalties on that patent agreement."

Well, the university didn't agree with them, and they filed suit and eventually arrived at a settlement.

Is this a market? Again, something is broken in that market that needs to be addressed or fixed, and we have new discoveries that are valuable to us that they sit on for 10 years in the marketplace, when we have patients who need those AIDS medications.

Mr. BURTON. Ms. Watson.

Ms. WATSON. We have a severe problem as we try to address providing programs to our seniors. Our seniors are living longer, and the reason why they are living longer is because there are now medications that assist them. So, in order to provide a safety net—and that is our responsibility—we are going to have to be able to lower the cost of the pharmaceuticals that they depend on for their very lives and the quality of their lives.

Not for a minute do I feel that we are going to provide the disincentives that drug industries feel are going to drive them out of manufacturing. I don't think that for a minute, because they have paid time and time again and recouped the money on developing aspirin.

So, what we need to get from the panel is how do we provide the benefit for our seniors who have paid their dues, they worked, and now they are on a fixed income; and in these United States there are drugs, and I want to thank the gentleman who brought this chart in, and maybe——

Mr. GUTKNECHT. No, that is actually my chart.

Ms. WATSON. Oh, your chart. I mean, this is astounding. This is astounding. We share two borders, the northern border with Canada, the southern border with Mexico, and I have been told by my constituents—I represent Los Angeles—that they get in the car, they drive 2 hours, they go over to Mexico, and they get their lifesaving drugs, because the costs are so different.

Now, Mr. Moore, I want you to help me understand why you don't consider giving a break to seniors a good move for business when—if those seniors can consistently live longer and consistently buy those drugs, there is going to be profit, because, you see, once you do your R&D and you produce these drugs, the cost of a single pill is just nominal.

Can you help us with trying to work through the challenges of providing a safety net for our seniors whose fixed incomes might be $800 a month and they have to pay $360 for Tamoxifen here, and they can get it for $60 in Germany—this is the Munich airport?

Can you help us with that?

Mr. MOORE. Well, just a couple of points. One is don't forget for every profitable drug like the ones you have mentioned, there are dozens, scores, hundreds of drugs that fail, that don't make it to the market. So the ones that you are talking about that are very profitable are subsidizing the ones that are failures.

Ms. WATSON. These are the ones I am talking about. I am not talking about the others.

Mr. MOORE. No. But I am saying that the reason there is so much profit in these drugs that you are talking about is because only one in maybe—you probably know the numbers better than I do—but 1 in 20 or 50 or 100 of the drugs that these companies are working on ever make it to the markets. So that drug has to subsidize all the research that is being done on other less successful or never successful drugs.

Let me suggest—actually, I do have an idea about how you could do this prescription drug benefit that actually maybe Democrats would like more than Republicans.

Ms. WATSON. We are open.

Mr. MOORE. You ought to just loan the money to seniors, and then when they die, you know—why should the taxpayers pay for this—take the money out of their estate.

Ms. WATSON. Oh, please, Mr. Chairman. Let me respond to that. I will invite you to come to my district. I represent 650,000, just like my colleagues do, and I want to tell you the range of income goes from zero-minus up to the top of the scale.

Mr. MOORE. Right.

Ms. WATSON. The people who qualify for these programs are the ones who are at the bottom of the scale, and their needs are greater, because I find within the communities that I represent, the poor people come into the system when they are more acutely ill, and they have various conditions that the traditional provider understands and will prescribe a drug that will get to that condition. There are a lot of ethnic minorities.

So an estate, what are you talking about?

Mr. MOORE. No, for those who do have estates. You are right, there are many, many low-income seniors who have no estate.

Ms. WATSON. Would you believe millions?

Mr. MOORE. Millions. But you know what, seniors have the highest rate of home ownership, for example. Why should the heirs get the home rather than the taxpayers who paid for the drug?

Ms. WATSON. You are getting off into something else. Let me give you some facts. I am dealing with facts every day. I am dealing

with the people who march into my office, call my office, write my office, fax my office. I am not dealing with hypotheticals. Forty million uninsured in the United States of America. Eight million of those are in California. And 600,000 of those are probably in my district.

Now, there is no estate. They can't even pay for their burials in many cases.

Mr. MOORE. What about the wealthier? Wouldn't you be in favor of the wealthier people who get the benefits coming out of their estates? Rather than taxpayers paying for it? I mean, I concede your point that there are millions of low-income seniors who have no estate, but there are also millions of higher or middle-income seniors who do have an estate, and the question is who should pay for their drugs. Should it come out of their estate or should it come from your children and my children? And I would say it should probably come from the estate.

Ms. WATSON. I don't even understand how you are defining estate. There is no estate. These are people who have been living on this fixed income, living on Social Security, maybe a little retirement, who cannot afford their drugs.

Mr. MOORE. Yes, but even upper-income people are going to derive benefit.

Ms. WATSON. Who get on the bus down to Mexico or Canada to help them out. So I don't think your proposal is really practical. Can you come up with something else?

Mr. MOORE. That is my idea.

Ms. WATSON. Thank you.

Mr. VAUGHAN. I would just urge in terms of the kind of constituents you are talking about, to take a good look at the Senate bill which does so much a better job for those under 160 percent of poverty. The House bill, because it doesn't cover the low income through the doughnut, is going to be real tough for some of our most vulnerable. I hope in conference that some way could be found to help with that.

Ms. WATSON. This idea that the wealthy can take care of it, but the poor, you got to perish, or we loan something and your estate pays, it is not the real world that we are dealing with. And as we grapple with this problem, I am hoping that you panelists who have been researching and studying this can be helpful to us. Because we really are looking for a way to do what we need to do, and that is develop a safety net, and particularly for our seniors.

So, anyone else?

Mr. LOVE. One of the persons that was invited here today was Dr. Tim Hubbard who is in England at the Wellcome Trust. He worked with John Salston, who won the Nobel Prize last year. Tim and John Salston worked on the human genome project. And Tim and I were invited by Aventis last September to meet with 20 executives of Aventis for 3 days in Strassburg to discuss what might happen down the road, because Aventis, a big drug company, said they were running into this wall.

Insurers, governments, are tired of paying this. They don't know how sustainable the increases in prices are, and they saw the success of the activists on the AIDS movement, they saw the human genome project, they saw all these things going on, so they are ask-

ing themselves—they asked us if our side won, all these activists and the open source development guys—what would the world look like in 20 years was the question. They put that question to them.

So, what Tim wanted to do was develop a no intellectual property scenario, but not a scenario where there was no development of new drugs or there was no money. He wanted to design a situation that actually increased the amount of money that went into research and development, but created a different model for development, a different business model for development, one where the products were priced at marginal costs when they are developed, so whether you were rich or poor, you bought them at manufacturing costs, but you financed the R&D in a different way.

The system they came up with—it was modeled in the United States, and I worked on this—was that it was a tax of between $100 and $200—not a tax, but it was an obligation on employers to contribute $100 to $200 per year, per person, on a plan into an R&D fund, and in return for that, they get all the drugs as generics. All the products became a generic. It was about $700 per year, per capita, in the United States for medicine, so that was a big decrease in the price the plans were paying for medicine. So they came out ahead of the game, way ahead of the game.

Then the idea was that the firms would then give their money to intermediaries. It was a whole system of competitive firms who did drug development, but they competed against each other and the employers could give the money to the firms they thought did the best jobs. So there was a competitive market being created for innovation. It was private, profitmaking, you know, businesses, competing against each other, decentralized decisionmaking, employers funding these R&D entities.

That replaced the current system. This was a scenario that they sort of worked out with Aventis management, and the person that worked on it just practically got fired by Aventis afterwards because it was considered too provocative internally. But it was a radically different approach.

But I am telling you, if you feel uncomfortable as I did when Bristol-Myers asked me to check with somebody who needed a cancer drug, Taxol, and find out if the person owned their own house and if they had mutual funds, and I said, well, why is it that you need to know that? And they said, "Well, people put money away for a rainy day," they said, "and this is that rainy day. It is an uninsured cancer patient."

So if you are uncomfortable with those situations, as I am, and you realize that the ultimate goal of the drug companies is to have the net worth of every person who has got a terminal disease and basically tell them what the price of the drug is, that is sort of the ultimate efficiency of the market. If you don't like that and you don't want to fall into this trap of just sort of saying look, we need to make new drugs, you have to—you are not buying drugs, you are buying research and development.

And if what you do is you say to a company, you go out and do stuff, you find something that will save somebody's life, and then tell us afterwards what it is going to cost and how much you want, and we will see if—you know, it is going to be a very uncomfortable situation, a very uncomfortable negotiation.

You are going to have to pay for R&D, but you don't have to pay for it the way you do now. And if you continue this way, you are going to have a lot of these hearings and you are going to be lectured by the Cato Institute about there is no free lunch and you have to pay for R&D, and if you decrease the profits and have weaker intellectual property rights, there will be less money for our U.S. drugs. And that is right, because if you stick with the current system, if you just do nothing else but weaken the intellectual property rights, you will hurt profits.

The thing is that the current system is an incredibly inefficient way of funding R&D, because my allegation is that you are getting 5 cents on the dollar back in meaningful R&D based upon the evidence that we looked at from the IRS.

In the old days you could afford it. It was like the market for shoelaces. It was an inefficient market, but who cares about it? It just wasn't important. It is no longer the shoelace market anymore. It is 2 percent of GDP and it is heading north, right? So at this point you got to get serious about squeezing the fat out of the system.

Mr. SCHONDELMEYER. I agree with Mr. Love that we need to look for a new way to finance R&D in the pharmaceutical industry. I don't think I have heard any of you say, nor would I want to be quoted as saying, we don't want R&D in the pharmaceutical marketplace. We do. But we need to look for new and creative ways to finance it.

I will give you one suggestion that is a bit tongue-in-cheek, but then again maybe we should rethink it, and maybe it isn't. Each time a person buys a prescription at the prices they are paying in the United States today, perhaps they should be given a share of stock in that company, because the people buying those prescriptions are doing as much or more to finance the R&D in this country as the venture capitalists we have heard about.

Now, I am all for venture capitalists, too. We need them, they are important. But much more revenue comes from the people buying those prescriptions than from the people putting up the venture capital to finance the R&D in the pharmaceutical marketplace today. Maybe we need to consider that.

A second proposal to help you make good policy is—I know it is your goal as Members of Congress. We have heard most of you commenting, either through direct comments or questions or other things, a frustration about you can't get any information in this marketplace. I think one of the most critical things you can do that has very low actual outlay costs is require transparency of transactions at every level in this marketplace.

Markets work when we know prices and values and can make conscious, value-driven decisions. We can't make conscious, value-driven decisions in this pharmaceutical marketplace given the way it is structured.

I understand that folks from the Pharmaceutical Benefit Managers came before some committee in Congress and said, no, we can't tell you our cost structure, how we make our money. It is a secret. Pharmaceutical companies hide behind a law that you yourselves set up that says, give us average manufacture price and best

price to help get better prices under Medicaid, but we can't tell you—the people who set it up—what those prices are.

Change the law. Require transparency of pricing transactions at every level.

Now, I have seen statements out of the administration suggesting that if you simply require transparency at the end point, the retail level, that takes care of it, because all the other prices wash out on the way down.

No, they don't. What doesn't wash out on the way down are all of those reverse-perverse prices that we keep stumbling onto that get doctors to prescribe the high-price drugs instead of the low-price drugs that create reverse-perverse economics. If you want the market to work better, ask for transparency in pricing.

Mr. GUTKNECHT. Thank you, Dr. Schondelmeyer.

Mr. Sanders.

Mr. SANDERS. Thank you, and I will be brief.

First of all, I want to congratulate Dr. Schondelmeyer for his many years of research and work. I am very familiar with your work and it is very nice to meet you.

Jamie Love, thank you for your years of path-breaking work that you have done, especially on international issues.

Mr. Vaughan, thank you for the work that USA Families does.

And, Mr. Moore, we thank you for coming here today. I think you kind of knew that you were walking into a lion's den, but it is important to hear your point of view as well. I was a little bit disturbed that you didn't see me as one of your heroes of the Cato Institute, but that is OK.

Mr. MOORE. Sometimes we do.

Mr. SANDERS. That is right. Sometimes we do. We do work together.

I would say that the issue here—I don't think really there is much of an intellectual debate—I think the issue here comes down to the fact that there is an industry which has billions of dollars of resources, which at the drop of the hat, if they needed to raise $500 million tomorrow for a political campaign to defeat any effort to lower prescription drug prices, they could do it. They have unlimited sums of money. And what we are seeing now is not I think an intellectual debate about which way to go. I think that debate is over, and I think, frankly, we have won it. The American people know what is right and wrong on this. Every poll shows that. But I think that we are up against very, very powerful political forces who have contributed huge sums of money to the White House, the Members of Congress, and that is what the debate is about: whether big money and special interests continue to dominate the political process, or whether Members of Congress can free themselves from that, whether the White House can free themselves from that, and that we protect ordinary Americans.

Mr. Moore, obviously you have been very provocative today. You have gotten my interest. I just wanted to ask you one question. I think there is a line that some folks use coming from your perspective that if we have free importation with Canada, in a sense we are going to import Canadian price controls. I think you made that point.

Mr. MOORE. That is right.

Mr. SANDERS. If we accept that logic—now, as you may know, I am not a free trader. But right now we have a $100 billion trade deficit with China. You are aware of it. I was in China a few months ago, and as you know, everybody knows, there are many Chinese workers who make 20 to 30 cents an hour. They don't elect their leadership. If they try to go out on a demonstration to protest against their working conditions, they go to jail. You have a fierce dictatorship in China, but we import $120 billion of product from China.

Now, when we import $120 billion from China, the shoes we are wearing and the clothing that we are wearing and the food that we eat, why aren't we importing China's dictatorial, authoritarian system when we do that? And why, if we do that, can't we import Canada's democratic system? That is my question.

Mr. MOORE. I am not sure I followed the end of that.

Mr. SANDERS. Well, the ending of it is you are saying we are importing price controls from Canada. And I am saying, yes, maybe, but that is what—you believe in free markets.

Mr. MOORE. Right.

Mr. SANDERS. That is the Canadian Government. That is what the people in Canada want.

If we can import product from a dictatorship in China which puts people in jail for standing up for their rights, I don't hear you saying, "I don't want to import the Chinese system in here."

Tell me what I am missing here.

Mr. MOORE. China—with respect to the drug issue in Canada, what Canada is is a free rider on a system basically.

Mr. SANDERS. So we don't have to argue, I will accept, others may not, I think there are price controls in Canada. I believe in price controls.

Mr. MOORE. They are essentially a free rider on the system. Unfortunately, that is bad for everybody.

Mr. SANDERS. Don't run away from my question. Stay with me in my question. You are saying we will import price controls from Canada, and you don't like price controls.

Mr. MOORE. Right.

Mr. SANDERS. Fair enough. I am saying if we carry your logic, we are going to import dictatorship and killing innocent people and crushing workers from China——

Mr. MOORE. If we import the Chinese system.

Mr. SANDERS. You would suggest that we not import products from China?

Mr. MOORE. Oh, no.

Mr. SANDERS. Is that your view?

Mr. MOORE. Now I understand your question.

Mr. SANDERS. I am sorry. Maybe I wasn't clear.

Mr. MOORE. I just don't agree with the premise that because we import goods from China at some price, that somehow we are importing their—in fact, I think actually the process works the reverse; that through free trade we are actually leading to a more open society in China.

Mr. SANDERS. So you don't accept the premise that we are importing the Chinese system.

Mr. MOORE. Right.

Mr. SANDERS. But you do accept the premise that we are importing negative price controls from Canada and we should not be able to do that.

Mr. MOORE. Yes, because what you are essentially doing is you are essentially—if we allowed every American consumer to buy drugs at the Canadian price, then you would accept the premise that what we are essentially doing is essentially having a price control system here in the United States.

Mr. SANDERS. I won't argue with that. And what about importing stuff from China? Are we inheriting a dictatorship?

Mr. MOORE. But that is where I sort of lose you.

Mr. SANDERS. What I am saying is I would think there would be more consistency if you guys believe—you guys believe, I think, in pretty much unfettered free trade; is that right?

Mr. MOORE. Yes.

Mr. SANDERS. That is the Cato Institute's position, right?

Mr. MOORE. Yes. My position is generally a free trade position, yes.

Mr. SANDERS. OK. What I am saying and the point that Mr. Gutknecht has made is, I guess—Gil, correct me if I am wrong—if you believe in free trade when you bring pork bellies in from China, what is wrong with bringing prescriptions from Canada? And all that I am saying——

Mr. MOORE. I understand.

Mr. SANDERS. I think there is a major inconsistency in your point of view.

Mr. MOORE. I am not sure, I have been struggling with this very issue myself about what do we do about countries that are sort of undermining the price system by imposing these price controls. It is bad for everybody that they do it, because this also is undermining our R&D process in drugs.

Yes, we have a lot of R&D, but we would have more if China and Canada and Britain and so forth were not imposing price controls.

Mr. SANDERS. OK. Jamie.

Mr. LOVE. The issue is being presented, and I actually see things in some ways the same way Mr. Moore does, is that there is an issue about free riders. The United States, I think everybody recognizes that we are definitely—not only are we not the free rider, we are like paying multiples of what other people pay. So we are paying more.

So, but it is not about prices; it is about research and development. I think that is what is important. So what we have been pushing for lately, and there is a big—actually in the last year, this brand new social movement on this issue, it is to change the trade agreement from specifying intellectual property provisions to specifying how much money each country has to spend on R&D, telling the country what percent of the GDP each country would be reasonable. We are shooting initially to get people intellectually to think about 10 to 15 basis points of GDP.

Basically under that situation, you wouldn't care whether Canada had price controls or they had patents or they had government-funded things or they were Marxist or Cato Institute policy. It wouldn't make any difference.

All you would care is at the end of the day, can they show you that they are funding R&D? They could really be horrible to their seniors or nice to them. They could make it up one way or the other.

The problem you got now is you have a trade agreement that only deals with part of the equation. It doesn't deal with prices, it doesn't deal with social funding, it only deals with intellectual property rights. So countries, they just load a lot into that system right now. Then you have this kind of race to have higher and higher levels of IPR, because you want higher and higher levels of things.

But it is not a very balanced agreement. There is no focus on public goods. A lot of things can happen. So the social movement—which there is a big, big, huge meeting in Geneva in April on this, and there are two more meetings in the fall scheduled—is just to sort of get people focused on a completely different paradigm.

The trade framework is this: In January, the World Health Assembly has a resolution on innovation in health. The U.S. Government forced in May the words "public goods" to be taken out of this resolution as to how they frame this issue. So it is just IPR and innovation. But there is a battle about that.

But the idea is if the WHO has a soft norm about best practices for R&D, including the free rider issue, how much you actually support R&D, both public and private sector research, that during the Cancun negotiations, the trade negotiations on the next round, at some point a developing country will come up and say if we exceed best practices, can we get out of the TRIPS agreement? In other words, does it become essentially an alternative to the TRIPS to do the best practices?

The best practices become essentially a more rational way to think about burden-sharing, about free ridership. It actually becomes a public health agreement on funding R&D, not a commercial agreement. What you have right now is something that Pfizer designed, not something that public health people did, and you can't replace the Pfizer agreement with nothing. You have to replace it with something real that deals with the free rider issue that Mr. Moore spoke about.

So this is basically the strategy, to get people on board to actually develop this best practice agreement, and then wait for the right moment to sort of say, you know, this can actually be a way to buy yourself out of the TRIPS obligation by following the best practices.

Mr. SANDERS. I will conclude, Mr. Chairman, by just saying if one is a free trader, and the bottom line of free trade—Mr. Chairman, you have made this point—you buy the product at the best place anywhere in the world, right? I think you have made the point that it is stronger than armies, right?

If one holds that view, there is no rational—I am not a free trader, by the way, but free trade is here. I don't want to see Chinese economic policies destroying America's economy.

But if you hold that view and if free traders hold that view, you cannot make a rational argument why people cannot go and buy goods from Canada. You can buy pork bellies——

Mr. MOORE. Mr. Sanders, take that point, though, to the extreme. AIDS drugs. You know, let's say that we develop a new—exciting new vaccine for AIDS that is wonderfully effective. And let's say where AIDS is most epidemic, in Africa, we want to sell that AIDS drug for 50 cents apiece there.

Well, we can't sell it here for 50 cents. We can't then say OK, you know, we are going to sell it for 50 cents in Africa, and Africa can sell it back to us for 50 cents.

Mr. SANDERS. Mr. Moore, you have raised a question that we will need another hearing to get into. I think when it is a life-and-death thing, that it is the responsibility for government in a democratic society to make sure that people don't die. If it is 50 cents or 20 cents or you give it away, you give it away. You don't let people die because they can't afford a medicine.

OK, that is my view. But thank you all very much.

Mr. Moore, I appreciate your comments.

Mr. GUTKNECHT. Thank you.

Mr. Allen.

Mr. ALLEN. Thank you, Mr. Chairman, and I second Mr. Sanders' comments. I really do appreciate the fact that you are all here and gave us your views. It is good to see many of you. Many of you I have known before. Jamie Love, I have read a lot of your things and followed what you do in the international arena, and it is important. And I like the idea of finding a different way to fund and reward research. It makes a lot of sense to me, and I will come back to it.

Mr. Moore, I can't resist. Probably I should. You know, you said in your testimony that you hoped you weren't being simplistic or patronizing, and my sense is that you are being both. So I want to just talk about sort of the intellectual assumptions that are in your paper and explain why they are so hard to accept by a group of people who deal every day with constituents who can't afford their prescription drugs.

First of all, when you use "never" and "always" consistently, and you say "Price controls never work," "The free market always works." "The government always is the entity that is driving up prices or making life more complicated or whatever," it feels like you are creating straw men. You are creating straw men.

So you are talking about things that in our world have no real application, because this is not a case about locking in a price control and saying thou shalt never charge that amount. It is not a case of saying we have to let the existing system run as it does because otherwise we will be compromising innovation in a way that will do great damage.

What is missing from the type of analysis that you—two things are missing. One, it is evidence free. I mean, the stuff going on in the real world doesn't seem to impinge.

Second, you seem unable to deal with competing goods. When you have been asked questions about what we could call the distribution of the benefit, you just get stumped, because you don't know what to do except to say borrow from the estate.

You know, 98 percent of the wealth in this country, 98 percent of the wealth in this country is held by the upper 50 percent. So

the bottom 50 percent of the people in this country have 2 percent of the wealth.

The seniors we deal with, they don't have an estate. I mean, that is ludicrous. So many of them.

So what we are trying to deal with, and what I suggest will be helpful, is to try to figure out how we deal with the problem where we value innovation on the one hand but we care about distribution of the benefit on the other. Because we are not talking about sailboats and how sailboats are distributed. We are—if you run the gambit from sailboats to automobiles to clothes to food to health care, you are running a gambit where we really care that people have some clothes and some food, and we do care that they have health care. Therefore, this is not widgets, it is not sailboats; it is a place where we need some balance, where we need to be able to deal with competing goods, where you can't have everything.

I wanted also to say a couple things. We need people to recognize that there are markets, there are markets, and there are markets. And they are not all free markets. There would not be a market here, there would not be any market, if we didn't have the patent system. And the more you lengthen the patent period, the more you create what you can call monopolies; the more you shorten it, the more you allow competition. You can increase it and create more pressure for innovation; you contract it, you create less.

You have a research and development tax credit. You have so many ways in which the government is integrally involved in the development of prescription drugs. You have NIH.

What the market is doing out there is, in some cases, Celebrex and Vioxx, it is producing products that can be advertised but produce very marginal benefit for a very small percent of the population. That is a market failure.

On the other hand, you have the problem of—and Mr. Love deals with this all the time. In many countries you have much-needed drugs that will never return a profit to the pharmaceutical industry, so they don't do the research and they don't produce the drugs. Whether it is malaria or sleeping sickness or all those other tropical diseases, they don't do that.

So what we need is a balance, an involvement of the private sector, an involvement of the public sector, so that each is fulfilling a role; so the private sector is fulfilling the role of innovation in those areas where there is an opportunity for a return, and the public sector is fulfilling a similar role where the private sector will not.

I would like a couple of charts. Could we have those charts put up?

The other thing I would just like to say is that every time there is a major prescription drug bill before the U.S. Congress, the pharmaceutical industry comes in here and says if you pass this law, we are going to have to cut back on research and development. I think that is the most frequently repeated wrong argument that we hear in these Chambers.

They made this argument just before the Hatch-Waxman Act was passed. They made this argument before the Medicaid rebate was passed. And look what happened, the chart on the left. R&D

expenditures continued, actually accelerated, after those acts were passed.

Look at the chart on the left. Firm profits accelerated after those acts were passed.

There are lots of reasons for the system we have. There are lots of reasons why the industry does do research in some areas and doesn't in others. But just to make it all the government versus the free market I think undermines what you might otherwise be able to contribute to this discussion.

I guess I am happy to hear your comment on that, Mr. Moore.

Mr. Love, I would appreciate a few comments on one of those market failures I mentioned, just the fact—some examples of these cases where there is no incentive for the industry to develop drugs that are much needed, but, frankly, don't produce a return. I know you have dealt with them in a number of different countries, and the pharmaceutical industry, only in AIDS and other cases, has been very reluctant to help out there, but they are in some cases.

Maybe Mr. Love, and then Mr. Moore.

Mr. LOVE. The World Bank is having a meeting today where one of the tracks is on research and development. One of the first findings is there is this difference between what the private incentives are for research and development and what the public health or the sort of social objective would be.

One of the problems, as you mentioned, is diseases, primarily for the poor: Lysemias, which apparently kills about a half million people a year; certainly tuberculosis, malaria, river blindness, sleeping sickness. There is a whole series of diseases where there is almost no research and development. There has been almost no development of new products.

So there is not a very good match between the suffering and death that illnesses cause and the amount of money that goes into the various illnesses.

So one of the global market failures is the fact that research and development does not really focus on areas of greatest need from that point.

Even in the northern market there is a tendency to observe a big market, like Viagra, whether it is an ulcer drug or something like that, and have companies try and actually decrease the profits of the first company in by trying to come up with similar products and basically filling out a bunch of competitors to the market. It actually reduces the returns of the first innovator by just sort of copying it. So that is a pretty well-known problem.

Then there is the problem of the more innovative things. If they can't guarantee they can capture all their returns, they don't want to do that kind of research, and so there is underinvestment in basic research or higher risk projects or areas that are more speculative.

So a lot of areas where you see the big innovations come from are areas where there is a lot of public sector research. And that is why we spend about $100 per capita on public sector research for health care. We spend a lot in this country. Unfortunately, the rest of the world spends next to nothing on public sector research.

We have such a good story to tell in R&D, it is funny. Of all the foreign aid stories we could tell, the best story we have in the

world is the research and development story, because the public sector and the private sector are outliers. We are way out there.

Now the human genome project was an interesting one, because that was a case where there was a private company, Craig Venter's outfit, which was going to try and sequence the gene and patent the gene, venture capital, the whole sort of good story, private investor. Then you had several governments, six governments get together and publicly fund, or donor fund in the case of the U.K., research in order to prevent Craig Venter from patenting the gene. It was a public sector approach to create an open-source data base of human genome, because they believed that openness was the big deal in research.

There are a lot of people influenced by Linux and the whole open source software movement. What they are saying is what the software movement told them is there is this idea that if—with enough eyeballs, all bugs are shallow with the software version; but the idea was the more researchers looking at the data, the more researchers would have access to the information, the more researchers working on the problem, the faster the R&D process goes.

So the patent problem in some cases discourages innovation, because once somebody has locked up a patent position in the field, nobody wants to do research in it, because it is sort of, you know, you can't develop something unless you sort of consolidate all the rights.

Mr. ALLEN. You are buying litigation.

Mr. LOVE. You are buying either litigation or there is just, you know—people are very aggressive in their licensing thing, is another problem.

That was a case where a big pharmacist supported a public domain, public, good project. They supported the human genome project, beating Craig Venter. And Craig Venter, he is in the nonprofit sector now, and his whole firm is no longer in the data base sector. That was a case where that open-source project basically won.

So now a lot of people, like Sir John Saltsen, who won the Nobel Prize last year, and Tim Hubbard, are now saying well, if we did this with the human genome, imagine what we could do in other areas. And then they are looking at the resource flow and saying if you are spending $400 billion a year worldwide on medicines, and $200 billion—what is it, Steve, in the United States? You made me feel like the numbers I got are wrong. But it is a lot, right?

Mr. SCHONDELMEYER. $280 billion.

Mr. LOVE. $280 billion. You are approaching 3 percent of GDP in the United States. It is a huge number.

If only sort of anywhere from 5 to 10 percent of that is going into interesting research anyhow, he is saying maybe we could actually have more innovation, increase the amount of flow going to actual research communities, and still have—still feel comfortable about the price that seniors pay. You know, it becomes a form of social insurance, because if you can find a way to fund the R&D, it is trivial to pay the costs of the drugs by manufacturing costs.

The other thing is they just feel like how long can we go in the world—I mean, we are in a situation where D–42, this product was about $4,000 in South Africa a few—about 2 years ago. It is a drug

I worked on quite a bit. Now you can buy a year's supply for less than $50 in South Africa. Now we hear people say, well, what happened if people buy it in South Africa and bring it up here? So what is the solution? The solution used to be just let everybody in Africa die. Fine, that is the solution, because we don't want to upset the R&D thing.

You got to understand, literally with 40 million poor people infected with AIDS, people were willing to make that call because they thought it was necessary to preserve the whole R&D system. Well, you have to ask yourself, you know, how far do we go with this idea that you really sort of allow one generation to suffer so the next generation can benefit from the medicine, which is sort of a particular way to fund R&D.

We think it is just ethically—it becomes a moral issue. Actually, the National Council of Churches and some of these religious groups are now getting involved in this issue, and what they are saying is ethically, morally, because the world isn't just about economics, there is a moral dimension to this. Can we really rely on a thing that denies and rations medicine to the most affluent? Is it even the moral thing to do?

It wasn't like this 15 years ago. You didn't have $20,000, $50,000, $100,000 medicines. You didn't have people really, really suffering economically because of medicine. They suffered from diseases, but they didn't suffer economically.

So this idea, this sort of thinking, this new idea on funding research and development, this throws people for a loop, because they think the—they are prisoners of the dogma that there is only one way to fund R&D, which is hand over a 20-year marketing monopoly. Anything else just is impossible, because we have government-funded and we have the patent system, and that is it. So some people are saying, well, maybe if you got rid of the whole patent system altogether and replaced it with something completely different, there is actually lots of research being done on what you could replace it with. A whole lot of people think you could do it faster, more private sector research. There are different ways it could be done.

Mr. ALLEN. Mr. Moore.

Mr. MOORE. Well, actually, that is about the most dangerous idea I have heard. I mean, I really think what is driving this wonderful innovation in drugs is precisely the profit motive; that you have this vibrant venture capital industry——

Mr. LOVE. I am fine on the profit motive. That is not a problem. The whole challenge is to design a system where you ride the profit motive, you ride the efficiencies, but you change the rules in such a way that firms are responding.

A simple example. Right now, let's make it really a big tax, make it $200 per capita, and employers had to do it; then you were putting in like $50 billion or something like that into the private R&D. Every year that $50 billion, which is like twice what is going in it right now, roughly, in the private sector research community right now. If everybody knew that $50 billion was going to be spent every year, there would be like an amazing private sector experience to get that $50 billion. I don't care what the rules were, you would have lots of stuff going on. If you didn't think that was

enough, you could make it $60 billion. It would just become an instrument of policy, how much R&D you wanted to have.

Believe me, it would be profits, you would have venture capital, you would have people putting their kids in private school, you would have all that good stuff that we love, right? But you wouldn't necessarily tie it to sky-high prices after the product went into the market. You would essentially pay off the innovators early rather than with this 20-year IOU, to just basically make people suffer for 20 years and then we will turn it into a free good.

You would say we will make it into a free good quickly, and we will pay you off faster. In fact, you are wasting an enormous sum, because expenditures on marketing, by everyone's estimates, are several multiples of what you are spending on R&D, and it is not a social good. In fact, it is a corruption of the evidence base. It is essentially leading to irrational prescribing, all kinds of problems, and a lot of wasteful R&D is essentially trying to convince insurers to pay for this very similar drug to be paired to this similar drug. And some of the biggest trials are where the differences in the drugs are the most marginal.

The truly innovative drugs for severe diseases a lot of times will come into product with less than 1,000 patients in clinical trials. You can have a product that is competing against an existing therapy, not much different, with 20,000 patients sometimes in clinical trials, because they have to squeeze out that little bit of information as to the relative pharmacokinetic benefits, because how else are they going to persuade people to pay $4 a day for a drug that is about the same as another drug?

Mr. MOORE. Well, if that idea worked, you wouldn't need to set a tax, you could just set up—Mr. Love could just set up a venture capital fund and you could raise $50 billion and you could do the innovation the way you are talking about, and you would not have to impose a tax on anyone.

But my point is, the day is getting late, so let me just summarize. We have this incredibly vibrant, profitable, lifesaving industry, that for some crazy reason on Capitol Hill is treated like this villain industry, when it has saved more lives than any other industry in the history of civilization.

It is profitable. The drugs that have come out, just in the last 30 years, the way life has changed so dramatically as a result of this wonderful combination of our venture capital industry that funds the drugs, of the biotechnology companies that come up with it, the drug companies that then sell it, it is like you are sitting here trying to solve a problem that doesn't exist.

Yes, there is a problem that when these new drugs come on the market they are very expensive. And you are right; in some cases it takes 10 or 15 or 20 years for those prices to come down. But it is very similar, I see it very similar to every other kind of high-technology industry we have today. The cellular telephone industry: When cellular telephones came on the market 25 years ago, they cost a gazillion dollars. Now they damn near give the things away.

Mr. ALLEN. Mr. Moore, wait a minute. Wait a minute.

Mr. MOORE. It is very similar.

Mr. ALLEN. If people don't have a cellular telephone, they don't get sick or die.

Mr. MOORE. I understand that. But that is all the more reason you don't want to mess around with an industry that is saving so many tens of millions of lives.

Mr. ALLEN. Mr. Moore, this will be the last time I will say this, because I know we are done. But what is astonishing to me, and I think to others, is that you can talk about this industry without talking about the problem that brings us here. The problem is not that the industry generates expensive new and wonderful drugs. They do that. The problem is that people can't afford them.

Mr. MOORE. They can't afford them when they first come out, just like anything.

Mr. ALLEN. No, no, no. The patents last for a considerable period of time.

Mr. MOORE. That is true.

Mr. ALLEN. They can't afford them when they first come out, and it is not the single drugs. We have thousands and thousands and thousands of constituents in our districts, in each one of our districts. They may not be taking any of the new, exciting, expensive drugs. They are simply taking several drugs. And they are living on $800 a month, or $1,500 a month, or, if they are lucky, $2,000 a month, and they have hundreds and hundreds of dollars in pharmaceutical expense. They can't afford to take the drugs that the doctors tell them they have to take.

And your view does not even deal with that problem, and that is what brought us here today.

Mr. MOORE. Don't forget, we are the healthiest society in the history of civilization. We have the best health care system.

Mr. ALLEN. Well, we are not.

Mr. GUTKNECHT. We may have opened up a whole new area of debate. I can't stay forever, and I know Mr. Allen can't, and I know you can't, so I am going to exercise the prerogative of the Chair. I had the first word, and I don't want to necessarily have the last word, but I do want to throw out a couple of things.

I want to thank you all for coming, and I mean all of you, because in some respects I want to say this is a very special tribute to Chairman Burton. This is an enormous issue of public policy. It has received virtually no congressional attention. We are putting together a massive bill with very little what I would describe as real testimony from various sources with different points of view.

To the credit of Chairman Burton, he has invited the presidents of large pharmaceutical companies, he has invited consumer groups, he has invited doctors, he has invited people with Ph.D.'s in pharmacology. We have tried to bring in a broad group of people.

Now, that is not to say we are going to agree. Obviously we are going to disagree. But in some respects, as policymakers here, and as one who spent the last 4 years putting an awful lot of time and effort into this issue, I still feel like the blind man describing the elephant. This thing is incredibly complicated.

The one thing I have concluded, though, is as a Teddy Roosevelt Republican, I don't think there is anything wrong with the word "profit," but there is something wrong with the word "profiteer." And at some point you cross that threshold. I am not certain where

that is, but it is sort of like pornography; I kind of know it when I smell it, and it is out there.

And I don't think you can talk about market forces in what essentially is a monopolistic marketplace. By that I mean we, for example, if we gave an exclusive franchise for a company to provide electricity for the entire United States of America, we certainly wouldn't say, "Oh, and by the way, you can charge whatever you want to, and you have 17 years to do whatever you want to with it."

I think we all understand that at some level there is a public policy question, and the reason I think we are wrestling with this is how much the world has changed in the last 20 years.

I am so proud—and, Mr. Love, you said it correctly. We represent as Americans less than 6 percent of the world's population, and yet we represent over 50 percent of all of the basic research done in the world. And most of the rest of the world is getting a free ride on the research that we pay for, either as taxpayers, through the research that is done by foundations and universities, the National Science Foundation, NIH, and all the rest, even DARPA. We do that, and I am proud of that. I think we should, and I believe in research.

But there is something else that has changed in the last several years, and we need to get our arms around it, and there is almost a moral quality to it. Especially as someone who grew up in the fifties, we all have a huge debt of gratitude to a fellow by the name of Dr. Jonas Salk. He literally saved millions of Americans and people around the world from an incredibly terrible disease. I mean, that is the best way I can describe it.

Now, he did not retire a pauper, but he did not retire a billionaire either.

Let me give you an example, too, and I am so proud of what they do at the Mayo Clinic, and I happen to represent Mayo Clinic, and I am proud of the University of Minnesota, and they are finally starting to work together, believe it or not, for the first time ever. But at Mayo Clinic, they developed a number of years ago a drug called cortisone. Cortisone is a multibillion-dollar market potential drug. You know what they did with it? They gave it to the world.

Something has changed in the ethics of research in this country, and now we are trying to patent genes, and it seems to me that we as a Congress have to come to grips with what has changed in this world, the monopolistic powers, and somehow try to bring some sanity into this system; because it is about our patent laws, it is about what we will pay for prescription drugs, it is about what is a fair rate of return.

For example, this Congress contracts with defense contractors to build unbelievable aircraft. We watched what they can do, and we watched in real time on Fox News and others. But we also have the right and we reserve the right to audit those defense contractors. We guarantee them a reasonable rate of return.

We have nothing like that in the licensing agreements we have for new patents and new technologies and new processes and new pharmaceuticals, and it seems to me this committee—this actually should be a full committee—and we should be meeting all the time,

talking about and trying to figure out what the right thing to do is.

I don't know what the right thing to do is. I mean, personally, I am not sure that even reimportation is the right answer, but it is the best answer we can come up with to try and at least bring some discipline, market discipline to this.

I just throw that out. If any of you want to respond to anything I just said? Maybe it makes no sense.

Mr. Vaughan.

Mr. VAUGHAN. Just one thing. When Edward R. Murrow asked Dr. Salk about how he was going to deal with patenting, Salk replied, "Could you patent the sun?" and I think you make a great point. What have we lost in the sense of a golden mean or moderation? I mean, how much is enough? And these guys don't seem to have any sense of enough is enough. So it is, to us, profiteering.

Mr. GUTKNECHT. Let me just say that—and I think that is the point. You think up to this point we as policymakers have pretty much been laissez-faire. But, you know, when a company starts—some of the behavior we have seen in the last several years, we have one company that is spending $3.9 billion, by their own admission in front of this committee, $3.9 billion advertising and marketing products that consumers can't get without a doctor's prescription. You know, it just seems to me then they have sort of crossed the line, and people on this side of the desk have to do something about it. I am not sure what the right thing is.

Mr. Love, you were going to say something?

Mr. LOVE. Well, if I would think about two themes in terms of followups out of here, one would be a meeting where you just focus on the issues of transparency. Steven mentioned that. I think it is quite important.

This is an area where a big part of the agenda of companies is to prevent anybody from knowing what is going on. I mean, everyone is supposed to have like, I don't know, a blindfold on or something like that. I think the idea that being blind is somehow a good thing for everybody needs to be challenged.

But also, you know, it would be really interesting to kind of walk through a list of things that people should know that they don't know: like what clinical trials cost, what is the NIH license, how much money does it get on its licenses, what are prices, how much of GDP are we spending, or how much of this, that or the other thing?

It would be good to kind of start out with an evidence base, but also policies about transparency and where that needs to go. I think that moves us toward actually having better information for making decisions.

Then the second one is to, I think, really sort of go back and look at this R&D issue and not be afraid of it. I mean, what I think you need to do is to take their strongest argument and make it your strongest argument, because otherwise you are going to suffer.

I can tell you that if R&D is their argument, and you are on the other side of that one, that is an unpleasant place to be for everyone that has someone that suffers from an illness that there is not a good cure for.

I mean, Americans are optimistic. We want the next drug. We want the next thing. So you have to basically champion R&D, but do it from a public health point of view, not the current way. You have to reinvent the R&D issue in a way that really you believe in, that suits your objectives in terms of it.

It has to be consistent with access, R&D consistent with access, and efficiency, because we are economists.

One thing he didn't hear the Cato Institute talk about, and I am really disappointed in this—in fact, I am really constantly surprised—is scarce resources, efficiency, bang for the buck, cost/benefit analysis. Bringing cost/benefit analysis into the process is something that is just overdone.

This are a lot of these so-called incentive things that are just sort of open-ended corporate welfare schemes, and they don't pass the muster as far as cost/benefit analysis is concerned.

More cost-benefit analysis is your friend in this area. And I think that, you know, bringing some rigor into how you think about R&D would be really a fun work program. And if you put those two things together, you know, building up the evidence base better, and then bringing up the sort of cost-benefit and rigor into how you buy R&D issue, I think you begin to really change the debate.

Mr. SCHONDELMEYER. I've heard arguments about free trade and opening up the market with Canada, importing price controls. I would argue that just the opposite might occur, that we might export free trade, to Canada, to Europe, and maybe raise the prices and get the rest of the world to quit being free riders. What's wrong with that? Basic economics. Second thought. I would challenge, what do we mean by price controls in Canada? We have thrown that around a lot today. I think there's a lot of rhetoric around that.

Mr. GUTKNECHT. And Dr. Schondelmeyer, I am so glad that—frankly, I wish we had more time. I would love to have just a hearing on this issue, because I think this is the most misunderstood, misstated, and abused concept about exactly how price controls work in Canada and some of the other countries. So, please——

Mr. SCHONDELMEYER. I'll just briefly phrase it. I would encourage—actually, the AARP bulletin, their newsletter that just came out in June 2003, great article: Why Drugs Cost Less up North. Now, it doesn't definitively answer that question, but it talks about their system of paying for drugs.

First of all, Canada does have a law at the Federal level that sets up a Patent Medicine Price Review Board that reviews the prices of all new drugs approved in Canada. It's been in operation for just over 15 years, and in the 15 years they have only taken legal action to set the price of four drugs. Four drugs. Twenty other drug products, the drug companies voluntarily adjusted their prices because they sensed that the Board was uneasy. So we have had 24 products in 15 years have their prices substantially influenced by the price controls in Canada.

The Canadian Federal Government does not pay for prescription drugs, just like the U.S. Government doesn't pay for drugs under Medicare in general in the U.S. Drugs paid for in Canada are paid for through the Provincial Government Health Plans, and their Government Health Plans are much like our Medicaid program.

But they include not only the poor but the elderly. They do take care of the elderly at the Provincial level, and a much broader group than just the elderly. Middle-income people in most provinces have their prescription drugs either fully or partially paid for. And the Provincial Governments do not set prices. They set a formula of, here are the drugs we will cover, here are the prices we will pay. Just like the private market, the PBMs, HMOs, managed-care organizations in the United States a set, a formulary, say here's how much we will pay. So Canada operates just like the U.S. market.

Mr. GUTKNECHT. Can I just clarify that?

Mr. SCHONDELMEYER. Yes.

Mr. GUTKNECHT. So, in other words, they say what they will reimburse just like if it were an insurance company.

Mr. SCHONDELMEYER. Yes. And if a consumer wants a drug that is not on the formulary list, they are welcome to buy it and pay the full cost, and the drug company can charge whatever they want for it. Those prices are not set. So, to my knowledge, four drugs have had their price set and another 20 have had their prices influenced. I would argue we have had more price controls on pharmaceuticals in the United States than Canada has. I know for a fact Medicare set the price on Epogen, and in their discussions with TAP and Astrazeneca and Bayer, the groups that have settled with the Department of Justice, they had them adjust their prices that they list. They didn't tell them what the price would be, but you have to report an accurate and true price—a novel concept.

Mr. GUTKNECHT. And in each of those cases, they reimbursed the government to the tune of hundreds of millions of dollars.

Mr. SCHONDELMEYER. And they paid back hundreds of millions of dollars to the government. So you could argue those prices were set in a sense. We have had as many price controls in the United States. Maybe we run a danger of importing or exporting price controls to Canada.

Mr. GUTKNECHT. Well, thank you, Dr. Schondelmeyer. And I would really, for the benefit of the staff, I would like to have a subcommittee hearing if—and I'm not even on the subcommittee, and here I am chairing it, but I really would. I think that's the subject in itself of a hearing of exactly how a few of these other countries really arrive at the prices that are ultimately paid. And I think it would be eye-opening for members of this subcommittee, certainly for me, because the more you learn about this industry—again, I go back to the analogy of the blind man describing the elephant. The more you learn, the more curious this is about the way this whole process works.

But I want to thank all of you sincerely. This has been a very good hearing, at least from my perspective. And this is the kind of thing that we need a lot more of to get to the bottom of this, so that we can actually set good public policy. The concern I have, and I will editorialize here, is we are going to be asked to make a very important decision in the next 36 hours on an enormously expensive entitlement, which I don't understand, most Members don't understand, and could cost us for generations to come. That's my editorial point of view. I think we should have had literally many,

many more hearings like this to try to get to the bottom of what the correct public policy course is to take. Thank you so much.

We will keep the record open for 10 days so that members may revise and extend their remarks or put extraneous materials into the record. Any other materials that you would like, including the article which you quoted from, Dr. Schondelmeyer, if you wouldn't mind, if we could make that a part of the permanent record, we would appreciate it. Any other items that you would like put in the record, we would be delighted to put in. With that, I would adjourn this meeting.

[Whereupon, at 5:26 p.m., the subcommittee was adjourned.]

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