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INTERNATIONAL PRESCRIPTION DRUG PARITY: ARE AMERICANS BEING PROTECTED OR GOUGED?

HEARING

BEFORE THE

SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

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INTERNATIONAL PRESCRIPTION DRUG PARITY: ARE AMERICANS BEING PROTECTED OR GOUGED?

THURSDAY, APRIL 3, 2003

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

The subcommittee met, pursuant to notice, at 2:03 p.m., in room 2157, Rayburn House Office Building, Hon. Dan Burton (chairman of the subcommittee) presiding.

Present: Representatives Burton, Gutknecht, Sanders, Tierney, Duncan, Watson, Cannon, Shays, and Cummings.

Staff present: Beth Clay and John Rowe, professional staff members; Mark Walker, staff director; Nick Mution, press secretary; Mindi Walker, clerk and legislative aide; Tony Haywood, minority counsel; and Jean Gosa, minority assistant clerk.

Mr. BURTON. Good afternoon. 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 be included in the record. Without objection, so ordered.

Congressman Gil Gutknecht has been a leader in the House on drug reimportation issues and has agreed to join us today.

I appreciate your being here, Gil, so much.

Mr. GUTKNECHT. Mr. Chairman, I appreciate your having this hearing.

Mr. BURTON. Thank you. And I ask unanimous consent that Congressman Gutknecht be permitted to serve as a member of the subcommittee today. Without objection, so ordered.

We will have also Congressman Joseph Crowley, we believe, and Congressman John Duncan, who is from the full committee, here I guess some time before too long. Congressman Crowley we'd like to be able to serve, as well. Congressman Duncan is a member of the full committee but not our subcommittee, and we want to allow him the courtesy of being here.

Given that this is the first hearing of the subcommittee, all my colleagues aren't here, but I will mention them. We're going to have Chris Cannon of Utah, Congressman Chris Shays of Connecticut, and Congresswoman Ileana Ros-Lehtinen of Florida on our sub-

committee, and on the Democrat's side of the aisle we'll have Diane Watson as the ranking minority member and Congressman Bernie Sanders of Vermont and Congressman Elijah Cummings of Maryland, who will also be serving. During my tenure as chairman of the full committee, each of these Members was very active and involved in our health oversight hearings, and I am very pleased that they are going to be joining me on this subcommittee.

It is often the case that Congress acts as a fulcrum seeking to find the appropriate balance between opposing parties on key policy discussions. The subject of today's hearing is no different. On one side of the debate is the importance of preserving the free enterprise system. The pharmaceutical industry tells us that it now takes between $500 and $800 million to bring a drug to market.

We are also being joined by Mr. Tierney.

This estimate is a bit misleading, though. While the actual costs of research and development on bringing a single drug to market can be high, the actual dollar figure is much less. Only 10 to 30 percent of the products in development actually make it to the marketplace, so companies add the cost of failed products into the R&D of drugs that ultimately are approved; thus, the American consumer, by and large, shoulders the cost associated with drug research and development.

On the other hand, Congress must consider the needs of American consumers to have access to safe and affordable prescription drugs. As many as 108 million Americans have one or more chronic health conditions such as diabetes, high blood pressure, asthma, and heart disease, and many require prescription drugs to manage these conditions. Of Americans age 50 to 64, 75 percent are on at least one resource drug, and 14 percent of women age 65 are on five prescription drugs in any given week.

As we all know, the price of prescription drugs is higher in the United States than in any other country in the world. As one mechanism to address this issue, in the year 2000 Congress overwhelmingly passed and the President signed into law the Meds Act to allow U.S. consumers, pharmacists, and wholesalers to purchase FDA-approved prescription drugs on the international market. However, the FDA has never implemented this law.

Today's hearing is focusing only on consumers' access to prescription drugs purchased from Canadian pharmacies. One of the witnesses we will be hearing from today is Mr. William Hubbard, Senior Associate Commissioner of the FDA. Mr. Hubbard was quoted in the media 2 weeks ago as saying that anyone facilitating Americans importing prescription drugs from Canada faced potential civil and criminal liability. He went on to say insurance companies and health plans that pay for prescription drugs purchased outside the United States may be violating the law.

Now, you know, that sounds pretty strong, but, you know, I want to take a couple of words that he said. He said they faced potential—potential. Nevertheless, the civil and criminal liability scared people. And then he went on to say, "those who aid and abet a criminal violation of the act or conspire to violate the act can be found criminally liable." And he also said that those who aid and abet may be violating the law. He said, "Insurance companies and

health plans that pay for prescription drugs purchased outside the United States may be violating the law."

Well, the law was pretty clear. It was passed by Congress and signed by the President, but the President had some concerns about making sure that the FDA was watching what was coming in. And that's what we want to ask about today—whether or not the FDA is working with the Canadian Government to make sure that the drugs coming into this country are safe.

It is my understanding that the drug companies in Canada are policed very, very stringently, and so in some cases their dealing with the pharmaceutical industry up there is even tighter than what the FDA here in the United States does.

He went on to state that, "We, the FDA, believe that virtually all drugs imported to the United States from Canada by or for individual U.S. consumers violate the U.S. law." We're going to ask about that today because the law is pretty clear. What the FDA has not done is they have not worked with Canada, and so they are saying that their interpretation is that, because the FDA hasn't worked with Canada and checked these drugs out one at a time or checked with their counterpart in Canada, that the consumers are violating the law.

I, for one, am very puzzled about this. How can the FDA officials feel that Americans are violating U.S. law when 3 years ago this law was signed by the President? And this bill clarified that it was legal for Americans to purchase prescription drugs internationally. But we're only talking about Canada today, and we're talking about Canada because they are our neighbor and because a lot of seniors, well over a million Americans—and most of them are seniors, I believe—are buying their pharmaceuticals from Canada.

We're a country with three branches of government—judicial, executive, and legislative. It is not the FDA's job to make law. It is not the FDA's job to make law. It is Congress' job to pass laws and the executive branch to sign them and they're to enforce them, and it is their responsibility to implement the laws that Congress passes, and that includes the Meds Act, which was signed 3 years ago. So far the FDA has shirked its responsibility in this area, and this needs to change. The FDA claims they cannot implement this law because they cannot assure the safety of the products being shipped into the United States.

I understand that the gentleman from the FDA brought a bunch of drugs in from countries around the world where they were counterfeits, but they weren't from Canada. We were talking about Canadian drugs. It is very well policed up there by their drug agencies.

I believe that the FDA needs to do some innovative, out-of-the-pillbox thinking. Health Canada's regulatory model offers safeguards to ensure the safety of products for Canadians. Last week, Mr. Hubbard told me that he was not aware of a single incident that an American had been harmed by a product purchased in Canada. They did mention one in Oregon—one in Oregon. We have found that aspirins and other drugs sold over the counter in this country cause more problems than one in Oregon caused by a Canadian pharmaceutical.

Obviously, if the FDA wanted to find a solution to implementing the law they could, and I am pleased today that we are going to be hearing from a number of people. Congressman Roger Zion was going to be with us, but unfortunately I guess he has a health problem and he's not here today. We'll also hear from Mr. Robert Hayes of the Medicare Rights Center in New York; Dr. Elizabeth Wennar from the Coalition for Access to Affordable Prescription Drugs; and Dr. Andy Troszok, the vice president of standards for the Canadian International Pharmacists Association. They'll be giving us information on their perspective, and he will be giving information from the Canadian perspective.

Earlier this year GlaxoSmithKline sent letters to Canadian pharmacies threatening to suspend shipments to them if they continued to sell drugs to American consumers. Now, the reason they did that was because they don't make as much money in Canada. They still make a profit, but they don't make as much money in Canada as they do here in the United States. In fact, I don't think they make as much money selling drugs any place in the world as they do here in the United States. So what they were doing is they were fighting this on the issue of profit and loss.

It's interesting to me that the FDA at almost the same time was saying that they had concerns about drugs coming in from Canada. You might wonder why the FDA would be bringing the subject at the same time that GlaxoSmithKline was trying to stop selling drugs to pharmaceutical companies in Canada because they don't make as much profit. GlaxoSmithKline seems to be using strong-arm tactics.

Now, this is kind of interesting because GlaxoSmithKline, during very tough economic times last year, had a 15 percent growth rate, and I believe Congressman Sanders said they made $10 billion. Is that what you said, they had $10 billion in sales?

Mr. SANDERS. Just $9 billion, Mr. Chairman.

Mr. BURTON. Just $9 billion. And their CEO is making $20 million a year.

Just last week a member of their firm told me that even with Canada's price controls GlaxoSmithKline makes a profit, just not as much as they make in the United States. So I have cosponsored legislation with Congressman Sanders and 54 other legislators—and we believe we'll have a lot more—that will institute monetary fines on pharmaceutical companies that reduce access of Americans to lower-cost drugs via the Internet from Canadian pharmacies. And I hope the FDA will try to work with the Canadian Government to make sure that they are in concert with us as far as importing drugs to the United States.

I invited Mr. J.P. Garnier, the chief executive officer of GlaxoSmithKline to testify at the hearing today; however, he declined to participate or even to submit testimony. Had I still been chairman, I would have subpoenaed him, but the Chair of the committee chose not to subpoena him, so we'll have to make do with

an empty chair when we start questioning GlaxoSmithKline. His unwillingness to participate at the subcommittee today I think speaks volumes.

I want to thank you all for coming. I look forward to hearing from our witnesses.

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

Opening Statement of Chairman Dan Burton

Subcommittee on Human Rights and Wellness

At the Subcommittee on Human Rights and Wellness

Hearing

"International Prescription Drug Parity:
Are Americans Being Protected or Gouged?"

April 3, 2003

2247 Rayburn House Office Building
2:00 pm

Given that this is the first hearing of the Subcommittee, I want to take a moment to welcome all of my colleagues. I am pleased to be joined on the Subcommittee by Congressman Chris Cannon of Utah, Congressman Christopher Shays of Connecticut, and Congresswoman Ileana Ros-Lehtinen of Florida.

I am also pleased to have my distinguished colleague from California, Congresswoman Diane Watson as the Ranking Minority Member, as well as Congressman Bernard Sanders of Vermont, and Congressman Elijah Cummings of Maryland serving as members from the other side of the aisle.

During my tenure as Chairman of the Full Committee each of these members was actively involved in our health oversight hearings. I am pleased that they are joining me on the Subcommittee. The diverse membership of this Subcommittee covers the entire spectrum of political philosophy. However, we all share a common desire to improve the policies and programs that affect the health and well-being of all Americans.

It is often the case that Congress acts as a fulcrum seeking to find the appropriate balance between opposing parties on key policy discussions. The subject of today's hearing is no different.

On one side of the debate is the importance of preserving the free enterprise system. The pharmaceutical industry tells us that it now takes between $500 and $800 million dollars to bring a drug to market.

This estimate is a bit misleading though. While the actual costs of research and development on bringing a single drug to market can be high, the actual dollar figure may be much less. Only 10 to 30 percent of the products in development actually make it to the marketplace. Thus, companies add the costs of these failed products into the R&D of drugs that ultimately are approved. Thus, the American consumer, buy and large, shoulders the costs associated with drug research and development.

On the other hand, Congress must consider the needs of American consumers to have access to safe and affordable prescription drugs. As many as 108 million Americans have one or more chronic health conditions such as diabetes, high blood pressure, asthma, and heart disease. Many require prescription drugs to manage these conditions.

Seventy-five percent of Americans age 50 to 64 are on at least one prescription drug, and fourteen percent of women aged sixty-five are on five prescription drugs in any given week. As we all know, the price of prescription drugs is higher in the United States than in any other country in the world.

As one mechanism to address this issue, in 2000, Congress overwhelmingly passed and the President signed into law, the MEDS Act to allow U.S. consumers, pharmacists, and wholesalers to purchase FDA-approved prescription drugs on the international market. However, the FDA has never implemented the law.

Today's hearing is focusing only on consumers' access to prescription drugs purchased from Canadian pharmacies. One of the witnesses we will be hearing from today is Mr. William Hubbard, Senior Associate Commissioner of the FDA.

Mr. Hubbard was quoted in the media two weeks ago as saying that anyone facilitating Americans importing prescription drugs from Canada faced potential "civil and criminal liability." He went on to say, "insurance companies and health plans that pay for prescription drugs purchased outside the United States may be violating the law."

Mr. Hubbard further stated, "Those who aid and abet a criminal violation of the act, or conspire to violate the act, can be found criminally liable."

He went on to state, "We [the FDA] believe that virtually all drugs imported to the United States from Canada by or for individual U.S. consumers violate U.S. law."

I, for one, am puzzled. How can FDA officials feel that Americans are violating U.S. law when three years ago the President signed into law a bill that Congress had passed? This bill clarified that it was legal for American's to purchase prescription drugs internationally?

We are a country with three branches of Government – Judicial, Executive and Legislative. It is not the FDA's job to make laws. It is their responsibility to implement the laws that Congress passes. And that includes the MEDs Act. So far, the FDA has shirked its

responsibility in this area. This needs to change. The FDA claims they cannot implement this law because they cannot assure the safety of the products being shipped into the U.S.

I believe that the FDA needs to do some innovative, "out of the pillbox" thinking. HealthCanada's regulatory model offers safeguards to insure the safety of products for Canadians. Last week, Mr. Hubbard told me that he was not aware of a single incident that an American had been harmed by a product purchased in Canada. Obviously if the FDA wanted to find a solution to implementing the law, they could.

I have just learned that my old friend and fellow Hoosier, former Congressman Roger Zion is ill and not able to join us. Roger serves as Chairman of the Sixty Plus Association.

We will also hear from Mr. Robert Hayes of the Medicare Rights Center in New York.

Dr. Elizabeth Wenner from the Coalition for Access to Affordable Prescription Drugs, and Dr. Andy Troszok the Vice President of Standards for the Canadian International Pharmacists, will be giving us information from the Canadian perspective.

Earlier this year, GlaxoSmithKline sent letters to Canadian pharmacies threatening to suspend shipments to them if they continued to sell drugs to American consumers. I find these strong-arm tactics very disturbing.

This is a company that during tough economic times had a 15 percent growth last year. Just last week, a Glaxo representative told me that even with Canada's price controls, GlaxoSmithKline makes a profit - just not as much as they make in the U.S. marketplace.

I have co-sponsored legislation with Congressman Sanders and fifty-four other legislators that will institute monetary fines on pharmaceutical companies that reduce access of Americans to lower-cost drugs via the internet from Canadian pharmacies.

I invited Dr. J.P. Garnier, the Chief Executive Office of GlaxoSmithKline to testify at the hearing today. However, he declined to participate, or, even to submit testimony. He also declined to voluntarily provide another GlaxoSmithKline representative. His unwillingness to participate at the Subcommittee hearing today speaks volumes!

Thank you all for coming. I look forward to hearing from our witnesses. I now recognize Ranking Minority Member, Congresswoman Diane Watson, for an opening statement.

Mr. BURTON. I now recognize the minority member, Congressman Diane Watson. Since she is not here, I'll go ahead and recognize Mr. Sanders. Mr. Sanders.

Mr. SANDERS. Mr. Chairman, thank you very much for holding this important hearing. And the truth is, we owe you a real debt of gratitude because there are not many Members of Congress who are prepared to stand up to the most powerful lobby in this country, and that is the pharmaceutical industry. This is a huge issue, and I really do thank you for holding this hearing.

The high cost of prescription drugs and what that is doing to the health and well-being of Americans and senior citizens is something that I have been involved with for many, many years. In 1999, in order to help Vermont citizens, I led the first effort to take constituents over the Canadian border to purchase medicine at a fraction of the price that they were paying in the United States. And I will never forget as long as I live the women who were with me who were struggling with breast cancer and who purchased tomaxaphin, Mr. Chairman, which is a widely prescribed breast cancer drug, for one-tenth the price, 10 percent, the same, exact medicine. And these women, many of whom did not have a lot of money, could not believe that.

Several years ago I introduced reimportation legislation. I know Mr. Gutknecht and I have worked together on various pieces of legislation in that area which would have allowed Americans to purchase FDA-approved drugs anywhere in the world. While a variation of this legislation was passed in Congress and, as you indicated, is still in existence, we've got to work out some of those loopholes that remain in there. And, as you've just indicated, you and I and others are working on legislation to stop Glaxo and other companies from limiting their supplies to Canada. We have 54 cosponsors on that legislation.

Let me briefly describe what this problem is, what we're talking about today, and why this hearing is so important.

More and more Americans are dependent upon prescription drugs to maintain their health and well-being and to keep themselves alive. At the same time, more and more Americans simply cannot afford the outrageously high prices that the pharmaceutical industry is charging them. While Americans pay by far the highest prices in the world for their medicine, the pharmaceutical industry, which receives huge tax breaks and subsidies from the U.S. Government, continues to be the most profitable industry in this country and provides huge compensation packages to their CEOs. In 2001, the industry's profit as a percentage of revenue, Mr. Chairman, was 18.5 percent. Not too many businesses that you and I know make 18.5 percent profit.

I will submit information for the record on the compensation issue, but I would point out here, for example, that C.A. Hinebold, Jr., former chairman and CEO of Bristol Meyers Squibb in 2001 received total compensation of over $150 million in 1 year. Elderly people all over this country are suffering and in some cases dying because they cannot afford the high cost of prescription drugs. One executive receives $150 million in 1 year from one of the largest drug companies in this country.

In addition, in order to protect their profits and make certain that nothing is passed in Congress which protects the American people and lowers the cost of prescription drugs, the industry has spent hundreds of millions of dollars in the last few years on campaign contributions, lobbying, and advertising. If you can believe it, the industry has over 600 paid lobbyists, including former top leaders of the Democratic and Republican parties, in their payroll in order to stop Congress from doing anything to lower the cost of prescription drugs and protect the American people.

Mr. Chairman, in recent years Americans have begun to express their disgust and anger with the pharmaceutical industry and with the high cost of prescription drugs by utilizing the marketplace. When they understand that they can purchase the same exact medicine in Canada for up to 90 percent less than they are paying at home, they are beginning to flock into that market. Estimates are, as you have indicated, that up to 1 million Americans are either going across the border to buy their medicine or are using the Internet. In recent years, dozens and dozens of new international Internet pharmacies have sprung up in Canada to serve that market.

And what has been the response of the pharmaceutical industry to that reality? Have they said, "Well, maybe we should stop ripping off the American people and lower our prices?" The answer is no. Their response, as you have just indicated, is to say, "Uh-oh, we had better do something about the fact that more and more people are going to Canada, and what we want to do is close that border, close that opportunity for Americans to buy safe and affordable prescription drugs in Canada."

As you indicated, quite appropriately, I don't think it was a coincidence that on 1 day Glaxo says, "We're going to limit the supplies to Canada," and then a few days later guess what happens, the FDA suddenly says, "Oh, we are really interested in this issue, really concerned about the safety issue." The argument that the drug companies and their allies—including, I'm afraid to say, the FDA—are giving is that they are concerned about the safety issue and their desire to protect the health and well-being of the American people.

In my view, this position is absolutely false and without merit. The truth is that all of the medicine being provided to Americans by registered pharmacies in Canada is highly regulated and that the Canadian pharmaceutical drug regulatory system is quite as strong as what exists here in the United States.

Interestingly—and you made this point, Mr. Chairman—despite the fact that some 1 million Americans who are now buying medicine in Canada, there is not, to the best of my knowledge, one instance in which adulterated or unsafe medicine has been sold to an American. But if the FDA is interested in health and safety, then let me tell you what you may want to take a hard look at.

Today in the United States one out of five Americans are not taking the medicine that their doctors prescribed because they cannot afford that medicine. One out of five. That, Mr. Chairman, is a huge health and safety issue. In fact, I intend to ask the GAO for a study to give us an estimate of how many Americans are dying

because they cannot afford the outrageously high cost of prescription drugs that are being charged.

I also want to know in that study how many Americans are seeing a deterioration in their health and an increase in suffering because they can't afford the medicine that they desperately need. My guess is that the answer will be thousands of Americans are dying, tens of thousands of Americans are seeing the deterioration in their health care because they can't afford the high cost of medicine. And meanwhile the FDA is running to worry about medicine coming in from Canada where zero Americans have been negatively impacted. Now, why is the FDA working with the drug companies to stop Americans from buying medicine in Canada?

And let me just speak for myself on this issue. I think the answer is obvious. I think that the drug companies are now asking for payback time. They have contributed huge amounts of money to the political process to protect their profits, and now they are calling in those chips, and I think that this is sad and it is outrageous.

Mr. Chairman, let me conclude by simply saying that if you and I think that the situation is bad today, think about what is happening right now in America. In Vermont, in Massachusetts, in Oregon, all over this country, because of huge deficits that State governments have, they are cutting back on the subsidized prescription drug programs that exist right now.

I will introduce into the record a newsletter from a senior citizen center in Medford, MA. And what the senior citizen center says is that in Massachusetts the State program is no longer welcoming seniors into the program, and if you want to get reasonably priced prescription drugs go to Canada. And now what the FDA is saying to those elderly people who are going to be thrown off of their State programs, "You've got an option. You could die. You get sick. But you can't get safe and affordable drugs from Canada." That is an outrage.

I thank you very much, Mr. Chairman, for holding this hearing.

Mr. BURTON. Thank you, Mr. Sanders.

Mr. Duncan.

Mr. DUNCAN. Well, thank you very much, Mr. Chairman. I will be very brief. Let me first say that I appreciate very much you calling this hearing on this issue that is so very, very important to so many Americans at this time and has grown by leaps and bounds in importance every day and every year in this country. And I want to commend you, Mr. Chairman, because you have a consistent record of calling for hearings and trying to do things about the problems that are of greatest concern, I think, to average Americans throughout the Nation.

Mr. Gutknecht has given me a publication—he gave it to me a few days ago—that said that the CBO, the Congressional Budget Office, has estimated that American seniors will spend over $1.8 trillion on prescription drugs over the next 10 years. And I can tell you that this is a problem that is of concern to more than just seniors. While they buy the highest percentage of the drugs in this country, still the younger and middle-aged people are having to spend many, many billions on prescription drugs, and then also baby boomers see what is happening to their parents who are going

through medical problems and are thinking about some of these problems and their retirements and so forth themselves, possibly for the first time.

I have come here today to try to learn a little bit more about this. I'm not the expert on this problem that you are, Mr. Chairman, and Mr. Gutknecht, who has done such great work, and Mr. Sanders, but I will tell you that I have seen in many different industries the more highly regulated an industry becomes the more it ends up being controlled by the big giants, because when the rules and regulations and red tape become so strangling, the small businesses and medium-sized businesses just don't have a chance. And I think that most people at least have the impression in this country that the FDA and the drug industry is controlled by a few big giants, very much to the detriment of the consumers in this country.

And I can tell you this is one of the major—this is one of the very top concerns of my constituents in Tennessee. And I don't represent some Appalachian poverty district; I actually represent a district where the economy is pretty good and average incomes and so forth that are about the national average or maybe even slightly above. And I can tell you that something is going to have to be done.

I look forward to working with you, Mr. Chairman, and Mr. Sanders and Mr. Gutknecht to try to see what we can do to do something for the American people in regard to these drug prices that in many cases have become almost outrageous or obscene in some ways.

I yield back the balance of my time.

Mr. BURTON. Thank you very much, Judge Duncan.

Mr. Tierney.

Mr. TIERNEY. Thank you, Mr. Chairman. Mr. Chairman, thank you for your graciousness in allowing me to join you today, even though I am not on this particular subcommittee. I think you know of my interest, as well as the interest of the other Members here, all of whom I congratulate, along with yourself, for that prolonged and constant interest that I think is focusing the light on this issue that cannot be shut out.

We have to stay persistent on this and we have to move on this. Mr. Sanders' comments were right on the money from beginning to end, and he has been a champion of this, as have you, Mr. Chairman.

We have, amongst the Members that are here at this subcommittee meeting today and others in the Congress, a number of bills addressing the cost issue on prescription drugs. Whether it is preserving access to safe, affordable Canadian medicines that was recently filed and many people have signed onto it, or whether it is Tom Allen's H.R. 1400 that talks about having prescription drugs for all seniors at a price that is no higher than the average drug in Canada, France, United Kingdom, Spain, Italy, or Japan—however we try to come at this problem, we seem to be getting more and more people signing on because all of the factors that Mr. Sanders and you addressed in your opening statements are becoming more and more evident.

Not too long ago another subcommittee of this Government Reform Committee, one on which I do sit, had hearings in Boston. Chairman Shays, Mr. Lynch, I, and others were at that hearing

and had members of the Veterans Administration in to testify about the program that they run, how they purchase prescription drugs for veterans and the enormous savings that are involved in doing it the way they do it because they are able to buy for such a large market and negotiate for the companies. We do that for veterans. We do that for Native Americans. We do it in medicine. And but for the resistance of the prescription drug companies and their champions, we could do it for Medicare, and that would solve an issue for a lot of seniors who are otherwise shut out of affordable prescription drugs and run into all of the circumstances enumerated in Mr. Sanders' statement.

I think the most disturbing part of this is the continual drum beat we hear from the industry and from those who are, in my estimation, much too close to the industry, although they are supposed to be regulating them and having oversight over them, and that is this drum beat for market forces.

The fact of the matter is that this is an industry that does not operate under pure market forces and the public is finally catching onto this, and I think as we move forward people are going to realize that there has to be a quid pro quo. There are patents that these companies get and they hold them for a substantial number of years, which essentially gives them a monopoly. That is not a pure market force. That is something that the public at large, through its representatives in government, give to those companies to encourage them to invest in research, to encourage them to develop prescription drugs, and to make and return a reasonable profit for their efforts.

In addition to that, by some estimations they receive almost one-half of their research and development moneys through the National Institute of Health and other Government sources, and yet they want to talk about an open and free market.

Fact of the matter is that this Congress is derelict in its duties if we don't start demanding back for those things that the American public has given them—patents, given them research moneys and cooperation in every other way, providing through taxpayers money an FDA program that enhances the value of their products by having a system that establishes what is safe. It is taxpayer money and it is inuring to the benefit of that company, of those companies.

For all of those reasons, we ought to be able to demand that they make a reasonable profit, and certainly that we don't impinge on the abilities to have good research and development for more prescription drugs that will be of assistance to people. But we ought to be able to set up a system that protects research and development through some regime and allows a reasonable profit while at the same time insisting that, in return for all the benefits this industry is getting, the American people get a fair, affordable price and that they can access these necessary medical prescription drugs.

Mr. Chairman, I just want to end on that note and thank you again and all the other Members that are here today for their continued insistence on this. Sooner or later we will put together a majority and it will be tripartisan in this body and we will get the American people so riled up that something will have to be done.

The FDA, if you really want to put your efforts toward safety, my request of you is don't tell us how you can't bring prescription drugs in over the Internet and don't tell us how you can't reimport them; tell us how you are going to take action to protect the efforts of the American people to use the Internet and to reimport at affordable prices until the prescription drug companies are otherwise brought into the fold and made to produce drugs that are accessible and reasonably priced.

Thank you very much.

Mr. BURTON. Would the gentleman yield?

Mr. TIERNEY. I certainly would yield.

Mr. BURTON. One thing that I meant to say in my opening remarks is that we are going to pass a prescription drug benefit paid for by the taxpayers of this country before too long, and when we do that I want to make sure that the taxpayers, who are going to be paying for an awful lot of these prescription drugs, are getting the best price that they can, because it is paid for by all the taxpayers, not just the people getting those prescription drugs.

So I am very, very concerned that once we pass that prescription drug benefit the pharmaceutical companies, who charge more here in the United States than any place in the world, are going to be loading all that profit on the back of taxpayers with the complicity of the Food and Drug Administration, and that really, really bothers me because you've got one agency that is paid for by the taxpayers getting money from the taxpayers, and then the taxpayers funding not only them, who is supposed to be their watchdog, but they are also funding the profits from the pharmaceutical companies.

Mr. TIERNEY. Reclaiming my time, those are excellent points. You know, we've had legislation filed here. A notable thing is how long the industry resisted putting this program into Medicare because they didn't want any constraints on their ability to charge. And we had various pieces that came to the floor of the House. One provision, in fact, had language that would disallow any effort to control price, and another provision in a separate bill that would insist that, in fact, if it went in Medicare, that Medicare did use some means of trying to bring these prices under.

Either these insurance companies have left totally without any regulation at all are going to bankrupt individual seniors one by one by one, or if they get into some system where the Government assists in the purchase of prescription drugs for seniors or others and there are no controls on the price and the profits that they can get while they're getting all these other benefits from the taxpayers' money, they will bankrupt this Government in one large chunk. So we have an obligation here specifically and particularly while we are producing such benefit for them through public taxpayer dollars to make sure that the regulation is there.

This is one instance where I think my friends on both sides of the aisle here understand that some regulation is necessary and Congress ought to get about the business of deciding what is appropriate.

I yield back.

Mr. BURTON. Mr. Gutknecht, you have been a champion of this for a long time, and so we are joining your cavalry.

Mr. GUTKNECHT. Mr. Chairman, I just would like to also thank you on behalf of Mr. Sanders, and especially myself who have essentially been laboring in this vineyard for a very long time. It has been very difficult to get some of the committee chairmen to take this issue seriously, and it is a very serious issue. It is huge.

When you look at the numbers, as the gentleman from Tennessee mentioned, our own Congressional Budget Office estimates that seniors, alone, will spend $1.8 trillion on prescription drugs over the next 10 years.

I've got a chart, if we can have that put up. I'll just point out—and these are not my numbers. They are a number of independent groups. This is from the Life Extension Foundation. You all have a little copy of this chart in the little handout I put out. I'll just point out a couple of things.

The differences between what American consumers pay and what consumers in the industrialized world pay for the same drugs—just look at the first four. Augmentin is a very commonly prescribed drug. The U.S.' average price for a 30-day supply is $55. In Canada that is $12, and in Europe the average price is $8.75. Cipro, a drug that we learned a lot about when we had anthrax here in these buildings, the average price in the United States is almost $88, the average price in Canada is $53, and in Europe that same drug sells for $40.

Incidentally, let me mention, Mr. Chairman and Members, that these drugs are essentially made in the same plants under the same FDA approval, so we're not talking about something different in Europe and Canada. These are the same drugs under the same FDA approval.

Glucophage, a very important drug for diabetes, in the United States, according to Life Extension Foundation and their research, about $124 for a 30-day supply. That same drug in Canada is $26, and in Europe the average price is $22. We're talking about enormous differences.

Mr. Sanders and I may not agree on everything, but we agree that there is something wrong with a system that allows those huge disparities, and in his discussion Mr. Sanders mentioned the drug tomaxaphin, a very important anti-cancer drug. Most of the basic research, most of the cost was done by the NIH. The bulk of the costs that were ultimately shouldered by the pharmaceutical company that patented it were for attorneys and for marketing, not for research and development. That's a very important drug for women here in the United States, and it is an example where we pay disproportionately more for the same drug, even though the drug was developed principally at taxpayer expense.

The arguments we are going to hear and we have heard consistently are about safety, but these are just specious arguments. Once you get below the surface and scrape off that thin veneer, you find out that it is, in fact, first and foremost the Food and Drug Administration, and every day this country imports millions of pounds of food.

Let me give you some examples. Last year the estimate is we estimated—we are told that we brought in 331 million pounds of apples. We brought in 19 million pounds of blueberries into the United States. We brought in 1.2 billion pounds of asparagus. We

brought 64 million pounds of strawberries into this country. We imported over a billion pounds of cantaloupes. The reason I mention that is, according to the FDA's own studies—and the FDA ultimately is responsible for the health and safety of those products coming into the United States—by their own estimates of these fruits and vegetables coming into the United States, their own tests, 2 percent of these products are contaminated with food-borne pathogens, including things like salmonella. Now, salmonella can kill you, and yet what is the FDA's response to foods coming into the United States? Almost nothing.

And Mr. Sanders is absolutely correct—the FDA keeps very good records, and as far as we can tell there has not been a single death related to importing of legal prescription drugs into the United States. As a matter of fact, the only real example that we can find where you have adulterated drugs was done by a pharmacist in Kansas City, MO, not in Alberta, Canada, not in Mexico, not in Europe. It happened in Kansas City, MO. That pharmacist, Robert Courtney, is currently serving a 30-year sentence in a Federal penitentiary.

So the idea of safety it seems to me is grossly overstated. And I want to make this point, and it is made by Steve Shondelmeyer, who really is the top expert in the United States on pharmacies and pharmaceutical costs. He is a professor at the University of Minnesota, and this is a quote I hope you'll remember—"A drug that you cannot afford is neither safe nor effective, and we are forcing too many seniors, too many Americans to make a choice they should not have to make because they cannot afford the drugs that are available."

Finally, let me just say—and I've already spoken longer than I should. But again Mr. Sanders is correct—this is not an issue between Republicans and Democrats. This is not even an issue between right and left. This is an issue of right versus wrong. It is wrong to force American consumers to pay the world's highest prices, because, after all, we are the world's best consumers.

The real answer it seems to me is to open up markets, to de-fang the FDA, to allow American consumers to have access to world-class drugs at world market prices. We should not permit our own FDA to stand between American consumers and lower drug prices. It is not really a matter of shame on the pharmaceutical industry, but for Members of Congress it is a matter of shame on us. We have allowed this system to exist. It is time for us to do something about it, and when we do we can save American consumers upwards of $600 billion over the next 10 years.

Again, thank you, Mr. Chairman, for having this hearing. This is an important beginning. I think it is going to yield important results for American consumers.

Thank you very much.

Mr. BURTON. Thank you for all your work, Mr. Gutknecht. You've done a great job in the past and I know you will continue.

Mr. Cannon.

Mr. CANNON. Mr. Chairman, thank you for holding this hearing. It is a very important hearing. I apologize that I can't be here longer, but I did want to ask unanimous consent to submit an opening statement for the record and some questions for the record.

Mr. BURTON. Sure. No problem.

Mr. CANNON. Thank you very much. I'll stay here as long as I can.

Mr. BURTON. Without objection.

Mr. Shays.

Mr. SHAYS. Thank you, Mr. Chairman. Mr. Chairman, I want to thank you, as well, for holding this hearing. I'm sorry I didn't get here to hear the comments of my other colleagues, but I want to say to Mr. Gutknecht he is a real hero to me on this issue. And I realize there are reasons why it exist, but we need to find a solution, and I hope he pursues this. I believe that we should be having a debate on this issue on the floor of the House. I think it is disgraceful, frankly, that we haven't had the kinds of hearings we should on this legislation and that we haven't been debating it in a very meaningful way. And let us learn from that debate, but in the bottom line for me prices are too expensive in the United States, too cheap elsewhere. I think that because of price controls I think prices probably need to come up a little bit overseas, they need to come down over here. And I think this legislation is a way to help force that issue.

Mr. BURTON. Thank you very much, Mr. Shays.

Ms. Watson.

Ms. WATSON. Mr. Chairman, I would like to thank you very much, and as we begin this inaugural hearing of this newly created Subcommittee on Human Rights and Wellness, let me first say that I look forward to working with you and all of the other members of this subcommittee to conduct meaningful oversight of Government operations in the area of health and human rights within our jurisdiction.

As the ranking minority member, let me also commend you for choosing an important issue to start with. We appreciate it.

The problem of discrimination in the pricing of U.S. pharmaceuticals is well documented, and it is of enormous consequences to millions of Americans who need affordable access to prescriptive drugs. Americans pay substantially more for prescriptive drugs than purchasers in other countries, and the problem is particularly acute for our Nation's uninsured seniors. Because Congress has failed to establish a Medicare prescriptive drug benefit, seniors who do not have private prescription drug coverage must pay for prescription drugs out of their pockets. Research by the minority staff of the Government Reform Committee has shown that seniors in Congressional Districts across the country pay twice as much for prescriptive drugs as their counterparts in other countries. For some drugs, they pay as much as 10 times as their foreign counterparts.

For these American seniors and the rest of America's 40 million uninsured, this can mean having to choose between going without food on the one hand or going without their medicine on the other.

Lower drug prices abroad have led millions of Americans to purchase drugs from foreign sources. Internet pharmacies, the subject of a recent full committee hearing, facilitate these transactions, and their recent proliferation has raised serious concerns about whether American consumers can receive appropriate medical supervision.

Mr. Chairman, despite the incessant pharmaceutical industry complaints to the contrary, research by the committee's minority staff demonstrates that international pricing disparities are not explained either by the duration and the cost of the FDA approval process or by the disproportionate U.S. research and development cost. It is within our power to correct this problem if we have the will to do so.

So today we have an opportunity to hear the perspectives of the FDA, GlaxoSmithKline, and representatives of interested professional and consumer organizations, including former Representative Roger Zion, chairman of the 60 Plus Association. I want to thank all of our witnesses for appearing before us today, and I look forward to hearing their views on pending legislative proposals and any other measures they might suggest to bring before us.

Thank you so much for allowing us this opportunity.

Mr. BURTON. Thank you, Ms. Watson.

I look forward to working with you as well as Mr. Sanders and Mr. Tierney and Mr. Shays and the judge and, of course, Mr. Gutknecht.

Mr. Hubbard, would you and Mr. Taylor please approach the table and stand to be sworn?

Do you swear to tell the truth, the whole truth, and nothing but the truth, so help you God?

Mr. HUBBARD. Yes.

Mr. BURTON. Be seated. Do you have an opening statement, Mr. Hubbard?

Mr. HUBBARD. Yes, Mr. Chairman. We have written testimony, but I'll make a few opening remarks, if I may.

Mr. BURTON. OK.

STATEMENT OF WILLIAM K. HUBBARD, SENIOR ASSOCIATE COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY JOHN TAYLOR, CHIEF, ENFORCEMENT GROUP

Mr. HUBBARD. As you noted, I'm accompanied today by Mr. John Taylor, the Chief of our Enforcement Group at FDA.

As you know, the emergence of the Internet has given consumers a new tool to carry out commerce in a number of ways. One of those uses, the purchase of prescription drugs, offers convenience, but also particular risk to unknowing consumers. Seniors in particular are using the Internet to purchase their medications from sites offering lower prices and are even traveling to other countries for that purpose, as well. There is no doubt that some drugs can be obtained more cheaply from foreign Internet sites and from foreign prescriptions; however, I should note that generic drugs, while less expensive in the United States than in many other countries—indeed, 7 percent less expensive in the United States than in Canada, and our new Commissioner, Mark McClellan, has made getting generic drugs on the market for seniors and others a high priority. In fact, he tells us frequently that we need to get cheaper drugs to patients, but we need to do it safely.

We certainly understand consumer concerns about the high cost of drugs. We all know that. But please understand that FDA's principal job is to ensure the safety of the drugs. We are not a price

agency. And we are very concerned about the trend toward foreign purchase of drugs, and we'd like to give you a few examples today of why we are concerned.

Here on the dais—and I believe you have a hard copy—are some posters of some Web sites. This first one looks like a very legitimate site with a picture of a physician, a pharmacist there, and it looks very American, it looks very legitimate. It says, "Your source for high-quality, FDA-approved medication." So our investigators have traced this site to its source. It's in Thailand.

The second one, if Sarah could flip for us, is again a site offering the drug Acutane, and Acutane is a drug that has very serious restrictions in this country because of its potential to cause severe birth defects. It is marketed under what we call a risk management program, in which very careful warnings are given for it not to be taken by women of child-bearing age or women who are pregnant. This site also talks about FDA-approved products and mentions that the products were made in New Jersey. This site is in Thailand, as well, and the drugs that we have purchased from this site come with no warnings to pregnant women.

The third site I will mention sells Viagra, and it, interestingly, even gives its address. It is at 164th Street in Miami Beach, FL. But, in fact, our investigators have found this site is in Israel.

We have other sites that we have given you in hard copy that all sell drugs from Canada, and these sites, when our investigators pursued where they were, they found they were registered in Barbados. Now, they also say they are in Canada, but the point is we don't know where they are and we have no way to reach to them to learn where they are. And if we don't know where they are, we don't know where they get their drugs.

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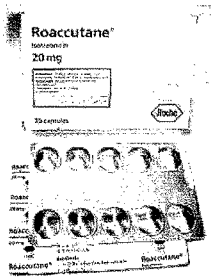

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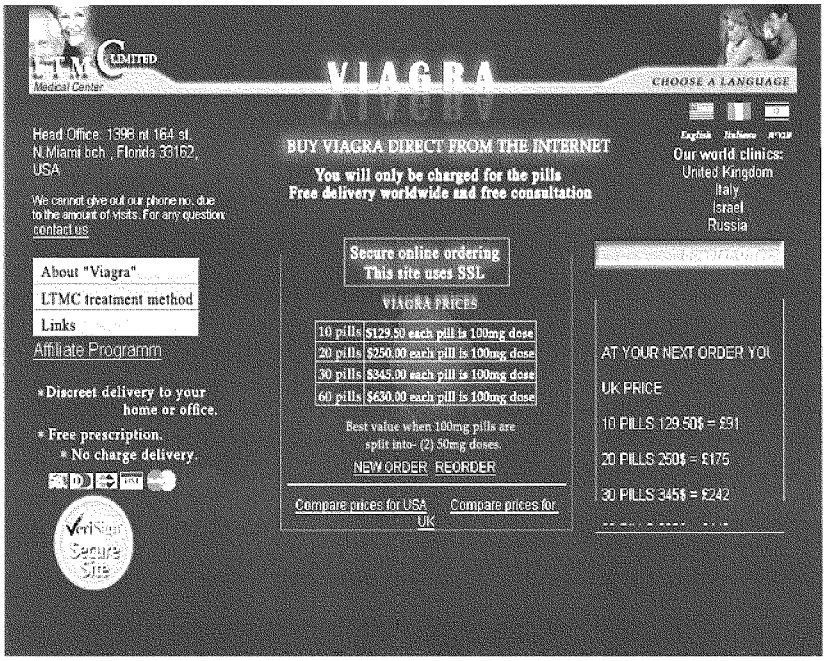

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Mr. HUBBARD. Let me show you, Mr. Chairman, just a few of the drugs that people buy from these sites. This is one we took out of the mail yesterday at Dulles Airport. That's what the patient gets—a bag of pills. It doesn't even give a name of the drug, no warnings.

Mr. BURTON. Where did that come from?

Mr. HUBBARD. It came from the International Mail Facility at Dulles Airport. It was purchased, we believe, over the Internet and mailed to an individual whose name I will not mention in Ashford, VA.

Mr. BURTON. But where did it come from?

Mr. HUBBARD. This drug—the return address it does not show, I'm afraid, although I have others that do show. I won't bring all of these out, but let me give you just one example. The return address on this one is Bangkok, Thailand, addressed to a person in Durham, NC. Apparently this was addressed to a person with a female name, and apparently she has bought some estrogen, some female drugs. But she has also purchased a drug called phenesteride. This drug is only for men. It is so toxic that if a pregnant woman even handles the pill from this box she could cause severe birth defects in her child, and this seal has been broken. This stuff is crumbling out of here.

So these are the sorts of things that people really get, Mr. Chairman, when they go on these Internet sites. None of the drugs that we got from the airport yesterday appear to have been made in the United States. They all have no labeling or foreign labeling and appear to be from sources other than the United States or North America.

Now, we are told that some of the drugs that come from Canada are, in fact, perfectly safe, and that may be true, but we don't have any way to know.

One of the best things that Congress ever did, we believe, was create the drug approval process that set up a process for drugs to be approved as safe and effective by the FDA and manufactured under very stringent manufacturing controls with very stringent marketing controls and regulation by the States of physicians and pharmacies. Patients in this country have total confidence they are getting a safe drug. People that buy these sorts of drugs cannot tell the difference.

And I'll make one last point. In foreign countries—in some foreign countries half the drugs are counterfeit. These are two identical drugs. One is real and one is counterfeit. I can't tell the difference. Our scientists can't tell the difference. And so if you open up the world to these sorts of drugs, the bad guys are going to have a way to get in. Right now it is very hard to market that product in the United States, very hard to get into the system. But these Internet sites give patients and nefarious sellers of drugs access to that system.

So with that, Mr. Chairman, I'll take your questions, and so will Mr. Taylor. Thank you.

Mr. BURTON. Thank you.

[The prepared statement of Mr. Hubbard follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

WILLIAM K. HUBBARD

ASSOCIATE COMMISSIONER FOR POLICY, PLANNING, AND LEGISLATION

"INTERNATIONAL PRESCRIPTION DRUG PARITY; ARE AMERICANS BEING PROTECTED OR GOUGED?"

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

U.S. HOUSE OF REPRESENTATIVES

April 3, 2003 -- UPDATE

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Committee, I am William K. Hubbard, Associate Commissioner for Policy and Planning at the Food and Drug Administration (FDA or the Agency). Today I am accompanied by John M. Taylor III, FDA's Associate Commissioner for Regulatory Affairs. We are pleased to come before the Subcommittee to discuss the benefits and risks of pharmaceutical sales over the Internet and what the Agency has been doing to address issues related to the sale of drugs from foreign sources.

With greater and greater frequency, consumers are using the Internet to access health related information and products. Sales of consumer products over the Internet have grown rapidly, including the sale of drugs. The growth in online drug sales by reputable pharmacies has provided significant benefits to consumers. Many managed health care organizations are searching for ways to achieve cost savings and are turning to online prescription plans as a means of providing quality service at a lower cost.

Online drug websites, however, also present risks to purchasers and unique challenges to regulators, law enforcement officials and policy makers. FDA is concerned about the public health implications of Internet drug sales, and we are responding to these concerns as we develop and implement risk-based strategies to protect the public health. FDA monitors the Internet to evaluate the quality of information being provided, and we encourage consumers to remain vigilant about their purchases and to rely on reputable Internet sites.

Although other products regulated by the Agency, such as medical devices, medical diagnostics, foods, dietary supplements and animal drugs also are sold online, this testimony will focus on the purchase of prescription drugs from foreign sources, whether this occurs through online sales or other forms of personal importation. We will discuss the advantages and risks, outline FDA's authority and enforcement activities in this area, and describe initiatives we are taking to better respond to the regulatory challenges we face.

In the context of prescription drug sales over the Internet, the private sector also has an important role in promoting consumer education and in providing assurances to consumers about the quality of products and services they offer. Our challenge is to make sure that protection for consumers who purchase prescription drugs in cyberspace with the click of a mouse is just as strong as the protection consumers enjoy when they purchase drugs at their corner pharmacy. Rapid technological developments have magnified the challenges we face. We constantly struggle to design appropriate solutions to meet these challenges. As electronic commerce embraces global markets, we should strive for consistent policies that promote safety regardless of the jurisdiction in which a U.S. consumer resides or the location of the pharmacy.

Let me begin by providing an overview of FDA activities and concerns relating to drugs purchased on the Internet including drugs purchased from foreign sources:

- **OUTREACH AND EDUCATION**: FDA is continuing its campaign to better educate U.S. consumers about the potential risks associated with the purchase of prescription drugs from foreign sources. Consumers take genuine risks when they purchase drugs from Internet sites that dispense foreign drugs or are not licensed and operated under state pharmacy law. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or

medication without adequate directions for use. Unsafe or inappropriate drugs put consumers at risk for dangerous drug interactions and serious health consequences. FDA continues to meet with organizations representing consumer health practitioners and industry. The Agency's website and brochures contain information for consumers on safely purchasing drugs online.

- **WORKING WITH STATES:** State pharmacy boards primarily regulate licensing and the dispensing of drugs at the state level. FDA has been working with the states to address concerns regarding importation of foreign prescription drugs. In February 2003, FDA hosted a nationwide call with 38 state boards of pharmacy, other state regulatory agencies and consumer groups to discuss current Internet drug sale practices. While some state laws are stronger than others, FDA has actively engaged with a number of states in jointly pursuing illegal Internet sites. FDA will continue to expand its cooperative activities with states in order to effectively address the many challenges in this area of electronic commerce.

- **CANADIAN COOPERATION**: FDA is actively working with the Health Canada regarding the increasing number of U.S. pharmacies that are advertising and promoting sales of prescription drugs from Canada. We have asked the Minister of Health to investigate a list of 45 Canadian websites that are selling drugs to U.S. citizens for investigation. We agreed to designate respective agency contacts on this issue and continue our discussions about Internet sales.

- **ENFORCEMENT**: Recent criminal and civil cases are evidence of the seriousness of the risks to public health that regulators uncover when responding to Internet drug sales. To date, FDA has initiated the following actions:

  - 372 Internet drug criminal investigations, 90 involve domestic Internet pharmacies.
  - 150 Internet-related drug arrests, 60 involve Internet pharmacies, and 92 convictions, 26 convictions involve Internet pharmacy cases;
  - 100 open Internet drug criminal investigations; 90 sites are under active review for possible regulatory or civil action;
  - Nearly 200 cyber warning letters have been sent to domestic and foreign online sellers;
  - 5 preliminary injunctions;
  - 15 product seizures;
  - 11 product recalls and the voluntary destruction of 18 illegal products.

BENEFITS OF ONLINE DRUG SALES

The Internet is rapidly transforming the way we live, work, and shop in all sectors of the economy.

In the health sector, tele-medicine allows people in remote areas to access the expertise of doctors

in the nation's finest health centers. The Internet permits individuals to obtain extensive medical information to help them understand health issues and treatment options. Millions of Americans used the Internet last year to find medical information, either in documentary resources or through online discussions with health professionals. Conducting research regarding health concerns is the sixth most common reason that people use the Internet, according to the market research firm, Cyber Dialogue Inc.

The sale of most consumer products over the Internet has grown rapidly in recent years, including the sale of prescription medications. FDA is aware that many reputable Internet pharmacies provide consumers seeking prescription drugs with a measure of safety, privacy and convenience. They provide information on drug interaction, and may e-mail customers if the drug they ordered has been recalled, a cheaper generic version of the drug becomes available or to remind them of prescription renewals. Some sell drugs for less than traditional "brick-and mortar" pharmacies, which is particularly important for people with limited income or without insurance coverage.

Prescription drug sales over the Internet can provide tremendous benefits to consumers. These benefits are many and include:

- Access to drugs for the disabled or otherwise homebound, for whom a trip to the pharmacy can be difficult.
- The convenience of shopping 24 hours a day; and a complete selection of pharmaceutical products.
- Privacy for those who don't want to discuss their medical needs in a public place.

Hyperlinks and search programs provide online customers with written product information and references to other sources of health information more easily than in the traditional storefront.

Finally, as the use of computer technology to transmit prescriptions from doctors to pharmacies expands, a reduction in prescription errors may be possible.

While online pharmaceutical sales are important for some customers, brick and mortar pharmacies can offer benefits and services that are often not available through the Internet, such as immediate access to prescription drugs needed for immediate treatment.

In matters relating to pharmaceutical sales over the Internet, the challenge for government at both the state and Federal level is to develop and implement policies that will allow legitimate electronic commerce to flourish while continuing to assure safety. Consumers must have confidence that protections for online consumers are equivalent to safeguards at brick and mortar pharmacies.

CONCERNS ABOUT ONLINE SALES

As beneficial as this computer technology can be, the Internet also has created a marketplace for the sale of unapproved new drugs, prescription drugs dispensed without a valid prescription, or products marketed with fraudulent health claims. Consumers may have difficulty identifying which sites sell legitimate products. As FDA considers the issues related to online drug sales, we recognize that there are various types of websites used for drug sales. Many sites focus on selling prescription drugs and are referred to by some as "Internet pharmacies." These sites offer for sale either FDA-approved prescription drug products, or in some cases, unapproved, illegal versions of prescription drugs. In many cases, FDA cannot provide consumers with any assurance that the

drugs purchased over the Internet were manufactured under current good manufacturing practices (cGMP) requirements even if the website appears to be based in the U.S. The Internet sites of legitimate, properly licensed pharmacies provide genuine benefits to consumers. However, sites that are unlicensed or otherwise engaged in the illegal dispensing of prescription drugs pose a serious potential threat to the health and safety of American citizens. While the increase in "Internet pharmacy" sites engaged in illegal sales is seen by some as a particularly potent threat, FDA believes that some of the non-pharmacy sites are also harmful. We have moved aggressively against those other drug sites unlawfully offering unapproved drug products, products making fraudulent health claims, or drugs for recreational use.

Consumers can, and should, be cautious when purchasing drugs online. There is no foolproof way of checking a site's reliability. Although there are legitimate sites that sell drugs, some sites do not employ licensed professionals and may not sell you the real drug. Consumers should check with their State Board of Pharmacy or the National Association of Boards of Pharmacy to see if the online pharmacy possesses a valid pharmacy license and has met state quality standards. In addition, consumers should use the same common sense they would apply to anyone they have never purchased a product from before: Does the site have a good reputation for the service it provides? Have people you trust used them and were they satisfied? If it is a site that cannot be verified – such as an overseas site – it may be best to avoid it. There is usually a local pharmacy that will have what the consumer needs.

FDA AUTHORITY

The unique qualities of the Internet, including its broad reach, relative anonymity, and ease of creating new or removing old websites, pose new challenges for the enforcement of the Food, Drug, and Cosmetic (FD&C) Act. FDA has found that many Internet sites are actually comprised of multiple related sites and links, thereby making investigations much more complex and resource intensive. The global nature of the Internet creates special problems for effective law enforcement. Different approaches to drug approval and marketing in foreign countries further complicate law enforcement issues for U.S. officials. FDA and other U.S. government agencies need to work closely with foreign governments to share information and to develop mechanisms for cooperative law enforcement.

The types of unlawful conduct that can occur when drugs are sold over the Internet are similar to unlawful activities that occur in other contexts. Under the FD&C Act, FDA has the legal authority to take action against:

- The importation, sale, or distribution of an adulterated or misbranded drug;
- The importation, sale, or distribution of an unapproved new drug;
- Illegal promotion of a drug;
- The sale or dispensing of a prescription drug without a valid prescription; and
- Counterfeit drugs.

When the Internet is used for an illegal sale, FDA, working with the Department of Justice (DOJ), must establish the grounds for a case, develop the same charges, and take the same actions as it would if another medium, such as a storefront or a magazine, had been used. FDA has investigated and referred cases for criminal prosecution and initiated civil enforcement actions

against online sellers of drugs and other FDA-regulated products, particularly sellers of drugs not approved by the Agency.

STATE REGULATION OF THE PRACTICE OF MEDICINE, PHARMACY AND DISPENSING OF DRUGS

The states have enacted laws regulating the practice of pharmacy and the practice of medicine to protect patients from harm resulting from the use of unsafe drugs, and the improper practice of medicine and pharmacy. Under many of these laws, to receive a prescription drug, a licensed health care practitioner who determines the appropriate treatment and issues a prescription for an FDA-approved drug generally must examine a patient. The prescription may also authorize refills. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets state standards.

These safeguards are not always in place when drugs are purchased over the Internet. A consumer may not be examined by a health care practitioner prior to purchasing drugs online. A patient-doctor relationship, in many cases, is not established. However, attempts to stop some U.S. doctors and online pharmacies from issuing online prescriptions without a physical examination have not always been successful. States face many obstacles when it comes to online pharmacies. State and state medical boards may have limited resources for enforcement and state regulations may currently address the Internet context. There is also the difficulty of prosecuting or taking legal action across state lines. Doctors may or may not be in the same state where the patient lives, so states may have difficulty prosecuting under their existing criminal or consumer protection laws. Only a handful of state legislatures have passed legislation to address issues that arise from online prescribing.

USE OF INTERNET TO BYPASS REGULATORY SYSTEMS

Even with these Federal and state systems in place, the Internet provides ample opportunities for circumventing established safeguards. The speed, ease, and anonymity of ordering products on the Internet can attract unscrupulous sellers. Individuals not licensed to sell prescription drugs can easily create websites that appear to represent legitimate pharmacies. The fact that operators can quickly change the location and appearance of their Internet site makes enforcement all the more difficult. More than many other types of electronic commerce, the unauthorized sale of prescription and unapproved drugs poses a potential threat to the health and safety of consumers.

Patients who buy prescription drugs from an illegitimate site are at risk of suffering adverse events, some of which can be life threatening. These risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions or drug contamination. Patients are also at risk because they often don't know what they are getting when they purchase some of these drugs. Although some patients may purchase genuine product, others may unknowingly buy counterfeit copies that contain inert ingredients, legitimate drugs that are outdated and have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Moreover, consumers who are desperate for a cure to a serious medical problem may be more than willing to accept a product of unknown origin.

FDA is concerned about the proliferation of sites that substitute a simple online questionnaire for a face-to-face examination and patient supervision by a health care practitioner. According to the American Medical Association, a health care practitioner who offers a prescription for a patient he

or she has never seen before, based solely on an online questionnaire, generally does not meet the appropriate medical standard of care. The Federation of State Medical Boards, Special Committee on Professional Conduct and Ethics, has found that "Prescribing of medications by physicians based solely on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct." This finding is especially important in light of the primary responsibility of states in regulating the practice of medicine. FDA is also concerned that the use of such questionnaires may jeopardize the privacy of a patient's medical records. We will continue to play a role in the Administration's efforts with the private sector to implement appropriate protections for patient's medical information. We also will continue to distinguish legitimate online communications from unlawful conduct that poses risks to patients.

The Agency is equally concerned that in some Internet transactions there is an apparent absence of any health professional/patient relationship. This is a particular concern where a patient may be using a prescription drug for the first time or where the patient may be taking other medications. FDA is concerned that the selection of prescription drug products or treatment regimens for a particular patient should be made with the advice of a licensed health care practitioner who is familiar with the patient's current health status and past medical history. In situations where a customary physician-patient relationship does not exist, the patient may be practicing what amounts to self-diagnosis. Consequently, the risk of negative outcomes such as harmful drug interactions, contraindications, allergic reactions or improper dosing is potentially magnified.

FEDERAL, STATE AND INTERNATIONAL JURISDICTION CHALLENGES

Online drug sales pose unique challenges for regulatory and law enforcement agencies at the state, Federal and international level. Internet technology can obscure the source of the product as well as provide a degree of anonymity to those responsible for selling and shipping the product. The parties to a transaction can be dispersed geographically and usually never meet. Thus, the regulatory and enforcement issues cross state, Federal, and international jurisdictional lines.

The sale of drugs to U.S. residents via foreign websites is an extremely challenging area. Some medications sold on the Internet may be legal in foreign countries but not approved for use in the U.S. Products not approved for sale in the U.S. often do not conform to the GMP and quality assurance requirements in U.S. laws and regulations, and it is illegal for a foreign pharmacy to ship such drugs into the U.S. Foreign sales pose the most difficult challenge for U.S. law enforcement because the seller is not within U.S. boundaries. Although FDA has jurisdiction over a resident in a foreign country who sells in violation of the FD&C Act to a U.S. resident, from a practical standpoint, the Agency has a difficult time enforcing the law against foreign sellers. FDA confronts the same obstacles facing other U.S. regulatory and law enforcement agencies seeking to hold foreign actors accountable for violations of U.S. law. FDA efforts are mostly limited to requesting the foreign government to take action against the seller of the product, or asking the Bureau of Customs and Border Protection (Customs) to stop the imported drug at a U.S. port-of-entry.

Canadian cooperation

On February 21, 2003, FDA representatives participated in a Forum on International Sale of Prescription Drugs from Canada in Ottawa, Canada. The forum was sponsored by the National Association of Pharmacy Regulatory Authorities (NAPRA), the voluntary umbrella association of Canada's provincial and territorial pharmacy licensing bodies. Some of the topics that related to FDA enforcement included: the need for clarification of legal status of international practice in the U.S., the legality of the sale of Canadian drugs to U.S. citizens, risks of the activity for U.S. and Canadian citizens, the legal recourse for any harm caused, the legal issues within the U.S. (at the Federal and state level) and the need to investigate and shut down non-pharmacy operations selling prescription drugs.

In February 2003, FDA participated in a call with officials from Health Canada to discuss his concerns regarding the increasing number of U.S. pharmacies that are advertising and promoting prescription drugs from Canada. FDA shared a list of 45 active websites based in Canada that are selling drugs to U.S. citizens for additional investigation.

Just last week, based on an FDA warning letter to the storefront operation, Rx Depot, the Manitoba Pharmaceutical Association (the pharmacy regulatory authority in the province of Manitoba) told a Manitoba pharmacy filling prescriptions for Rx Depot that the pharmacy that such conduct violates the Standards of Practice and the Code of Ethics in Manitoba. The pharmacy has been given 14 days to provide a satisfactory written response to the Manitoba Pharmaceutical Association or further action may be taken.

ADDITIONAL FDA ACTIVITIES TO PROTECT PUBLIC HEALTH

FDA cannot assure U.S. citizens that the prescription medications they are buying over the Internet from foreign countries such as Canada are safe. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S. approved prescription drugs are, in fact, of unknown quality. The rise of Internet drugs sales presents substantial safety questions about these products.

FDA is taking a number of steps to protect the public health of U.S. citizens including: (1) educating the public to the possible safety issues of drugs purchased from foreign countries, (2) working with professional groups to disseminate FDA's message on Internet drug sales, (3) partnering with the individual U.S. states and other Federal agencies to develop enforcement strategies, share cases and discuss important policy issues, and (4) increasing enforcement and policing of rogue Internet sites.

Public Outreach

Public outreach is an important tool that the Agency uses to inform consumers about dangerous or inappropriate drugs. FDA is expanding its public outreach about dangerous practices associated with Internet purchases. We are also conducting outreach to explain what compliance and enforcement actions we already have taken. This effort includes FDA *Talk Papers*, articles in *FDA Consumer* magazine, and information on FDA's website to help educate consumers about

safely purchasing drugs online. FDA's website also provides consumers with an opportunity to submit information to the Agency about sites that may violate the FD&C Act.

FDA remains committed to developing more effective education and enforcement strategies. With this goal in mind, FDA has created public education brochures and posters entitled, "*Things you should know about purchasing medications outside the United States*" to alert consumers to the health risks of buying medications outside the U.S. Outreach to consumers and the media continues, and new public material will be added to FDA's website.

In October 2000, the Division of Public Affairs in FDA's Center for Drug Evaluation and Research (CDER) launched an education campaign on the subject of buying prescription medicines online, entitled, "Shop Smart." This effort is part of FDA's "Buying Rx Drugs Online" education program. The centerpiece of this multi-media campaign is FDA's website: *http://www.fda.gov/oc/buyonline/default.htm* (launched December 1999) that can be accessed from FDA's home page. The website includes information for consumers, including tips and warnings, how to spot health fraud, frequently asked questions (FAQ's) and where to report suspected "rogue" sites. The website is one of the most frequently visited web pages on the FDA website.

Another central piece of our campaign is a brochure entitled, "Buying Prescription Medicines Online: *A Consumer Safety Guide*." The brochure was produced by the CybeRx-Smart Safety Coalition, a partnership of Internet companies, trade associations, health and consumer organizations and other government agencies. The brochure is available in hard copy from FDA, the Federal Consumer Information Center and the National Council for Patient Information and

Education (member of CybeRx-Smart). It is also posted on the FDA web site. The number of consumer complaints received by FDA has grown steadily with the circulation of the brochure.

In addition, the January/February 2001 issue of the *FDA Consumer* magazine included an article entitled, "Buying Drugs Online: It's Convenient and Private, but beware of 'Rogue Sites.'" The article is available online and thousands of reprints have been distributed at conferences and exhibits around the country. To date, the release has generated 644 newspaper articles in 35 different states. In addition, a 30-second radio public service announcement was produced and distributed to stations throughout the U.S. The release has been broadcast on 233 radio stations in 46 different states with an audience of almost 6 million. Two print public service announcements (one for medical devices and one for prescription medicines) were produced and sent to over 100 national magazines. Many Internet drug sites are unknowingly in violation of FDA's regulations, and the "about me" section of the release provides guidance on how to meet FDA requirements.

In November 2001, FDA worked with the Federal Trade Commission (FTC) and the Centers for Disease Control and Prevention to produce a National Association of Boards of Pharmacy (NABP) newsletter article on Cipro and the dangers of buying antibiotics to treat biological threats over the Internet. The article is an abbreviated version of the FTC alert, which was posted on its website in October 2001. FDA's website continues to update and post frequently asked questions (FAQ's), warning letters, talk papers, etc. on the subject of Cipro and other antibiotics.

The Agency will continue working with consumer groups, health care practitioner organizations, and industry to encourage all parties to keep their constituents and the public informed about safe practices for purchasing drugs online.

Professional Outreach and Partnering

At the February 1999 meeting of health professional organizations, FDA, the Federation of State Medical Boards of the United States, the NABP, the American Medical Association and the Association of Food and Drug Officials discussed the roles of each organization in regulating prescribing and dispensing medication via the Internet and how the various roles could better complement each other. At that meeting, the NABP announced its program to verify the legitimacy of Internet sites dispensing prescription drugs. The program, known as the Verified Internet Pharmacy Practice Sites, or VIPPS, provides a NABP "seal of approval" to sites that apply and meet state licensure requirements and NABP's standards. Over time, this seal of approval may help to assure consumers that the designated sites are offering FDA approved pharmaceuticals. The VIPPS program is voluntary and requires the applicant to pay a fee.

FDA continues to meet with organizations representing state regulatory and law enforcement bodies, consumers, health care practitioners and industry. The purpose of these meetings is to gather information on: 1) how issues relating to online drug sales should be addressed, 2) who should regulate and how they should regulate, 3) whether and what changes to the current law should be enacted, and 4) when to develop partnering arrangements. The organizations we are meeting with include:

- The National Association of Boards of Pharmacy
- The Federation of State Medical Boards
- The National Association of Attorneys General
- The American Medical Association
- The American Pharmaceutical Association

- AARP
- The National Consumers League
- The American Society of Health-Systems Pharmacists
- The National Association of Chain Drug Stores
- The National Community Pharmacists Association
- The Pharmaceutical Research and Manufacturers Association
- Pharmaceutical Security Institute

Coordination with State and Federal Agencies

Several Federal agencies, as well as the states, have the authority to regulate and/or enforce U.S. laws related to the sale of drug products online. Due to the growth of potential cases involving the Internet, there are instances when working with another agency or state yields a more effective enforcement result. Working closely with the states is essential to effectively regulate the sale of drugs, as well as the sale of prescription drugs without a valid prescription over the Internet. FDA has established partnership agreements with several state bodies, including the National Association of Boards of Pharmacies and the Federation of State Medical Boards, to coordinate Federal and state activities aimed at questionable practices associated with the selling and prescribing of prescription drugs over the Internet.

Two weeks ago, acting in conjunction with action by the Arkansas State Board of Pharmacy, FDA issued a warning letter to Rx Depot, a storefront operation. The letter put the firm on notice that FDA considers their operation to be a risk to public health. The Arkansas State Board of Pharmacy issued their own letter to the firm instructing them to cease violating state law immediately. Rx Depot and similar companies often state incorrectly to consumers that FDA

condones their activities and even that their prescription medications are "FDA approved," which could lead consumers to conclude mistakenly that the prescription drugs sold by the companies have the same assurance of safety as drugs actually regulated by FDA. FDA believes that operations such as this one expose the public to significant potential risks associated with unregulated imported prescription medicines.

In addition, FDA stated on March 27, 2003, that the Agency supports the joint actions of the state of Oklahoma State Board of Pharmacy and the Oklahoma Attorney General's Office petition for injunction seeking to stop the Rx Deport storefront operation from violating state laws. The state authorities filed a petition in Oklahoma state court, alleging that Rx Depot is illegally operating an unlicensed pharmacy.

As these actions indicate, FDA intends to work closely with its partners in the individual states in support of their efforts to curtain illegal and potentially dangerous operations, especially when they involve misleading claims about drug safety. FDA has been working closely with states on illegal Internet pharmacy issues over the past four year to protect the public health.

FDA has increased coordination with other governmental bodies and has met several times over the past year with other Federal agencies and state officials to share information, discuss the roles and responsibilities of the parties regarding online drug sales and identify opportunities for partnering in enforcement actions. FDA maintains strong working relationships with the DOJ, including the Drug Enforcement Administration (DEA) and Federal Bureau of Investigation (FBI), the U.S. Postal Inspection Service, Customs and other appropriate Federal and state

agencies. FDA believes that cooperation among Federal agencies is particularly critical to address the sale of drugs to U.S. residents by foreign sellers. Customs, the U.S. Postal Service, FDA, and the DEA all have important responsibilities in countering the illegal importation of drugs.

FDA determines when and with whom to engage in joint enforcement activities based on the type and severity of conduct identified through various means, including Internet monitoring. Although FDA is expanding its own Internet monitoring capabilities, the Agency also is developing partnerships in this area with other agencies.

Enhanced Enforcement Activities

FDA has conducted investigation and enforcement activities relating to Internet drug sales by re-deploying FDA personnel, which necessarily results in a reduction of investigation and enforcement activity in other areas. The Agency has taken action because we believe that illegal online drug sales pose a significant public health risk. FDA has initially focused its online drug sales-related enforcement activities in the following areas, particularly where there is a significant public health risk:

- Unapproved new drugs;
- Health fraud; and
- Prescription drugs sold without a valid prescription.

FDA has increased its capability to monitor the Internet and identify sites that potentially violate the FD&C Act through the use of various search tools and by upgrading its data handling

capabilities. These actions help the Agency to better understand the type and extent of unlawful conduct on the Internet and to more accurately assess whether its enforcement efforts have had an impact on illegal behavior.

Over the last three years, in an attempt to better comprehend the universe of websites selling drugs, the Office of Criminal Investigation (OCI) has reviewed thousands of websites and identified hundreds involved in the sale of drug products. This review was based on an electronic search of websites, followed by a manual review of sites that appeared to involve the sale of drug products. Because new websites are launched everyday and old websites are taken down, the total number of these sites changes over time.

In June 1999, FDA established a case assessment or "triage" team with representatives from the Office of Enforcement and OCI within the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Office of Chief Counsel (OCC) and the Office of Policy. Under the triage process, FDA obtains leads on sites that potentially violate the FD&C Act from internal Internet monitoring activity, state, other Federal or foreign law enforcement agencies, consumers, Congress, and the press. The triage team evaluates leads and decides whether they should be pursued through a civil or criminal investigation. Priority is given to cases involving unapproved new drugs, health fraud, and prescription drugs sold without a valid prescription and products with the potential for causing serious or life-threatening reactions. The triage team makes referrals, when appropriate, for FDA follow-up.

The triage process results in a better coordination of criminal and civil enforcement actions at the appropriate Agency components and reduces overlapping effort. This process helps to ensure that decisions are made in a timely way. The Agency seeks an appropriate balance in terms of achieving a maximum deterrent effect while taking action, if needed, to remove harmful products from the market. The team will continue to oversee Internet-related enforcement activities while they are being investigated, and will ensure that they are brought to appropriate conclusion. In addition, the scope of this group is being expanded to cover all FDA-regulated products.

OCI, working with OCC, is responsible for investigations of pharmacy sites and other Internet drug sites whose operations involve potential criminal activity. The Investigative Analysis Branch analyzes the information collected by OCI. After the suspect sites are researched, and possible violations are identified, the OCI field offices receive assignment for investigative work, which often includes undercover buys. Further investigation determines the bona fides of the pharmacy and doctor(s), and examines the relationship between the patient and doctor and the doctor and pharmacy. OCI has ongoing cooperative relationships with Customs, DEA, FBI, the Postal Inspection Service and appropriate state law enforcement and regulatory agencies, and this has enhanced their investigative capabilities with regard to Internet drug sales.

To date, OCI has initiated 372 Internet drug investigations, 90 of which involve domestic Internet pharmacies, with each case involving a variable number of websites from 1 to 25 or more. These cases originated from multiple sources including interception at mail facilities, web-based research, consumer complaints, and a variety of other sources. OCI has effected 150 Internet-related drug arrests, 60 of which involve Internet pharmacy cases, and obtained 92 convictions, 26

of which involve domestic Internet pharmacy cases. OCI currently has approximately 100 open Internet investigations.

Currently, FDA has 90 sites under active review for possible regulatory or civil action. Warning letters have been sent to 55 domestic online sellers. In addition, FDA has sent 137 cyber letters to operators of Internet sites in many countries, including Canada, that offer to sell on-line prescription drugs or unapproved drugs. These sites may be engaged in illegal activity such as offering to sell prescription drugs to U.S. citizens without valid (or in some cases without any) prescriptions. Cyber letters are sent over the Internet to the suspect websites to warn the operators that they may be engaged in illegal activities, and inform them of the laws that govern prescription drug sales in the U.S. FDA also sends copies of its cyber letters to the home governments of targeted websites when the locations can be identified. However, follow-up depends on the ability and willingness of the foreign regulatory bodies to investigate and take actions against website operators who are illegally shipping drugs to other countries.

In cooperation with DOJ, FDA has obtained five preliminary injunctions against the sale of illegal products, including one product marketed as a weight-loss aid containing a potent thyroid hormone that could cause heart attacks or strokes, and an unapproved cancer therapy. The Agency has also conducted 15 product seizures, 11 product recalls, and the voluntary destruction of 18 illegal products (generally pertaining to unapproved new drug products). Finally, FDA has been involved in numerous cases that involve rogue websites. A synopsis of many of these cases is attached to this testimony. (See Attachment) This attachment also lists a number of studies and surveys conducted by FDA to gather data on unapproved drugs coming into the U.S.

Newly revised import alert

On December 9, 2002, FDA reissued import alert 66-41 to include certain drugs approved for restricted use (due to safety concerns) in the U.S. This import alert allows FDA district field investigators to automatically detain without examination the listing of drugs. The Agency has posted this special alert on its home page warning consumers that certain restricted distribution drugs should not be purchased over the Internet. FDA has also put these restricted distribution drugs on Import Alert, informing the Agency's import inspectors that shipments of these drug are not appropriate for admission into this country under FDA's personal importation policy. FDA has also specifically informed Customs about the fact that these dangerous drugs should not be admitted. Imported drugs subject to this import alert are not admissible under FDA's personal importation policy.

The FDA field guidance for this Import Alert provides that release of an unapproved drug for personal use may be appropriate if, among other considerations, the drug is intended for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means, and it is not considered to represent an unreasonable risk. The guidance is intended to apply only to: (1) persons who have received treatment in a foreign country with an unapproved drug that is not available in the U.S., and who, upon returning to the U.S., have imported the drug for their personal use in an effort to continue the treatment started abroad; and (2) persons who have made their own arrangements for obtaining an unapproved drug from foreign sources, when the drug has not been promoted in the U.S.

OTHER FDA ACTIONS TO REDUCE THE COST OF SAFE AND EFFECTIVE DRUGS

FDA recognizes that part of the concern affecting consumer behavior is the availability of lower costs medications through Internet websites selling foreign products. The Agency is taking various steps that we believe will have a beneficial impact on the cost and availability of medications.

Increased resources to speed generic drug review

In Fiscal Year 2003, FDA received a $5.3 million increase to improve review times for generic drug applications. The Agency will use these resources to:

- Hire additional reviewers and inspectors to support generic drug review.
- Make technology upgrades to meet the expected increase in generic drug applications.

This will allow the Agency to set a goal of reviewing 75 percent of generic drug applications within 6 months after submission and better monitor the quality of finished drug products and bulk drug substances entering the U.S. from overseas.

In Fiscal Year 2004, the Administration proposes a $13 million increase for the Generic Drug Program to expand the development of generic alternatives and further improve review times for generic drug applications. FDA will use this proposed increase to:

- Establish manufacturing monographs and standards for bioequivalence, so that generic drug products can be developed in additional product areas.
- Hire more review staff to complete review and action on 90 percent or more of original applications within 180 days and decrease median approval time.
- Hire more field investigators for inspections of generic manufacturing firms to allow faster action on generic drug applications.

- Enhance Internet technology capabilities to support electronic submissions for generic drug applications.
- Increase Agency external collaborations to improve information for prescribers and consumers to ensure safe and effective use of generic drugs.

FDA also has proposed regulatory changes designed to limit delays in generic drug availability due to patent extensions. FDA's proposal would speed generic drugs to market, achieving an estimated $35 billion in savings for American consumers over 10 years. Specifically, the proposed rule would allow only one thirty-month stay per generic drug application, clarify that certain patents cannot be listed, and beef up the declaration that innovators must make about the patents they submit to FDA for listing in the Orange Book.

The proposed rule was published on October 24, 2002, and the comment period ended on December 23, 2003. FDA is currently finalizing the review of the comments and plans to issue a final rule in the coming months.

New Drug Development

FDA is taking steps to support market competition as a means of addressing the cost of developing and manufacturing drugs, and the availability of generic drug alternatives. Two new FDA initiatives in the Agency's Strategic Action plan address important factors affecting the cost of new drug development and the cost of drug manufacturing.

New drug development presents uncertainties that increase the business risk and costs to the innovator. Higher costs can create barriers to competition for new drugs and new innovators, companies that don't have access to the capital available to more established drug companies.

Although some scientific and technical uncertainties are inherent and unavoidable in drug innovation, others can be reduced or eliminated. This will help speed patient access to new drugs and reduce the cost of drug development. FDA has begun major initiatives to reduce those sources of uncertainty.

Sponsors may be uncertain about what specific evidence is required to demonstrate safety and effectiveness for a given disease. As a result, they may continue research with a drug that will not lead to the required evidence.

FDA has identified several priority disease areas and new technologies that the Agency believes are good candidates for new work to clarify regulatory pathways and clinical endpoints. The targeted disease areas include cancer, diabetes and obesity. The targeted technologies include cell and gene therapy, pharmacogenomics and novel drug delivery systems.

A planned formal guidance for industry will help to minimize guesswork and improve the design of clinical trials. This will benefit participating patients and allow more cost effective use of Research and Development funds. FDA is also taking steps to identify and address the root causes of avoidable delays in new drug review through retrospective analysis, better review

management and prospective evaluation of our review process from the perspective of both FDA and drug innovators.

CONCLUSION

Mr. Chairman, online shopping for pharmaceutical products clearly provides many benefits for consumers. However, it also poses a number of significant risks. In addition, the nature of Internet technology presents law enforcement and policy makers with unique challenges. FDA is grappling with these challenges including our need to carefully balance consumer access to information and products with protecting the public health. We are using our existing compliance and enforcement tools to prevent consumers from obtaining adulterated and/or misbranded FDA regulated goods via the Internet and will continue to evaluate what changes in our procedures, regulations, or the law might be appropriate to enhance our efforts. Our goal is to ensure that the protections afforded to consumers who purchase drugs from their corner drugstore also extend to consumers in the electronic marketplace.

We look forward to working further with Congress on this important issue, and I would be happy to answer any questions you may have.

ATTACHMENT

FDA CASES AND STUDIES

CASES

Norfolk Men's Clinic

On February 16, 2002, a Federal jury in Alabama convicted Anton Pusztai and Anita Yates of charges arising out of the operation of the online pharmacy that illegally sold prescription drugs over the Internet to consumers. On June 18, Pusztai and Yates were sentenced respectively to more than 15 and 6.5 years. Pusztai, an Australian citizen, and Yates, a resident of Clanton, Alabama, were convicted of conspiracy to commit violations of the FD&C Act, conspiracy to commit money laundering, mail fraud, dispensing misbranded drugs, and operating a drug repackaging facility not registered with FDA. From fall 1998 to the summer of 2000, the defendants operated a website called *Viagra.au.com*, also known as Norfolk Men's Clinic, and related sites, that sold a variety of prescription medications.

In September 1999, OCI received information regarding the Norfolk Men's Clinic and the website. Based on this information, several covert purchases were made via the Internet. Search warrants were executed in October 1999 that resulted in the seizure of prescription drugs and business records. Based on these purchases and information gathered through numerous interviews, several individuals were indicted. In addition to defendants Pusztai and Yates, the president of a prescription drug wholesaler located in Miami, Florida, and the company itself, pled guilty to distributing misbranded drugs.

The company also plead guilty to obstruction of justice. In conjunction with the indictment, a second search warrant was executed in Clanton, Alabama, along with two search warrants in West Virginia. While most of the drugs sold in this operation were domestic product, some appeared to have originated in New Zealand.

Dr. Mario Alvarez-Valentin

On January 11, 2002, Dr. Mario Alvarez-Valentin was sentenced to 26 months imprisonment after pleading guilty to wire fraud in connection with the unlawful sale of Viagra over the Internet. Alvarez was a physician contracted with Internet websites for the purpose of authorizing prescriptions for Viagra to persons throughout the U.S. From April 2000 to January 2001, Alvarez, who was only licensed to practice in Puerto Rico, prescribed and caused to be prescribed more than 4,000 prescriptions for Viagra. In doing so, he violated the licensing laws of at least 20 states. United States v. Alvarez-Valentin, D.P.R.

Kwikmed

On October 1, 2002, a Federal Grand Jury in Arizona returned a 198 count indictment against Kwikmed, Inc., Cymedic Health Group, Inc., four owners of these corporations, and two physicians associated with the corporations. The indictment alleges that defendants operated Internet websites, two of which include *kwikmed.com and cymedic.com*, through which they sold prescription drugs, including Viagra, Celebrex, Xenial, and Propecia. The websites did not require a consumer to have a prescription

before receiving the drugs. Instead the customers were required to complete a questionnaire, which the website told customers would be reviewed by a physician.

Customers were charged a fee for this purported medical consultation. The indictment alleges, however, that for the overwhelming majority of applications, no medical reviews, consultations, or physical examinations by a physician took place before drugs were shipped to customers. The indictment also alleges that defendants repackaged drugs obtained from a drug wholesaler, even though defendants were not a registered manufacturer or a licensed pharmacy, and that there was never a licensed pharmacist in any way involved. The indictment also alleges that the drugs dispensed were adulterated because of the defendants' failure to follow cGMP in packaging, holding, and labeling of the drugs. The indictment alleges that during the course of the conspiracy the defendants and others generated sales in excess of $28 million, which was billed to consumers as charges for prescription drugs, doctor consultations, and shipping. These sales resulted from the defendants' distribution of at least 48,816 new orders for prescription drugs and 41,817 refills of those orders. The indictment charges defendants with several violations of the FD&C Act, as well as conspiracy, mail fraud, and money laundering. The charges were the result of an investigation by FDA and the U.S. Postal Inspection Service.

United States v. Carl David Roberts, (E.D. Tenn.).

On January 15, 2003, Roberts was sentenced to a prison term of 57 months. Roberts was chief administrator of an Internet business that used sophisticated technology to sell prescription drugs, including Schedule II narcotics, without any medical supervision.

He had directed an organization that sold drugs from within the U.S., and from abroad. His organization included drug suppliers from Mexico, the Netherlands, and Ecuador. In September 2002, he pled guilty to distribution of controlled substances and conspiracy to violate the FD&C Act.

United States v. Kimball, (11th Circuit).

On May 14, 2002, the Eleventh Circuit affirmed the district court's sentence. Kimball received a 13-year sentence for violating the FD&C Act. Kimball was found guilty after trial of putting prescription drugs into commerce without a prescription. His marketing efforts included use of the Internet.

Medications Express

On June 7, 2001, Gerald Bevins was convicted in U.S. District Court for the Southern District of California of conspiracy to defraud the U.S. and commit offenses against the U.S. by introducing misbranded drugs into interstate commerce and smuggling. On September 4, 2001, Bevins was sentenced to serve twenty-four months in prison. The case was initiated on information received from Customs concerning an Internet website called Medications Express. Bevins sold Mexican prescription pharmaceuticals from this website and claimed that no doctor's prescription was necessary. He continued to sell Mexican prescription pharmaceuticals through the mail from Sun City, California, even after discontinuing the Medications Express website. Bevins, his wife and daughter would receive orders via mail, travel to Tijuana, Mexico, to purchase the pharmaceuticals, and smuggle them back into the U.S. The three packaged the

pharmaceuticals into commercial courier boxes and shipped them to customers around the U.S. The drugs supplied by Bevins were labeled in Spanish.

Canadian Drug Store, Inc.

On May 14, 2002, the Ontario College of Pharmacists, a Canadian government agency, filed charges under Ontario law against The Canadian Drug Store, Inc., for unlawfully operating an unlicensed pharmacy and using an un-registered pharmacist in filling prescriptions for U.S. residents. The College also filed charges against a licensed pharmacist, pharmacy, and physician in Ontario for helping to facilitate the delivery of prescription and non-prescription drugs to U.S. residents. A drug wholesaler was charged with supplying medications to a non-licensed pharmacy.

According to a statement released by the College, there are many websites selling prescription and non-prescription medicines that have not been accredited as legitimate pharmacies by pharmacy regulators in either Canada or the U.S. Some websites presenting themselves as online "pharmacies" or "drugstores" may be operating without a pharmacy license and dispensing prescriptions without the oversight of a licensed pharmacist.

Total Remedy/Prescription Center II

According to news accounts, a Los Angeles pharmacy and two pharmacists were assessed penalties of almost $90 million in a California Board of Pharmacy proceeding in May 2002 for filling more than 3,500 illegal prescriptions over the Internet. The case

was brought under a state law that creates a requirement to fill a prescription pursuant to a good-faith medical examination. The Internet site concentrated on filling prescriptions for lifestyle drugs such as Viagra and Propecia (Associated Press, 5/29/02).

Pillbox Pharmacy

In March, 2002, a Texas pharmacist, three doctors, two corporations and an individual were charged in a Federal indictment alleging that they conspired to illegally dispense drugs in connection with an Internet pharmacy operation. The indictment charged one pharmacist, three physicians and two corporations, the S&H Script Shop and the Pillbox Medical Center, with conspiring to illegally dispense controlled substances and commit money laundering. According to the indictment, between January 1, 2000, and June 12, 2001, the defendants grossed more than $7.7 million from the Internet sales of just two drugs alone. The indictment alleges the doctors would issue prescriptions without establishing a patient history, performing a mental or physical exam, using appropriate diagnostic or laboratory testing, or providing any means to monitor medication response. The charges were the result of an 18-month investigation by FDA, DEA and IRS, working with the U.S. Attorney's office. In April, the pharmacist and two corporations pled guilty to illegally dispensing controlled substances, and agreed to forfeit $1 million.

STUDIES

Carson mail study

In early 2001, FDA and Customs conducted a survey of imported drug products entering the U.S. through the Carson City, California mail facility (the Carson pilot). The

purpose of the Carson pilot was to examine incoming mail shipments of pharmaceutical products over a specified time frame to identify both the volume and the types of drug products entering the U.S. We also wanted to better assess the level of effort and human resources required to handle drug importations at a mail facility, and to better understand the public health implications these importations may have for U.S. consumers.

The Carson pilot ran for a five-week period, with FDA inspectors present for 40 hours per week, a much higher staffing level than is normally possible. Although Customs took a baseline sample which indicated they could have set aside for FDA review an estimated total of 16,500 international packages (650 packages per day), FDA was able to examine only 1,908 packages during the five-week pilot, or an average of 381 packages per week. Unexamined packages were sent on to the addressees. Of the 1,908 packages examined by FDA, 721 parcels (38 percent of the total) originating in 19 countries were detained and the addressees notified that the products appeared to be unapproved for use in the U.S., misbranded and/or a drug requiring a doctor's prescription.

Analysis of the Carson Pilot Drug Parcels

FDA's Center for Drug Evaluation and Research (CDER) reviewed listings of the products detained during the Carson pilot to define better the nature of the risk to public health from the types of products coming into the U.S. through personal importation. CDER's review demonstrates that there are serious public health risks associated with many of the 721 drug shipments (composed of 197 different drugs) detained at Carson. There are primarily two types of risks that consumers of these drugs would face.

The first risk arises when consumers take drugs of unknown origin or quality. Second is the very significant risk associated with taking many of these drugs without first obtaining a physician's prescription and without the continued oversight of the physician.

In general, FDA has no information to establish where these drugs were actually manufactured and whether current GMP requirements were followed. There is also no assurance that the drugs were packaged and stored under appropriate conditions to avoid degradation or contamination. Approximately eight percent of the shipments contained drugs that could not be identified because they contained no labeling; some of these contain only foreign language labeling. Most of these drug shipments were contained in plastic bags; one shipment contained drugs taped between magazine pages.

Several drugs do not appear to correspond with any FDA-approved drugs and therefore the risks associated with the products are difficult to assess. One drug had been reviewed for FDA approval but was rejected because its efficacy could not be demonstrated. Several shipments contained three drugs that were once approved by FDA but have been withdrawn from the market.

The vast majority of the shipments were identified as containing prescription drugs. A number of controlled substances were also identified. Importation of these drugs containing controlled substances violates criminal provisions of the Controlled Substances Import and Export Act, including 21 U.S.C. 960 (unregistered importer/declared importation). These drugs have the potential for abuse, addiction or

risk of life-threatening overdose. A physician's prescription and oversight are essential for managing these risks. Additionally, drugs to treat diseases including diabetes, hypertension and serious infection were included in the Carson shipments, as were many drugs with serious contraindications and/or possible drug or food interactions.

Many of the drugs identified in the Carson pilot are intended to treat conditions that only physicians can properly diagnose. Consumers who bypass physician diagnosis and prescribing may be exposing themselves to risks and toxicities that cannot be justified by offsetting benefits. For example, almost ten percent of the shipments were for antibiotics, despite the fact that consumers are generally not able to diagnose whether their symptoms are caused by bacterial or viral infections.

Three Surveys

Within the last two years, FDA has conducted three surveys at U.S. borders to gather data on drug products carried by individuals entering the U.S. While these border surveys involve land traffic rather than mail importation, the results show some similarities to the findings from the Carson mail pilot, but also some significant differences.

Southwest Border Survey (August 2000)

A survey of prescription drugs being brought by pedestrians into the U.S. at eight ports-of-entry along the 2,000-mile border with Mexico was conducted by FDA's Southwest Import District (SWID) with the assistance of other agencies. The survey looked at activity during four hours on a Saturday (August 12, 2000) at eight border ports in

California, Arizona, and Texas. The purpose of the survey was to determine what specific types of products are being imported, and who is importing these products. The data collected from over 600 interviews indicated that the most common importers were bringing back primarily antibiotics or pain relievers. Prescriptions were held by 63 percent of the persons interviewed (59 percent U.S. prescriptions while 41 percent were Mexican). While many of these products are already available as FDA-approved drugs in the U.S., some are unapproved for sale in this country.

Canadian Border Survey

On January 6, 2001, in cooperation with Customs, FDA conducted a survey to obtain a snapshot of prescription drug products being brought into the U.S. from Canada via passenger vehicles. During the eight-hour survey at three ports-of-entry in New York, Michigan and Washington, a total of 10,374 passenger vehicles and 58 buses crossed into the U.S. Of these, 33 passenger vehicles (35 individuals) were referred by Customs to be interviewed. These individuals brought in a total of 47 containers of drug products from Canada. The largest group of products was pain medicines. The next largest group of products was herbal products, with the reason for importation being that the products were not available in the U.S. Some of these drugs are unapproved foreign versions of FDA-approved drugs, although some approved for sale as prescription drugs in the U.S. are sold as over-the-counter medications in Canada.

Southwest Border Survey (April 2001)

On April 11, 2001, FDA, Customs, and other agencies conducted a survey of prescription drugs being brought into the U.S. at seven ports-of-entry along the U.S./Mexican border. During the four-hour survey, a total of 586 persons imported in a total of 1,120 drugs. Approximately 56 percent had a prescription for the medicines (61 percent were U.S. prescriptions, 39 percent were Mexican). As in the earlier survey, many of these products are already available as FDA-approved drugs in the U.S., while some are unapproved for sale in this country.

Mr. BURTON. I want to give you some figures that we found very interesting. In 1990, the pharmaceutical industry gave $2.3 million in campaign contributions. In 1992 it was $5 million. In 1994 it was $5.2 million. In 1996 it was $9.3 million. In 1998 it was $9 million. And then in 2000, because there were questions about a lot of things dealing with the pharmaceutical industry, it went from $9 million to almost $20 million the last two election cycles. There are 600—over 600 lobbyists up here lobbying the Congress, the administration about pharmaceuticals, and there are many of us in the Congress that believe they do have undue influence. And there is also kind of a revolving door policy where an awful lot of the people who work at the FDA and our health agencies leave these agencies and go to work directly with the pharmaceutical industries. I'll be glad to give you some cases in point if you'd like to have those, but I think you probably are aware of that.

Now let me ask a few questions. Your testimony states that the FDA cannot assure U.S. citizens that prescription drugs they're buying over the Internet from foreign countries such as Canada—and that's what we're talking about today—are safe. On September 5, 2001, you testified before the Senate Committee on Commerce, Science, and Transportation that you've not looked at the chain of supply system in Canada. Have you looked at the chain, Canadian chain of supply system since you testified in 2001?

Mr. HUBBARD. We've certainly had discussions with our Canadian colleagues. However, FDA has no authority to go to Canada and assess their system.

Mr. BURTON. So you haven't looked at it?

Mr. HUBBARD. Other than having the Canadian counterpart to the FDA explain their system to us, no, Mr. Chairman, we have not.

Mr. BURTON. You haven't. Can you make the assertion today that the Canadian chain of supply system is unsafe for Americans?

Mr. HUBBARD. I would not want to characterize another country's drug safety system, Mr. Chairman.

Mr. BURTON. Well, I know, but you've brought all these packages in here, mostly from Thailand and every place else, but you didn't say anything about Canada.

Mr. HUBBARD. Well, we'll be glad to characterize the safety of drugs, but not of another country's drug approval system.

Mr. BURTON. How many cases do you know of where Canadian pharmaceuticals came in this country, caused damage to people?

Mr. HUBBARD. We think that is unknowable. How would you know if hundreds of thousands of patients are taking a Canadian or any other foreign blood pressure medicine and their blood pressures are being reduced by 10 points instead of 40?

Mr. BURTON. How many people——

Mr. HUBBARD. You might not know that for 10 years.

Mr. BURTON. How many people were damaged last year by aspirin? Do you know?

Mr. HUBBARD. I don't know, Mr. Chairman.

Mr. BURTON. Well, that's sold in the United States.

Mr. HUBBARD. Aspirin certainly has——

Mr. BURTON. That's over the counter.

Mr. HUBBARD. Yes.

Mr. BURTON. You don't know that, either?

Mr. HUBBARD. I don't know that specific number.

Mr. BURTON. How about Tylenol?

Mr. HUBBARD. Again, all of the non-steroidal, anti-inflammatory drugs have side effects.

Mr. BURTON. But you don't know how many here in the United States and you don't know how many from Canada were caused?

Mr. HUBBARD. I'm sure our physicians at FDA would know more about the domestic drug side effects.

Mr. BURTON. Mr. Hubbard, at this same Senate hearing a letter from the former FDA Commissioner, David Kessler, was read, and it stated, "The Senate bill, the Meds Act, which was signed into law, allows only the importation of FDA-approved drugs manufactured in FDA-approved facilities and for which the chain of custody has been maintained addresses my fundamental concerns. I believe the importation of these products can be done without causing a greater health risk to the American consumer."

Mr. HUBBARD. I do not believe we agree with that, Mr. Chairman.

Mr. BURTON. Well, he was the head of the FDA, wasn't he?

Mr. HUBBARD. He certainly was.

Mr. BURTON. Are you the head of the FDA?

Mr. HUBBARD. No, I am not, Mr. Chairman.

Mr. BURTON. Does the head of the FDA now take issue with this?

Mr. HUBBARD. I believe Dr. McClellan would say that it is important that consumers in this country get cheaper drugs, but safely, and that bringing in drugs from foreign countries would not be a way to do that.

Mr. BURTON. Mr. Kessler I think was talking about Canada in particular, wasn't he? And he said the chain of custody, because that's what they call it up there, "for which the chain of custody has been maintained addresses my fundamental concerns."

It addressed his concerns because he said, in effect, that the Canadian system did a pretty good job, and he said, "It addresses my fundamental concerns. I believe the importation of these products can be done without causing a greater health risk to the American consumer."

You don't agree with that?

Mr. HUBBARD. I believe he was referring to legislation that you referred to earlier, Mr. Chairman, that passed the Congress and was not effectuated either by the Clinton or the Bush administration.

Mr. BURTON. No. But the point is he was saying he had no concerns about that, didn't he?

Mr. HUBBARD. I think he was saying that legislation would alleviate concerns he had because it would set up a verified chain of custody of the drugs to confirm that they had gone to Canada from the United States and it would turn to the United States with a chain of custody maintained.

Mr. BURTON. Right. Well, I think that's pretty clear. He didn't have a great deal of concern. Do you believe that Canada regulates the quality of medications manufactured and sold there as rigorously as the FDA?

Mr. HUBBARD. Again, that's asking me to judge or characterize the Canadian——

Mr. BURTON. Well, let me ask you a question.

Mr. HUBBARD. All right.

Mr. BURTON. If you don't know, why don't you find out? You've got people here who are paying two and three and four times as much for drugs, and you sit back and say, "You might be criminally guilty if you abet somebody buying these drugs." And these people, as Mr. Sanders said, many of them can't afford to buy their drugs and food. And I know some of these people, and you're sitting there in your ivory tower and you're saying, "Well, I don't know about Canada. I don't know if their system is as good as ours." You had cursory conversation with them, but you really don't know. And yet you're making these decisions saying, "Hey, if you buy drugs from Canada you may be guilty of breaking the law," thereby implying that these people might be prosecuted.

Now, these senior citizens, many of them aren't as sophisticated as you and I. They know that you're probably not going to do that, but you scare the hell out of them.

Now, you know, the last thing I'd like to say to you is that this is not going to be the end of it. Today in the AARP publication going to 35 million people they are talking about this issue. We're going to contact every single senior citizens group in this country and keep pounding on them. Now, I know that the pharmaceutical industry gives $20 million a year in political contributions up here on the Hill and to the administration and to others. They do that both under Democrat and Republican administrations. And I also believe the FDA is influenced by the pharmaceutical industry, and anybody that doesn't believe that has got their eyes shut.

[The information referred to follows:]

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More Americans Go North for Drugs

50-Plus Consumers Find Price Relief in Canada; Internet Fuels the Trend

By Patricia Barry
April 2003

Just a few years ago, they took the bus to Canada—mostly older Americans from northern states who knew that filling prescriptions at Canadian pharmacies could save them big money. But now people from all over the country are doing it, too—by mail order via the Internet.

An estimated 1 million Americans use this cross-border pipeline—which many regard as a lifeline—to buy medicines at substantially lower prices than they can at home. The trickle has become a torrent, and the number of customers increases every day.

That volume of traffic has intensified debate on the legal and safety issues of buying prescription drugs by mail from Canada.

And it has prompted retaliation. One major pharmaceutical manufacturer, GlaxoSmithKline, has now stopped supplying its products to Canadian mail-order pharmacies that sell to Americans—an action widely regarded as a trial balloon for other drugmakers wanting to halt the trade.

For many people already buying drugs from Canada, Glaxo's action came as something akin to a declaration of war. Older Americans staged protests in several cities and began boycotting the company's nonprescription products. A consortium of consumer groups, in a full-page ad in The New York Times, accused Glaxo of cutting off vital supplies.

"People are terribly angry," says Peter Wyckoff, director of the Minnesota Senior Federation, a non-profit group that pioneered sending buses to Canada and now runs a mail-order service. "People are forced to buy drugs out of Canada because of inordinately high prices in the United States."

But the Food and Drug Administration (FDA), the federal agency that oversees prescription drugs, and the U.S. Customs Service say that the practice is illegal and may be unsafe.

So what are consumers to do? In a special investigation, the AARP Bulletin examines the differences in drug prices north and south of the border and the legal and safety issues involved in buying drugs from Canada.

PRICE DIFFERENCES

Pharmaceutical prices are usually (though not always) much lower in Canada than here, even for American-made drugs. This is mainly because Canada, like most other Western governments, regulates drug prices, whereas the United States does not.

Sometimes lower-cost generic versions of brand name drugs come to market more quickly in Canada because of different patent laws. The Canadian generic of the breast cancer drug tamoxifen, for example, used to cost one-tenth of the U.S. brand before an American generic was marketed, and still costs far less.

Lower Canadian prices often provide the only affordable option for Americans without drug coverage who do not qualify for low-income programs but cannot pay top dollar for medications.

Meredith Behrens, of Ardenvoir, Wash., lost her employer coverage when she retired at age 65. Taking Lipitor to reduce cholesterol, she found it "so expensive" that she cut back her dosage. "And my cholesterol level went up immediately," she says. "That was not a wise thing to do." Buying by mail from Canada, even with shipping costs, cut her outlay by 42 percent.

Sandra Barron, of Silver Spring, Md., used to spend a third of her monthly Social Security check on medications at the cheapest local pharmacy she could find. But last year, she says, "I discovered Canada. My drug costs went down from $430 to $160 a month. That's an enormous difference." She is saving more than $3,240 a year, or more than 60 percent.

Canadian mail-order pharmacies do not supply all medications. Typically they focus on long-term maintenance drugs—most often American-made—that older people commonly use. Even among these pharmacies, prices vary a good deal, and so far there is no website that allows consumers to compare them.

This is one reason why the Minnesota Senior Federation (MSF) formed its Prescription Drug Information Center, a program to help Americans of all ages get the best possible deal along with quality protections. During a seven-month pilot project, it vetted, tested and negotiated with a licensed Toronto pharmacy that agreed to cut its professional fees to provide even deeper discounts. This resulted in "the first consumer-negotiated rates to come out of Canada," Wyckoff says.

IS IT LEGAL?
A 1987 law, written before Internet pharmacies existed, makes it illegal to import prescription drugs, whether made in America or not.

In practice, the FDA and U.S. Customs have long turned a blind eye to people returning from abroad with up to a 90-day supply for their own use. And although in recent years both agencies have occasionally intercepted mail-order shipments from Canada, they have never prosecuted an American consumer. They simply haven't the manpower, they say, to enforce the law in a traffic that generates millions of packages a year.

But last month the FDA began taking a tougher line. It warned that health plans and other groups that "aid and abet" the importation of medications from Canada could be found "criminally liable." Although the FDA says it reserves the right to go after individuals, it also says that "our highest enforcement priority would not be actions against consumers."

Some insurers—including Humana Inc., United HealthCare Insurance Co., Anthem and Premera Blue Cross—have for years reimbursed for drugs purchased abroad for the convenience of travelers. (United HealthCare has contracts with AARP to provide health-related insurance products and services to members.)

Wyckoff of the MSF says the FDA's implied threat to close down groups like his "doesn't change anything legally. This is a gray area of law we're trying to get clarified."

Seeking to change the situation, Congress passed a law in 2000 that allowed American-made medications to be reimported from abroad. It was not implemented—because, then-President Clinton explained, the final wording was "so full of loopholes" it could guarantee neither patient safety nor lowered prices.

Another bill passed the Senate last year but died in the House. This year, Senate Democrats have included reimportation in their bill to add drug coverage to Medicare.

Taking a different tack, Rep. Bernie Sanders, I-Vt., is directly opposing the Glaxo ban. He has sponsored a bill that would make it illegal for any drugmaker to prevent Americans buying drugs from Canada.

"I'm outraged," he says, "that a huge company like Glaxo, which had profits last year of almost $10 billion and pays its CEO over $20 million a year, is trying to make it impossible for Americans to get affordable medicines from Canada."

While the law stays unchanged, and safety concerns remain, AARP says it does not encourage people to buy drugs from Canada. "However," says AARP

Executive Director Bill Novelli, "it is a national embarrassment when Americans must [go to other countries] in search of medications they need at prices they can afford."

Meanwhile, many consumers pay little attention to the legalities of importing drugs. Asked whether she'd still do it even if the trade was declared flatly illegal, Sandra Barron says emphatically: "Yep, yep, yep."

IS IT SAFE?

Speaking at a Senate hearing last year, FDA senior associate commissioner William Hubbard said that "importing prescription drugs for personal use is a potentially dangerous practice."

He and other witnesses gave examples of counterfeit, contaminated and otherwise harmful prescription drugs seized in the mail. Some originated from places like Southeast Asia —a notorious producer of fake "lifestyle" drugs like Viagra—and others from scam operations within the United States. None of those cited came from Canada.

"With a million Americans buying from Canada, I've not heard of one instance of impure drugs," says Sanders. Wyckoff and others who have worked directly with thousands of such customers say the same.

That is not to say it couldn't happen. Wherever money is to be made, abuse will likely occur. As Hubbard pointed out, plenty of Internet sites already offer medications without requiring a doctor's written prescription—a clear violation of sound medical practice.

But defenders of the Canadian trade say that the whole "safety" issue has become muddied because its critics do not distinguish the exploiters from reputable services run by licensed Canadian pharmacies.

"The drug companies would have you believe we're all renegades," says Andy Troszok, who runs an online pharmacy out of Calgary, Alberta. "But we are licensed pharmacists and professionals, and patient safety is our paramount concern," he says, referring to member pharmacies of the Canadian International Pharmacy Association (CIPA), a new group that he says is setting standards for the reputable side of the Internet trade.

A key question is how drugs sold in Canada measure up to those sold here. In a 2001 official response to questions by Sen. Byron Dorgan, D-N.D., the Congressional Research Service confirmed that Canadian authorities regulate the quality of medications manufactured and sold there as rigorously as the FDA does in the United States.

Troszok and many consumer advocates also argue that the problem of Americans not being able to afford drugs at home is in itself a safety issue. "If we enable them to take their medications, aren't we enhancing their safety?" Troszok asks.

He explained CIPA's standards at a recent "fact-finding" meeting in Ottawa attended by FDA officials, Canadian government regulators and representatives from the drug and pharmacy industries.

"An important point I put to the FDA," he says, "was that if our business is shut down in Canada, where will consumers go? To other countries that don't have the same level of regulation? And then will they have to deal with counterfeit medications from operations that are not legitimate?"

Though Glaxo said it imposed its ban "in the interests of patient safety," older Americans demonstrating outside the company's headquarters in Philadelphia accused it of being motivated by "corporate greed" in trying to cut off a pipeline on which so many Americans depend.

BETTER STANDARDS NEEDED

Nonetheless, at present the FDA is correct in saying that people buy drugs from abroad "at their own risk" in terms of safety. While consumers can take some steps to avoid scams [see How to Assess Canadian Internet Pharmacies], calls are increasing for more regulation of all prescription mail-order businesses, whether they operate from abroad or within the United States.

One new group, the Internet Mail-Order Pharmacy Accreditation Commission (IMPAC), is developing a rigorous system of quality standards for American, Canadian and Mexican mail-order pharmacies. It is run by doctors and pharmacists from all three countries.

IMPAC also aims to produce optical seals that cannot be counterfeited. Affixed to mailed drug packages, they would allow customs officers to see signs of tampering at a glance. Only mail-order pharmacies that meet IMPAC standards could use the seals.

IMPAC is the brainchild of Elizabeth Wenner, until recently president of the United Health Alliance in Vermont, a nonprofit physicians' group that runs MedicineAssist, a mail-order program for consumers to fill prescriptions in Canada.

The new system would reassure patients and take pressure off government regulators, Wenner says. "If quality is really the issue," she adds, "then let's do it."

Mr. BURTON. And so the last thing I'd like to say is this ain't going to go away. I'm going to be chairman of this subcommittee hopefully for 6 years, and you're going to be here a lot, and we're not going to quit until you guys do something about this and Mr. Gutknecht is going to get exactly what he wants. He's going to get all the hearings he can handle.

Who is next? Ms. Watson.

Ms. WATSON. I think that the Chair is correct because he feels the emotion of this issue. I would hope that the FDA would take a look at the pharmaceuticals that are being ordered through the Internet from Canada. I was told that there have been no negative effects. But I do know in other countries that the ingredients are different when they make up a compound, and I would like some research on how those ingredients would impact. You held up a package of a particular product that was made for the mail system, not the e-mail system, and I'm sure there are other kinds of pharmaceuticals that are in the hands of Americans today. They simply don't have the knowledge.

So I would hope that FDA, through one of its auxiliary branches, could do a little research on those particular pharmaceuticals and also on the Canadian products.

Am I correct to say that I have not heard of any negative effects of the products that come in from Canada, but there could be——

Mr. HUBBARD. That's generally correct, Ms. Watson, but, again, the system is a passive one. It's not set up to record these sorts of things. These drugs are in violation of the law, and should not be coming in at all, and so the system is not set up to record potential adverse events from drugs that shouldn't be here at all.

Ms. WATSON. Well, let me suggest to the Chair that maybe we would want to promulgate some legislation that would give the authority to the FDA and any other branch under maybe HHS to look into this matter, and I think it is a matter of directing and funding, but I think we might want to look into that.

Mr. BURTON. Would the gentlelady yield?

Ms. WATSON. Yes.

Mr. BURTON. Do you have this authority already?

Mr. HUBBARD. I think we would have the authority to test drugs coming in from Canada, yes.

Mr. BURTON. Yes. Well then why aren't we doing it if you have a concern?

Mr. HUBBARD. Other Members have asked us that. It would be a very expensive proposition and there are concerns about what you would be looking for. There are also concerns about that it would be only a snapshot of that batch of drugs that you test at any given time. So there are a number of logistical questions about that, but we would be glad to respond to that in more detail in writing, Ms. Watson.

Ms. WATSON. Let us do this as a committee, and I will work with the Chair on this—send a formal letter from the subcommittee to the FDA asking them to use their authority to take a look and do an evaluation of the drugs. It is an illegal procedure now and we would just like you to evaluate what is going on, you know, what you think the traffic is like, and the volume, and how many people are in violation. But I would like to know what the impact and ef-

fect these pharmaceuticals have on those who are ordering them. I think under that authority, if it requires additional funding you need to work through the system for that, but since you have that authority I'd like for you to take the responsibility. Maybe we can draft a letter to ask them to do that.

Mr. BURTON. I would be happy to do that with you, Ms. Watson.

Mr. Gutknecht.

Mr. GUTKNECHT. Thank you, Mr. Chairman.

I want to come back to a couple of things that you said, Mr. Hubbard. First of all, you said that your scientists could not tell whether that drug was, in fact, the real drug or a counterfeit, but isn't it really true that you could do the same thing with a drug that I would purchase down the block at the local pharmacy? Could your scientists tell by just examining the bottle whether, in fact, it was real or counterfeit?

Mr. HUBBARD. No. The difference though is that the system is so closed in——

Mr. GUTKNECHT. And that's a drug——

Mr. HUBBARD [continuing]. This country that you wouldn't ever even be looking for counterfeits in this country generally. They're very, very rare in the United States, very rare.

Mr. GUTKNECHT. Oh, it's very rare in the United States?

Mr. HUBBARD. Whereas counterfeits in foreign countries are very common.

Mr. GUTKNECHT. Because we don't test we know that it is very rare here in the United States? Well, Mr. Hubbard, I think you really should look at the facts. Counterfeiting is happening in the United States right now. And do you know why? It's because the prices are so high.

I want to come back to something that you said about a year ago in testimony before a hearing here on the Hill on September 5, 2001. You said, "The Canadian system is one that I have some knowledge of, and I would have some degree of confidence to say, as opposed to the Third World." In other words, the Canadian system is a pretty good system. We don't have Canadians dropping like cordwood from buying prescription drugs at their pharmacies, do we? I mean, is there evidence?

Mr. HUBBARD. That's right. I said that if I were in Canada and ill and saw a Canadian physician and was given a drug from a Canadian pharmacy, I would have a relatively high degree of confidence that I was getting a safe and effective drug.

Mr. GUTKNECHT. Let me ask another question about the FDA. You are responsible for fruits and vegetables coming into the United States, are you not?

Mr. HUBBARD. Yes.

Mr. GUTKNECHT. What do you say——

Mr. HUBBARD. Perhaps Mr. Taylor should answer this next question.

Mr. GUTKNECHT. Well, what does the FDA say to the roughly 1,012 people who have gotten sick in the recent years as a result of eating imported raspberries? Do we have a responsibility to those people?

Mr. TAYLOR. Absolutely. And——

Mr. GUTKNECHT. What about the 270 people who have gotten sick from eating imported strawberries?

Mr. TAYLOR. Absolutely.

Mr. GUTKNECHT. What about the 25,000 people who have gotten sick as a result of eating imported cantaloupes?

Mr. TAYLOR. Absolutely.

Mr. GUTKNECHT. Now, what do we know anything about where those cantaloupes come from?

Mr. TAYLOR. Actually——

Mr. GUTKNECHT. I mean, could some of them actually be coming from foreign countries in the Pacific?

Mr. TAYLOR. Actually, we do know a great deal about the cantaloupe situation, and, to answer your question more generally, in the last 2 years there has been an increase in our funding to deal with imported foods as part of the counter-terrorism efforts, so we have increased our coverage not only at the border, we've also increased a number of foreign inspection——

Mr. GUTKNECHT. So you stop and check every shipment that comes into the United States now?

Mr. TAYLOR. No, we do not.

Mr. GUTKNECHT. How many do you stop?

Mr. TAYLOR. I think the figures are that only 1.7 percent of the food that——

Mr. GUTKNECHT. That's 1.7 percent. Now, it seems to me—and I'm just—I have been watching this now for 4 years. You have set a bar in terms of imported drugs that is as high as it possibly can, even though even your scientists can't even prove drugs at the local pharmacy, whether or not they are, in fact, a real drug or a counterfeit, by your own admission. But you have a bar for imported drugs that is as high as the ceiling, and yet for imported foods it is almost zero. And we know the evidence. The empirical evidence is overwhelming. You are much more likely to get sick from an imported strawberry than you are an imported, legal, FDA-approved drug.

Now let me bring one more point. My time is almost up. Even in your own handout—Mr. Chairman, you need to see this. This is important for Members to understand. Even in your own handout you show something that the FDA does not require in the United States of America, and that is counterfeit-proof—I'm sorry, counterfeit-proof blister pack packaging. Most countries in Europe now require that kind of packaging, and the company that makes that packaging is the same company that provides the materials to our U.S. printing office that prints the $1 bills and the $5 bills and the $20 bills. The question I would have for the FDA: wy don't you require that kind of counterfeit-proof packaging here in the United States?

Mr. TAYLOR. Quite actually, we are looking into developing technologies that will help both industry and the FDA improve our ability to detect counterfeits. As you noted, the U.S. printing office has done a great deal of work on this, but there are also academic centers and others in industry who are trying to look at state-of-the-art ways that can improve our ability to detect counterfeits.

Mr. GUTKNECHT. But you would have to acknowledge that it is much more difficult to put a counterfeit drug in a counterfeit-proof

package, which you actually show on one of the Web sites that you introduced as evidence that this may not be, in fact, the same drug, right?

Mr. TAYLOR. I will admit that it is more evidence, but I will also say that, quite frankly, some of the counterfeiting these days is so high tech that, even though it makes it harder, it does not necessarily preclude the possibility that it will occur.

Mr. GUTKNECHT. But we are testing some of the drugs here in the United States and finding out that some of them may be counterfeit; isn't that correct?

Mr. TAYLOR. Absolutely. I mean, the suggestion—we should not suggest that there have not been instances in the domestic market where there have not been situations where we've discovered that products have been counterfeited. And that's absolutely right.

Mr. GUTKNECHT. I would yield.

Mr. BURTON. I just want to point out that we have a witness here today, and I don't know if you are going to stay for the witness. I hope you will. Ms. Elizabeth Wennar, she came up with an organization called "Internet Mail Order Pharmaceutical Accreditation Commission, IMPAC." They are developing a rigorous system of quality standards for American, Canadian, and Mexican mail order pharmacies, and they use this method of packaging so that you can't get in there and change it. You can't—if it is a prescribed drug and it is put in this container and it is sealed, it comes in. It can't be counterfeit. It has got to be the product that they purchased.

Now, what I don't understand, if she does this as an individual citizen, why in the heck hasn't the FDA looked into it with Canada, because if they did that they could work with these pharmacists up there, they could work with the Canadian Pharmaceutical Department, the government department, and they could make sure that there was some kind of a system where you would seal these things so that they came in without a great deal of risk. And the only reason that I could think of that you're not doing that is because the profit is so much greater here in the United States for the pharmaceutical companies. And I hate to think that. That's why I would hope—and I'm sure that my colleagues would hope—that you would look at these kinds of alternatives so that people can buy things safely on the Internet, especially from Canada.

Mr. Sanders, I think you are next. And thank you for yielding to me.

Mr. SANDERS. Thank you, Mr. Chairman.

Mr. Hubbard, you are under oath now, so I would like you to answer this question for me. For the past 15 or 16 years, the FDA has used its enforcement discretion to allow Americans to get 90 days of a prescription drug in Canada—and I know that because I went across the border with people from Vermont and other Members of Congress have done the same. Now—Mr. Burton alluded to this—it appears that the FDA is clamping down on this practice. Glaxo is withholding some of its medicine to Canada. And I find it somewhat coincidental that all of this is happening at the same time, as Mr. Burton indicated, huge sums of money are coming from the pharmaceutical industry into the U.S. Congress and, in fact, the White House.

Now, you are under oath. Could you please tell this committee who within FDA or the Department of Health and Human Services or elsewhere in the administration has advocated for or directed a retreat from the FDA's longstanding enforcement policy on this issue? Who gave you this idea suddenly after 16 years where, to the best of our knowledge, there has not been one problem, suddenly, coincidentally, when the drug companies are beginning to lose money the FDA is off and running. Who have you been talking to?

Mr. HUBBARD. I'll just simply say that in September I'll have 32 years in the Government as a civil servant working for both Republicans and Democrats, and at no time have I attempted to make any decision or recommendation based on any sort of political influence. The policy that you are referring to is what is called the "personal importation policy." It was created in the late 1980's to let patients with serious or life-threatening diseases such as cancer or AIDS patients go to a foreign country to access an unapproved drug, an experimental drug, and it allowed that patient to bring 90 days' supply in under supervision of a physician if there was no alternative treatment in the United States.

That policy has no relationship to people purchasing these——

Mr. SANDERS. But, in fact, because I did it, many of my colleagues have done it, and hundreds of thousands of Americans have done it, the reality is that for many, many years now Americans have been driving over the border or increasingly using the Internet without a problem. So my question is: if you have a program that is saving Americans huge sums of money, saving lives, why suddenly, all of the sudden—Mr. Gutknecht mentioned problems with fruits and vegetables. There are millions of people in this country probably getting sick because they can't afford prescription drugs. How did it occur to the FDA that one of their major priorities is to produce literature like this frightening the American people, investigating folks who are trying to keep themselves—where did this idea come from?

Mr. HUBBARD. Mr. Taylor will answer this.

Mr. TAYLOR. I notice that you were waving the pamphlet there. I haven't been here at FDA the whole period of time that the personal importation policy has been in place, but I have not seen even in the last few years a change in the policy, itself. We obviously have not focused on the individuals who are purchasing the product. The focus for us has been on the products themselves.

What we are trying to do, recognizing that people, indeed, are going to go across the border to purchase these products and, quite frankly, are going to purchase the products over the Internet, as we have discussed today, what we've tried to do and what we've tried to emphasize is the fact that we, the FDA, who quite frankly are given the mandate of trying to assure that people are receiving products that are safe and effective, cannot necessarily do so for these products. And what we are trying to do is educate people and help people make informed decisions, because we have seen an increase in the mischaracterization of certain products. For example, we've seen an increase in Web sites that have characterized products as FDA approved and——

Mr. SANDERS. Mr. Taylor, I have a limited amount of time. I apologize.

Mr. TAYLOR. OK. Fair enough.

Mr. SANDERS. This is not the best format to do these things. But let me ask you this.

Mr. TAYLOR. Sure.

Mr. SANDERS. This is my concern. You want to educate Americans. You know what I think you should be educating Americans about? You should be putting out pamphlets that say, "For the last 16 years people have been going across the Canadian border saving substantial sums of money, probably many instances staying alive rather than dying, improving their physical condition rather than seeing a deterioration, and there hasn't been one problem." How about putting out some leaflets on that?

The issue is you bring up these charts about Thailand. We are not talking about Thailand. We are talking about Canada. And the evidence again—and please contradict me if I am wrong—you have not indicated to us one instance of an American purchasing a prescription drug from Canada who has been hurt. And the answer is that Canadian pharmacies, as the chairman has indicated, are regulated to quite the level that our pharmacies are regulated; that, in fact, all drugs sold through registered pharmacies that come into the United States are exactly the same products as are sold to Canadians, and that, in fact, because the pharmaceutical industry continues to charge Americans so much money, out of desperation people are now going across the border.

Frankly, I think that pieces of literature like this are outrageous. I would agree with the chairman that I see it is really a strange coincidence that, with all of the money coming in from the industry, with Glaxo beginning to put pressure on the Canadians, that suddenly the FDA is paying attention to a non-problem rather than paying attention to a more serious problem.

Mr. Hubbard, Mr. Taylor, have you done any research into how many people in this country die or see a deterioration in their physical condition because they cannot afford the medicine that doctors prescribe? Do you have any studies on that?

Mr. HUBBARD. That's not the type of study that——

Mr. SANDERS. Really? You're supposed to protect the safety and health of the American people. Millions of people can't afford their medicine. They're suffering. Maybe instead of scaring the American people about not going to Canada you might want to do a study like that.

Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Mr. Sanders.

Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

I just want to say to the gentlemen I want to associate myself with the words of Mr. Sanders. It is so sad, incredibly sad that I have people in my District that I see—I hate to even go into a senior housing facility because over and over again I see people as late as about a month ago—well, actually, let's go back a year where a gentleman said, "Congressman, you know, don't worry about passing some type of prescription drug legislation for me." He said,

"I have been cutting up pills now for the last 3 or 4 years and I'll be dead. Do it for my fellow tenants here in this housing project."

Going back to Mr. Sanders' comments, I have constituents that go to Canada, too. They take busloads up there, trying not to just get rid of pain, in many instances trying just to stay alive, stay alive. And I would appreciate it very much, and I wish that they could—I started to say I wish they were here today, but I'll be honest with you—I think if they were here today they probably would be jumping over that table and be very upset, probably lifting up canes because they get that upset because they know their lives are on the line and they know that they are choosing between eating and buying prescription drugs.

The chairman is absolutely right. So often I think that we find ourselves divorced from the very people who we are supposed to be trying to help and trying to protect, and I would appreciate it if you would put just as much effort into trying to lift people up so that they can stay alive, stay alive, as you do in putting these little pamphlets together, because I think that sadly the American people are getting sick and tired of not being able to afford the drugs that they need.

It is so very, very painful. It is probably the most painful thing I do as a Congressman is to hear the stories, and so I beg you that if you can't find a way to do the kind of things that Mr. Sanders said, you ought to get out of the job and let somebody else do it. Let somebody else do it who will have the compassion for people and will help them stay alive. I think it is almost criminal. It is almost criminal when we come to a point where our seniors are being denied the kind of information that they need, because, I mean, this is what it's all about. I've told my constituents, you know, until we can get some kind of prescription drug bill for them, to do whatever you have to do. Take the bus. Go up there. As a matter of fact, I've told them I'd help them pay to get up there. And so then when I find out that—and, by the way, a lot of the drugs that they're talking about, you know, they look at the labels and they see that these drugs are the identical drugs, of course, and packaged same places here in the United States, and so they get very confused, I think as Mr. Gutknecht said. They get confused. They don't understand it. They don't get it.

And so I would just ask that you all look into that. Have you all looked into doing any of the things that Mr. Sanders just suggested?

Mr. HUBBARD. Mr. Cummings, we have spent countless hours trying to examine processes or procedures that can allow these drugs in safely, and we have simply given our honest appraisal that the ideas that we have come up with and that others have come up with can ameliorate the situation but cannot assure the safety. It will weaken the safety net that has been created, and if Congress wishes to do that because of price controls, that is an issue for the Congress. FDA has not found a magic answer to identify the safe drugs over here and the skeptical drugs over here.

Mr. CUMMINGS. Well, it would be—I think you need to keep trying.

Mr. BURTON. Mr. Cummings, would you yield on that point?

Mr. CUMMINGS. Yes, I'll yield.

Mr. BURTON. I'll give you some more time if you need it. Last week it was suggested that domestic Internet pharmacy sites get a seal of approval to validate that they are legitimate. Now you say you haven't thought of anything to get the job done. Why not do the same thing with Canadian pharmacies in concert with the Canadian Government? In other words, go to these various pharmacies up there and the ones here and validate whether or not—check them out, make sure they are legitimate. You've got a lot of people working for you. They could do that. Once they check out the Canadian as well as the American pharmacies, then there should be no problem. But to say you can't find an answer just begs the issue. I mean, the people here want to be getting these drugs at a fair price, and it is your responsibility to make sure that they get them at a fair price as well as make sure they're pure. And that can be done through the packaging. I talked about that just a minute ago, where they're sealed so that they come back and you know that they haven't been broken, or through making sure that the Internet sites are legitimate by working with the Canadian Government to have them license them. "Is this a legitimate one? Is it one we can work with?" You're talking about doing it here; why not there, as well? There's not as many of them up there as there are here.

The reason you don't want to do it, it appears, is because the pharmaceutical companies aren't going to make as much money and because they give so much money here on the Hill.

Mr. Cummings, I'll yield back if you have any additional——

Mr. CUMMINGS. I wanted to ask him to answer that. Can we do that? Can you do what the chairman just asked?

Mr. HUBBARD. Well, we certainly at the hearing last week did say that we thought the verify Internet pharmacy site was a good idea and gave consumers a way of identifying legitimate sites from illegitimate. The question of doing that for foreign sites raises some other issues we'd be happy to look at.

Mr. Taylor, would you like to add to that?

Mr. TAYLOR. Well, the National Association of Boards of Pharmacy, who sponsored the VIPPS program here in the United States, I believe have a Canadian version, but they do not provide a seal of approval for Canadian sites that sell their products in the United States because it violates State law, so they have a program that is a domestic Canada program and a domestic United States program, but they don't have a program that allows consumers in the United States to look at the seal and know that these products are FDA approved and manufactured in accordance with——

Mr. BURTON. If the gentleman would yield?

Mr. CUMMINGS. Yes.

Mr. BURTON. If you can do it here and there's limitations by State law or something, here is an agency for the whole country. I mean, why in the world can't you send an emissary up to Canada to talk to their agencies and work out an agreement? We passed NAFTA. We passed NAFTA so we could trade everything with Mexico and Canada, and you're telling me that you can't go to Canada, have somebody from your agency say, "OK, we want to make sure in a way to accredit these pharmacies, to make sure that they're doing the job right, just like we're going to do it in the

United States." That way the drugs can come in and they'll be safe because you will know that pharmacy is on the level.

I mean, to say that you can't do it or imply it by what you just said really bothers all of us.

I'm sorry, Mr. Cummings. Go ahead.

Mr. CUMMINGS. Mr. Chairman, I think that what disturbs me so much—first of all, I'm very pleased that this is a bipartisan effort. As you can see, we are on both sides of the aisle, we're very concerned about this. I remember years ago there used to be something in the boxing world called "rope-a-dope," and the boxer just laid against the ropes and took the punches like you are. You probably feel like you are taking punches today. And then when the fight was over they just walked out of the ring, and maybe they won or maybe they felt that they lost. But let me tell you something: I hope you are not rope-a-doping today because I've got too many constituents that are dying. And you cannot convince me for 1 second that you cannot do the kinds of things that the chairman is talking about.

In some kind of way I told my staff so often there are so many people that their main power is the power to say no. Everything is no, no. We can't do it. They find every excuse not to do it. I'm begging you—I'm not asking you, I'm begging you, because I'm begging for people who want to simply live—to find a way to do it.

And, Mr. Chairman, I would hope that we would try to maybe give these wonderful gentlemen some kind of time table to come back to us with regard to, if there are issues with this, showing us what the issues are and how we might be able to resolve those issues as a Congress. That's why we are here.

With that, Mr. Chairman, I yield back.

Mr. BURTON. Thank you, Mr. Cummings. We will honor your request.

Mr. Gutknecht, did you have any other questions?

Mr. GUTKNECHT. Well, Mr. Chairman, I want to again thank you for this hearing, and I want to thank them for coming and testifying.

The problem here it seems to me is much more about attitude. The FDA has taken the attitude that imported drugs are, by themselves, illegal, and in fact this is a relatively solvable problem. Technologically, the technology exists. It is off the shelf, it is inexpensive, and it is called "counterfeit-proof blister packs." They're available for most European countries. The FDA could require them in the United States. And it seems to me that if they really wanted to help us solve this problem, we could have this problem solved in 45 days.

It seems to me I agree with Mr. Cummings. I mean, it really is shameful that the FDA has taken the attitude that senior citizens who are simply trying to save a few bucks—and in many cases a lot of bucks—and, more importantly, to save and preserve their lives, are treated as common criminals by their own government. That is shameful. And it seems to me that the FDA has a responsibility, Secretary Thompson has a responsibility to do what it can to allow seniors, to allow American consumers to do this in a safe way.

As they said earlier in their testimony, they don't test American drugs. They assume that the drugs that you buy at the local drug stores are actually those drugs and they are not counterfeits. But the fact is it's happening more and more where the local pharmacists are dealing in counterfeit drugs. They don't test them. They assume that they're safe and effective.

We should at least assume that American consumers and most pharmacists, particularly in Canada and in the G–7 countries, are not trying to kill their own patients. There is no evidence that they are dying like cordwood. And, you know, it really is shameful that the FDA is not working with us and with consumers and with the producers to come up with a very simple, technologically effective way to guarantee to the maximum extent possible that these are, in fact, safe and effective drugs for American consumers.

Mr. BURTON. Any other comments? Mr. Sanders.

Mr. SANDERS. Let me just very briefly indicate my agreement with all of the comments made by my colleagues and just make this point: given the fact that we live in a global economy, given the fact that the lettuce and the tomatoes that we ate for lunch today came from God knows where, what kind of farm in Mexico, the grapes that I get from Chile—I don't know where they come from, I don't know what they have been sprayed on—and yet all of those products are imported into this country. Mr. Gutknecht gave some of those statistics.

If the Federal Government and the FDA can say it is OK for us to consume those problems, how in God's name are you not able to regulate a few dozen pharmacies in an advanced country like Canada which already has a regulatory system as strong as ours? That begs any rational explanation. You can do it. Of course you could do it. And if the chairman told you to come back in a month with a mechanism to do it, you could do it if you wanted to do it. And our frustration is we know you can do it if you wanted to do it, but for some reason—and some of us have our suspicion that it has to do with the awesome amount of money that comes into Government from the pharmaceutical industry—you choose not to do that.

So I would hope that you will come back to this committee and tell us how you can perform the relatively easy task of regulating and make sure that the products that come from an advanced country like Canada, which already has a strong regulatory system, are safe for the American consumers. We believe they are safe. We believe you could do that.

Mr. BURTON. And let me end up by saying—because I know you are tired. You have been here a long time—that you could do this one country at a time and you could start with Canada, and if you did that and it showed that it was going to be effective, then you could look at other countries one at a time. It's not something that has to be done all at once, but I think we want to make sure that Americans get the best price.

I'm very concerned that we are going to pass a prescription drug benefit, and if you guys don't do something like this over there that the Government is going to be incurring these huge differentials in the price between here in the United States and around the world.

And the last thing I would like to say are there are 600—I want to say this to my colleagues—there are at least 600 lobbyists here

in Washington that are paid by the pharmaceutical companies, and the $20 million that comes in every 2 years to Members of Congress and the White House, whoever is in the White House at the time, that $20 million and those 600 lobbyists aren't going to go away and we're going to have a fight on our hands. And the 600 lobbyists you can bet are being paid a heck of a lot more than $20 million. So this is something that we're going to have to fight at a grassroots level, and that's why we contacted the AARP, and they've already written an article, and we've got to contact every senior citizens group, and in your own Districts—and if you're talking to our colleagues, if you could talk to them about contacting their people, their senior citizens groups, and have there be a barrage of correspondence coming into Congress saying, "Hey, let's get this job done," then I think the heat will get so great that we'll be able to get it done, even in spite of all that money.

With that, Mr. Hubbard and Mr. Taylor, thank you for being here.

Mr. HUBBARD. Thank you for having us, Mr. Chairman.

Mr. TAYLOR. Thank you.

Mr. BURTON. We'd like to call now Elizabeth Wennar. She is an M.P.H., D.H.A., president and CEO of United Health Alliance, principle, HealthInova; Mr. Andy Troszok, vice president of standards, Canadian International Pharmacists Association; Mr. Robert M. Hayes—is anybody staying here from the FDA?

Are you with the FDA? I would like for you to stay and hear their testimony and maybe convey that back to Mr. Thompson.

Good, good. We appreciate that very much.

Mr. Robert Hayes is with the Medicare Rights Center; and Mr. J.P. Garnier, chief executive officer of GlaxoSmithKline. I know he's not going to be here, but we'll have some questions that we'll send him.

Would you please rise so I can have you sworn in?

[Witnesses sworn.]

Mr. BURTON. Be seated. We'll start with you, Dr. Wennar.

STATEMENTS OF ELIZABETH A. WENNAR, PRESIDENT AND CEO, UNITED HEALTH ALLIANCE, PRINCIPLE, HEALTHINOVA; ANDY TROSZOK, VICE PRESIDENT, STANDARDS, CANADIAN INTERNATIONAL PHARMACY ASSOCIATION; AND ROBERT M. HAYES, MEDICARE RIGHTS CENTER

Ms. WENNAR. First I would like to thank you, Mr. Chairman, for calling this very important hearing. I have submitted written testimony, but what I'm going to do is just attempt to synopsize what I have provided to you, with your permission.

You know, I'd like to talk to you a little bit about where I come from so that the panel can understand why we started this.

As you mentioned, I have a couple of different things that I'm involved with. You mentioned my name earlier in terms of some of the labeling that we have been working on, and I'll mention that a little bit later.

We first got involved as a provider network in a rural community because we were very concerned about compliance, and if you understand quality we really—that is a pure definition in a provider's mind. Compliance is really the ability for the patient to be able to

take their medications as prescribed so that you can get the outcome, the intended outcome.

Now, technology in the form of a pill is here to stay. It is a major component of health care. So as a provider, you're looking at this and you make an assumption. Sometimes it is a false assumption, but you make the assumption that if you prescribe it for your patient that they are going to take it as prescribed.

Now, when you find out that they cannot access it and its affordability, you have an ethical dilemma, you know. You prescribe something, it exists, and they can't afford to take it.

So from our perspective about 3 years ago we got very actively involved, and we do have to thank—we have much gratitude and appreciation to Congressman Sanders for starting the initiative up in Vermont. We just basically piggy-backed onto what he started and decided that if it could be done, we had so many individuals we were trying to serve that could not get on a bus, could not—you know, they just couldn't leave their home. They needed to have access.

We decided that it needed to be brought in through the mail and that we were going to be willing to attempt it. Our first case was with an individual who had breast cancer and needed tomaxaphin, and so we tried to come up with something very simple that would facilitate the process, and in doing so we suddenly became bombarded because we were initially concerned with just our local community. Since that time, we now are serving individuals in every State in the United States. We did a survey and counted that there were over 1.2 million individuals using this mechanism to access safe, affordable prescription drugs.

Now, having said that, what I'd like to do is just sort of summarize what I'd like to talk to you about today, and I would be more than happy to answer any questions.

The issues are very large from the perspective of if you look at it globally, we all know that, as has been previously mentioned here, employers are having a hard time trying to manage this problem, States are having a hard time trying to manage this problem, and certainly the Federal Government is having a hard time trying to manage this problem. We have a major crisis on our hands.

So for those of us that are out there trying to deal with it every day, I think that we are constantly trying to be creative and innovative, and I would say to you that if the FDA can't figure out how to do this in terms of some of the things you have mentioned, we have offered before in previous testimony that we would be more than happy in the private sector to take on some of the burden of doing this. This should not be your burden alone to do, and we are willing to step up to the plate, and I challenge physicians, I challenge pharmacists. It is part of their responsibility to do this, and that's the reason our physicians have gotten involved. They must be engaged in these conversations. You cannot solve this problem alone. They must be there helping you. So I tell you we will wholeheartedly help you solve this problem.

Having said that, I'd like to talk to you about some of the problems that exist right now in terms of the mechanism we have been using very effectively for over 3 years now to facilitate the process. I think I have heard some discussions about the legality of personal

reimportation. And let me be real clear: personal reimportation is the area that we have been focused on, trying to help one individual at a time. Having said that, we do know that there are employer groups now that are very concerned and considering this.

I have a gentleman here with me today who is the president and CEO of Aubuchon Hardware. He is a self-funded employer and he has been considering this effort. We did an analysis. He is currently using a PBM in the United States. With accessing medications from Canada, he could save another 25 percent over what he is saving here. He feels he has an obligation to his employees under self-funded to help them maintain their benefits. We agree. But he has now sort of been held at—it's a stalemate now because of the recent FDA letters that have been issued in terms of things, so he is now on a holding pattern in terms of doing this.

I think our major concern now is the recent activity with the pharmaceutical industry cutting supply, and I would like to get back to the compliance issue that I spoke to you about. If you know you have individuals that are complying with a treatment plan and having good outcomes, now do you call it good quality to cut that supply to those individuals that have been complying? I think not. By the very definition of quality, they are complying and we have good outcomes, so to cut the supply after 3 years of knowledge of this taking place borders on—I have to tell you, it is just intolerable, from my perspective, to think that would occur with an entity that professes to be part of a provider network. Major technology they provide to save people's lives, and now they are going to take it away from them. I think it is unethical. I don't want to talk about legal. I want to talk about ethics, and it is a major ethical dilemma for us.

Now, we have worked very hard to try and think about how we could help solve some of the problems that have been discussed around safety and quality. And if you put the right people in a room and sit and talk about it, you can come up with some very creative things. You mentioned IMPAC. IMPAC is Internet and Mail Order Pharmacy Accreditation Commission that has been licensed to a professional association made up of pharmacists and physicians from Canada, the United States, and Mexico that has just recently been put together. In fact, they've just recently had their first board meeting. Those individuals are looking broader than just reimportation. That's not their major mission. Their major mission is to look at things in pharmo-economics and pharmo-therapeutics that they might be able to do that will help us all across the country, the whole North American continent, to cross-collaborate not only with two sets of professionals that have never been in one single association, but across three countries that we could really use our resources much better.

IMPAC is an accreditation process that is much like the Joint Commission on Accreditation of Health Care Organizations. I'm sure many of you are familiar with it. All of our hospitals are required to be accredited before they are reimbursed for care. Physicians are held to a set of standards, as well. Prescription drugs are really the only one component, and particularly in the form of mail order—and now when you talk about Internet pharmacies I'd like a clarification here, please. Internet is mail order, first and fore-

most. We have mail order in this country, and I would challenge people to please tell me in mail order do you believe that when something comes from across the country to you in a package, do you have every assurance that is completely safe? I have yet to see them meeting a set of standards and meeting these accreditation standards that we require every other component in health care to do. I think it is time. The time is now.

Now, having said that, we believe that Canadian pharmacies are willing to step up to the plate to meet these accreditation standards. Once they meet those standards they would then be issued these non-counterfeitable seals, which I'm going to ask you, if you happen to have a $20 bill in your pocket, to pull it out and look at it, because it is the same technology that is utilized by our U.S. Mint. It is not counterfeitable, and I'm going to show you how. It is optical technology, and I do also have an expert here with me that can answer technical questions. But if you pull it out—thank you, Mr. Gutknecht—if you look at the right-hand corner of the $20 there you will notice that it is a different color. If you hold it flat under the light and rotate it, you will see that it optically changes. I could—if you just rotate it toward you, and you will see it change in color. That cannot be broken, that optical code. The FBI has not been able to break that code. And I would ask you one question: if it is good enough for our currency, is it good enough to be used here? I would profess that it is.

We have come up with a prototype label. In front of me I actually have something that's much broader that I would suggest you think about, and that is that anything that leaves an FDA manufacturing approved site, every manufacturer should have this labeling on their bottle. That's a good beginning in terms of stopping counterfeiting right there and endorsing safety.

But I'm going to say it again: if it is good enough for the U.S. Mint, it should be good enough for our prescription drugs.

With that, I would tell you that, again—I'll finalize my comments by saying three things. One, the interpretation of whether this is legal or not is where we're having a problem. The manufacturers' recent efforts in Canada to shut supply is our second issue. And third is the FDA's recent letters that they have been sending out in terms of threatening those of us that attempt to help our patients. Those are barriers to success in Canada.

And the last thing I will say is that Canada is not a Third World country. We do site visits to all the pharmacies that we utilize, and I don't understand, if we can do it in the private sector, why is it that they can't do it at the FDA? Of course, leave it to the private sector then. We will engage them in the conversation. We'll make sure they have a list of every registered pharmacy in Canada or any place else in the world.

Thank you.

Mr. BURTON. Thank you.

[The prepared statement of Ms. Wennar follows:]

Testimony of
Elizabeth A. Wennar, M.P.H., D.H.A.
President and CEO, United Health Alliance
Bennington, Vermont
and
Principle, Health*Inova*,
Manchester, Vermont
Testimony Before the
Subcommittee on Human Rights and Wellness,
Committee on Government Reform
United States House of Representatives
Hearing on
Re-importation of Prescription Drugs
April 3, 2003

Mr. Chairman, and Members of the Committee:

Thank you for inviting me to discuss re-importation of prescription drugs as a means of accessing safe, affordable prescription drugs from Canada and the current problems facing those individuals that are doing so [particularly our elders not currently covered under Medicare].

Today's healthcare market presents many challenges. None is more controversial than that of technology in the form of a "pill". Pharmaceutical spending has almost doubled in less than a decade. More often than ever, our policymakers and physician providers are being queried as to why it is that Americans, particularly the elderly, must pay many times more than their Canadian [and Mexican and European] counterparts for the same drug. As you know, over the past few years many of your constituents have been purchasing their medications from Canada. For these individuals, these medications are now affordable and even more importantly safe. From a pure medical standpoint, the most important part of a treatment plan that is intended to produce the best possible outcome for a patient, is the patients ability to comply with what 's prescribed by their provider/physician. Any medication that is not affordable and therefore not accessible, is neither safe nor effective for someone in need of it as part of their treatment plan.

Quality and Compliance

Many of the recent conversations around reimportation have focused on quality and safety issues. As providers of care, no one knows better than physicians and pharmacists how important quality is in the process of providing care. Quality can be defined in many ways, in this instance I want to discuss the importance of compliance for an individual/patient. When a physician/provider prescribes a medication as part of a treatment plan, they assume that the

individual will have access. Many do so because they [the provider] have used samples provided to them at no costs to give to their patients. So, when they have a patient that responds well to a particular medication provided as a sample, they do naturally what comes next in the process...write a prescription for the medication. Unfortunately, medications supplied as samples, in general, are the very ones that are not affordable.

Clearly as a provider network, our major concern is the ability of patients to comply with a given treatment plan. When a patient cannot afford their medications it is costly for all of us. Are we concerned about quality? Absolutely. And there is a quality issue and exist on this side of the border. When a patient cannot take their medications, they most definitely will consume services elsewhere in our system, such as the emergency room or by being admitted to the hospital. That simply is not rational. This is not about people that won't comply with a treatment plan, this about individuals that can't afford to purchase prescription drugs in the country they live in. Also, let's keep in mind that we are talking about Canada not some third world country. Having said this, these individuals are willing to take the risk associated with accessing their medications across the border. Many of them have told us that there is certainly no more risk in doing this than they are at by not taking their medications as prescribed or not at all.

Let's talk about quality and safety. I would ask you to reflect on when the last time was that you witnessed an armored vehicle delivering medications from manufacturer to the community pharmacy in this country. This is an extreme example, but I would like to make a point about safety under the guise of quality. Much propaganda has surfaced over reimportation of medications from other countries, particularly Canada. This attempt to frighten individuals that are already terrified of compromising their health by not being able to take their medications, creates a form of terrorism that is inexcusable. Some would have you believe that Canada's pharmaceutical supply is unsafe and of inferior quality. Ads placing pills side by side and questioning which one is the counterfeit drug, is a poor use of valuable resources and intended to produce fear. It does nothing to help address the problems associated with access.

Background on United Health Alliance and Medicine*Assist*

United Health Alliance is a nonprofit physician health system organization located in Southwestern Vermont. Our partners include a rural hospital, nursing home, home health agency and just over one hundred (120) community physicians. We serve residents of Vermont, New York and Massachusetts. Our mission is to promote a physician-driven organization whose principle services are to provide advocacy and leadership in the areas of care management, contracting, performance improvement and educational programs to maximize value for our physician-hospital membership and customers [patients]. Although we have committed to ten (10) guiding principles, none is more important to us than assisting the communities we serve at becoming the healthiest in the nation.

Approximately one year ago we found that although admirable, this objective was going to be very difficult to achieve given the circumstances that existed for some of our elderly. Very simply, they did not have access to affordable prescription drugs, therefore they were not able to comply with the treatment plans prescribed by their physicians. Although we had individuals that were seeking affordable medications via bus trips to Canada, we knew that this was not an option for the majority of the elderly in the communities we serve by virtue of their medical condition and/or their limited resources. One of our physicians came to us and requested our assistance at investigating how we could help a patient of his with breast cancer access her medications from Canada without having to get on a bus. Today that patient takes her medication because she can afford them. It cost her ninety (90) percent less in Canada. We compared the costs for 145 seniors for the first six months to see if what we had heard about the differences in pricing was in fact true. While these individuals would have had to pay just over $81,000 in the U.S., they paid approximately $22,000 for their medications in Canada (see Exhibit A). Our understanding is that there were no substitutions for the medications they were currently on. All medications accessed were for the treatment of chronic diseases such diabetes, heart disease and cancer. A price comparison of some of the more commonly prescribed medications for the treatment of these diseases has been provided along with this testimony. Although there is minor variation with some pricing in Canada, the savings are still significant and have been reported anywhere from thirty (30%) to (95%) percent (see Exhibit B). Although the majority of the individuals using Medicine*Assist* are the elderly on fixed incomes, with no prescription coverage, we are beginning to see individuals that have depleted their pharmacy benefits also attempting to access their medications from Canada. As we have conversations with employers located in the communities we serve about benefits and coverage for their employees we find many are concerned about how to continue the level of coverage they currently provide, particularly with the growth in their expenditures for prescription drugs. The implications are frightening for all of us.

Medicine*Assist* : Medicine*Assist* was created three (3) years ago to assist individuals in need of affordable prescription drugs access them from Canada. See website (**unitedhealthalliance.com**) and click on icon medcineassist for instructions and information on use. Maintenance drugs only and your personal physician must be involved. No membership fees. A Canadian licensed physician will review medical information and consult with your physician.

Points of Interest:

1. **Personal Re-importation:** A recent poll (06/02) identified over 1 million U.S. consumers using this as a means to access affordable prescription medications from Canadian pharmacies. Individuals from every State in the U.S. are currently using this mechanism. Some self-funded employers are investigating how they might help reduce health benefits cost by utilizing this

effort. Employers such as Marcus Moran, President of Aubuchon Hardware see this as moral obligation to their employees to reduce their [employees] costs of such benefits. It also means that coverage can be maintained or better yet, even be expanded.

2. **Compliance:** Physicians assume that when they prescribe a medication (write a script) that the patient will take their medication as prescribed. They don't have any interest in where you get it filled. This is not to say that they would not be concerned if they thought there was a safety or cost issue. They are concerned about compliance with regard to a prescribed treatment plan.

3. **FDA Site Visit:** The FDA completed a site visit/audit of the Medicine*Assist* I initiative on July 22, 2002 (almost 1 year ago). No notice to cease and desist was issued. Additional information can be provided to the Committee upon request.

Reasons for Price Differential in Canada and the U.S.

To put it in the simplest of terms: the Canadian government is the purchaser, therefore they have implemented controls over the costs. Next, they do not allow direct-to consumer advertising. My understanding is that this type of marketing is only allowed in the United States and New Zealand. Essentially our major mode of control is through the approval process by the FDA that essentially controls entry into the market, not pricing. In the U.S. with its non-universal coverage structure, cost containment is undertaken by a myriad of public and private decision-makers, each with their own agenda and objectives. The price differential is of course going to appear even greater when you compare a group that has no coverage and pays out of pocket. They have no purchasing power, because they have no coverage. This is particularly true for about one-third of the Medicare population.

Conclusion/Recommendations

Personal re-importation has for all intensive purposes, been implemented by the American consumer. It may or may not be a long-term solution, but it does provide an option, particularly for the elderly, until we can provide appropriate levels of coverage under Medicare without compromising current medical benefits. Long-term viability will depend on the development of a program that can be implemented not just signed into law [as evidence by MEDSA 2000]. Barriers to access are unacceptable. Reimportation of prescription drugs is working as a mechanism for access of affordable prescription drugs. Should the

current process be improved upon ...absolutely! Should there be controls in place to monitor quality of those involved...absolutely!

Clearly, there is no simple answer with regard to the issues we are discussing. Barring any type of regulation of the pharmaceutical industry on this side of the border, personal reimportation from Canada under controlled circumstances can provide an interim solution for those in need of access to affordable prescription drugs. With the cooperation of the pharmaceutical industry, the FDA, the Canadian regulators and U. S. physicians/pharmacists a controlled demonstration project could achieve results that would prove beneficial for all the stakeholders until we can produce a better solution.

Notation:

1. Canada (as does other countries) has the equivalent of the FDA with regard to oversight.
2. The literature does not support fears about counterfeit drugs being dispensed from Canada.
3. Customer satisfaction and compliance for those currently using re-importation (Canada) appears high.
4. Physicians and pharmacists are engaged in the process. Compliance results in better outcomes and potential lower costs.

FDA Oversight

From the perspective of safety and oversight clearly the FDA [and other agencies] must be concerned as to how any initiative that would involve re-importation of prescription drugs would be maintained under their current charge. Although challenging, it can be done. With regard to Canada it would not be that difficult to do. Other countries **may** be more difficult to monitor and manage.

The following could/should be considered:

1. In order to maintain and provide an efficient means of oversight by the FDA, all participating pharmacies would be registered with the FDA. In order to do so, they would have to be accredited, much the same as the Joint Commission (JCAHO) accredits hospitals and other health institutions here in the United States. After meeting a set of quality standards the mail-order pharmacy would be awarded accreditation. They would also have to provide data/information to the FDA. Once all requirements are met, the FDA or another entity, would issue non-counterfeitable seals/emblems for these pharmacies to use when shipping packages into the US (through Custom). No seal, no entry in to the U.S.

Note: Prototype to be provided during testimony. I have been working with Flex Products, Inc. to produce a prototype seal using SecureShift™ technology. Flex Products is a world leader in the development of optically variable technology for counterfeit deterrence. Their Optically Variable Pigment (OVP) security technology is currently utilized by over 87 countries, including the US and the newly designed $10, $20, $50 and $100 bills. (Technical expertise from Flex Products, Inc. will be available for the Committee if they have detailed questions about the technology).

2. With regard to monitoring of the quality of drugs being shipped, a proxy with the country (Canada) could be established. There is no reason that we can not accept the standards that are equal or higher established by another country. No country should be allowed to participate that does not have at the very least a set of standards equal to ours.

3. The role of US and Canadian physicians and pharmacists could be worked out through the development of a cross-border association (licensure/registration and protocol development).

4. Private/Public partnerships should be developed in order to reduce the costs at the Federal level [while maintaining the oversight and input of the FDA].

Major/Potential Barriers to Access from Canada:

1. GlaxoSmithKlines recent actions to discontinue supplies to wholesalers and pharmacists in Canada for export. Although they accuse others of breaking the law, what they are doing although legal, is very unethical. Many individuals have complying with their treatment plans for almost three years and now they propose to take away their medications. All in the name of quality and safety...their answer... a prescription drug benefit under Medicare. With no costs controls put in place on the front end.

2. No one central clearinghouse to manage the process on this side of the border.

3. Personal reimportation is still considered illegal and therefore puts agencies such as the FDA in a very awkward position [actually impossible position until the law is changed]. They are charged with enforcing what currently exists and it's almost impossible to do so. Their recent threats to prosecute those of us that aid and that we may "be found civilly and criminally liable" was expected at some point, but is such an incredible waste of time and resources. This will serve to accomplish only one thing and that to hurt the very individuals that we profess to serve. Those individuals that are currently complying with their treatment plans. All of

this in the name of quality and safety. [a drug that is not accessible because it is not affordable is neither safe or effective]

Final Note:

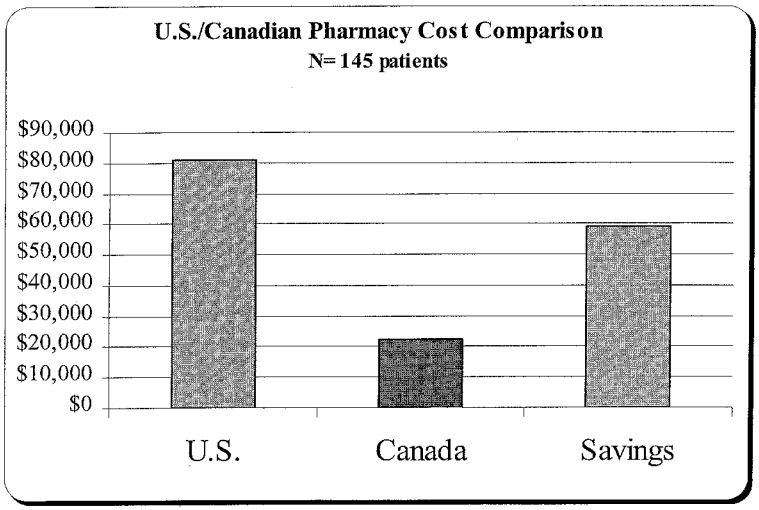
In reality the economic model regarding sales for the pharmaceutical industry actually improves: 1) they now get inconsistent sales (unstable purchasing currently exist). Although the new sales would be a lower price, it would result in stability of purchasing and consistent compliance would result, which according to their own mission is their objective. 2) data reported by the Canadian pharmacies to the FDA could be very beneficial to research and development efforts and the development of a Medicare benefit.

This concludes my prepared remarks. Thank you again for this opportunity and I would be happy to try to address your questions

Medicine*Assist*™

Six-month Summary Analysis

Time Frame: July – December 2000
Number of patients participating: 145
Number of physicians participating: 19
Number of drug names ordered: 106



Total cost of prescriptions in U.S.	$81,006.17
Total cost of prescriptions in Canada	$22,361.53
Total savings:	$58,963.84
Percent savings:	72.8%
Overall average savings:	68.4%
Range of savings by drug:	28% - 97%

Source: United Health Alliance 2000 (Medicine*Assist*)

Note: U.S. prices are based on AWP plus 30%. The actual cost of U.S. prescriptions will vary based on geographic area and by individual pharmacies.

Sample Drug Pricing

Drug	Number of Tabs	Canada	U.S.	Savings
Tamoxifen 10 mg	60	$7.05	$142.44	95%
Lipitor 10 mg	90	$106.33	$230.58	54%
Plaxil 10 mg	30	$33.01	$94.57	60%
Prozac 10 mg	100	$115.93	$361.28	68%
Coumadin 5 mg	100	$25.52	$90.07	72%
Glucophage 500mg	100	$15.70	$86.26	82%
Prilosec 10 mg	30	$33.88	$144.62	77%
Fosamax 10 mg	30	$36.40	$85.99	58%

Note: U.S. prices are based on AWP plus 30%. The actual cost of U.S. prescriptions will vary based on geographic area and by individual pharmacies.
All dollar figures are reflected in U.S. Currency

Mr. BURTON. I think that you have probably heard us and our suspicions of why, so take that for what it is worth. There's an awful lot of pressure being exerted up here.

Mr. Troszok. Is that right?

Mr. TROSZOK. Close enough.

Mr. BURTON. I want to make sure I get this right.

Mr. TROSZOK. We from Canada have strange names from different planets.

Mr. BURTON. OK. You guys play a lot of hockey up there too, don't you?

Mr. TROSZOK. Mr. Chairman, committee members, thank you for having the opportunity to discuss safety issues from Canada. I am a Canadian licensed pharmacist, and when I graduated I pledged an oath to take the health, safety, and well-being of my patients as a priority. I have the privilege of working in community pharmacy for 8 years, and also in academia, and I have had the ability to work with patients, and every time I did I took that to the strongest possible level.

I think patient safety and overall patient health should be the priority of any pharmacist working in any kind of realm, be it hospital, retail, or innovative delivery of service such as distance-based delivery or mail order.

Canadian pharmacy is recognized internationally as a leader in innovation, focus, and patient health and safety. Pharmacy is a highly regulated profession in Canada, and pharmacists must adhere to guidelines administered by the Federal and provincial regulatory organizations.

Health Canada has a branch called the Health Protection Branch that is responsible for approving and regulating medications in Canada. The Health Protection Branch has a similar role to the FDA in the United States. That's what kind of surprised me when Mr. Hubbard was talking about not understanding the Canadian approval systems, because, to my knowledge, the FDA and Health Protection Branch work hand in hand and know equally what one does.

Medications are approved and sold——

Mr. BURTON. Would you repeat that one more time? I want to make sure that we got that.

Mr. TROSZOK. To my understanding, the Health Protection Branch, which is the equivalent branch in our government to the FDA, to my knowledge works hand in hand in communicating between the border on issues of drug regulations. And I'm not an expert in this area. I would ask that you maybe subpoena someone from the Canadian Government that is, because I know that these two organizations do talk together.

The process of approving drugs in Canada is similar to that of the United States. In part, this process is facilitated by a high degree of collaboration between the Health Protection Branch and FDA, as well by the fact that a vast majority of prescription pharmaceuticals are manufactured in the United States and are bioequivalent or identical in both countries.

Now, the distribution of medications from drug manufacturers to pharmacies is also very highly controlled. Pharmacies can only purchase medications directly from a drug manufacturer or through a

wholesaler that is licensed by Health Canada to sell pharmaceuticals. Only pharmacies licensed by the provincial regulatory authorities can purchase prescription medications that are to be dispensed to the public. There are approximately 12 wholesalers in Canada, and their ability to control and regulate them is quite easy.

In Canada provincial pharmacy regulatory organizations called colleges or associations regulate the practice of pharmacy. A pharmacy must obtain a license from the provincial pharmacy regulatory organization to be able to dispense prescription medications to the public. Each province and territory has a legislative pharmacy act in addition to standards of practice and a code of ethics that pharmacies and pharmacists must abide by.

I am vice president of an organization called the "Canadian International Pharmacy Association." I handle standards. We were created in November 2002, and our main focus was to represent Canadian pharmacies practicing international pharmacy, but also to put forth standards and regulation into this industry. So we are willing to work closely with the FDA, with U.S. regulators to make this a safe and viable practice.

We currently have what is known as a CIPA certification process. As was mentioned by the FDA, we tried to become VIPPS certified, but we were denied a VIPPS certification because we could not get a license to practice pharmacy in each of the States. But our members were willing to take that process but were denied.

So what we did was we mirrored our CIPA certification behind the VIPPS certification. Now Dr. Wennar has mentioned that there is another certification program. I guess what I'd like to tell this committee is that regulated, licensed, professional pharmacies are willing to work with any U.S. organization that will enhance the safety and the well-being of U.S. patients.

Thank you.

[The prepared statement of Mr. Troszok follows:]

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International Pharmacy Practice In Canada

Patient safety and over all patient health should be the priority of any pharmacist regardless of the type of pharmacy practiced, be it hospital, retail, or innovative delivery such as distance based.

In a national poll the Canadian population ranked pharmacists as the most trusted health professionals. Canadian pharmacy practice is recognized internationally as a leader in innovation and focus on patient health and safety. Pharmacy is a highly regulated profession in Canada and pharmacists must adhere to strict guidelines administered by federal and provincial regulatory organizations.

The Health Protection Branch (HPB) is a department of Health Canada responsible for approving and regulating all medications, supplements, and herbs that are for resale. The Health Protection Branch has a similar role to the FDA in the United States. Canada is seen internationally as having some of the most advanced regulatory systems for the approval of medications. Medications that are approved to be sold in Canada are listed in the Food and Drug Act. The process of approving drugs in Canada is similar to the process in the United States resulting in a product that is safe for consumer consumption. In part this process is facilitated by a high degree of collaboration between HPB and the FDA as well by the fact that a vast majority of prescription pharmaceuticals are manufactured in the United States and are bio-equivalent or identical in both countries.

The distribution of medications from drug manufactures to pharmacies is a highly controlled process in Canada. Pharmacies can only purchase medication directly from a drug manufactures or through a wholesaler that is licensed by Health Canada to sell pharmaceuticals. Only pharmacies licensed by their provincial regulatory authorities can purchase prescription medications that are to be dispensed to the public. There are approximately twelve wholesalers in Canada that pharmacies have the ability to purchase through.

In Canada provincial pharmacy regulatory organizations (colleges or associations) regulate the practice of pharmacy. A pharmacy must obtain a license from the provincial pharmacy regulatory organizations to be able to dispense prescription medications to the public. Each province and territory has a legislative pharmacy act in addition to the standards of practice and code of ethics that all pharmacies and pharmacists must abide by.

The Canadian International Pharmacy Association (CIPA) was created in November 2002, to promote the growth and viability of the Canadian pharmacies that provide international services, as well as to provide a unified voice to address the challenges facing the industry at large. The Role and Mission of the Association is to support Canadian International Pharmacies in their delivery of high quality, affordable medications to patients around the world by doing all things necessary to attain these objects including, without limitation:

a) Developing creative solutions for superior patient access to affordable medications and health care products, while continuing to offer high quality professional patient care and services.
b) Working in conjunction with regulatory bodies and government agencies to establish standards and protocols to be followed by pharmacies providing international services to ensure the safe delivery of products and services to patients worldwide.
c) Supporting members in their efforts to meet and exceed existing professional standards of care and to develop standards of care unique to the international pharmacy industry.
d) Protecting the economic foundation of the international pharmacy sector to ensure continued access to high quality, affordable products and services to patients worldwide.
e) Promoting the satisfaction and health of patients by enhancing their relationships with international pharmacies.
f) Ensuring that all members develop policies and procedures that are in compliance with provincial and federal laws designed to protect the privacy and personal health information of patients in their care and be supportive of HIPAA compliance.
g) Ensuring members develop information technology and information management systems that ensure the security of the patient health information in their custody and control.

To ensure that CIPA pharmacies adhere to the above role and mission one of the criteria for membership is to sign a licensing agreement. By signing the agreement the pharmacy recognizes it must adhere to the following criteria:

Licensing

1. Provide the Licensor with verification of all required licensing of the Licensee within the jurisdiction in which its physical operation exists;

2. Provide the Licensor with verification that all persons in charge of the physical operation during its business hours are appropriately licensed and in good standing.

3. Appropriate verification shall include providing copies of all licenses and an affidavit of compliance on an annual basis.

Policies and Procedures
(these must be in writing and be available to the Licensor on request)

General

4. Maintain and enforce acceptable comprehensive policies and procedures in respect of the operation of the international prescription service;

5. Comply with all applicable statutes and regulations governing the practice of pharmacy within the jurisdiction where licensed.

Prescriptions

6. Maintain and enforce policies and procedures in accordance with statutes and regulations within the jurisdiction where licensed regarding the integrity, legitimacy and authenticity of any prescription received by the Licensee.

Patient Information

7. In jurisdictions where it is necessary for the originating U.S. prescription to be converted to a Canadian prescription, the Licensee shall ensure that the Canadian physician reviewing the patient's personal health information conducts an independent review to determine whether a Canadian prescription should be issued;

8. Maintain and enforce policies and procedures in accordance with statutes and regulations within the jurisdiction where licensed regarding retention and storage of patient records, reasonable verification of the identity of the patient, the prescriber and, where appropriate, the caregiver;

9. Maintain and enforce policies and procedures in accordance with statutes and regulations within the jurisdiction where licensed regarding the protection of the personal health information of patients (for example, the Health Information Act in Alberta; or the Personal Health Information Act in Manitoba and Federal legislation such as the Personal Information Protection and Electronic Documents Act) and ensuring that there are appropriate safeguards in place to prevent inappropriate or non-essential access or use of a patient's personal health information.

Communication

10. Maintain and enforce policies and procedures that mandate professional staff to offer meaningful consultation to the patients or caregivers, where required;

11. Maintain and enforce policies and procedures establishing a mechanism for:

i) patients to report suspected drug related problems and errors and for the Licensee then to take appropriate action;

ii) contacting patients and, if necessary, the prescriber, if an undue delay is encountered in delivering the prescribed drug or device;

iii) advising patients or caregivers of drug or device recalls;

iv) educating patients and caregivers about the appropriate means to dispose of expired, damaged or unusable medications in accordance with statutes and regulations within the jurisdiction where licensed.

Storage and Shipment of Products

12. Maintain and enforce policies and procedures regarding the shipping of drugs and devices via a secure and traceable means and within appropriate temperature, light and humidity standards applicable to the item being shipped in compliance with the latest pertinent data.

CIPA supports the ability for the US patient to file a complaint against a CIPA certified pharmacy. Therefore, in the licensing agreement a consumer complaint process is incorporated:

CONSUMER COMPLAINTS PROCESS
(excerpted from the by-laws of the Licensor)

1. A Complaint from a consumer about a Certified Member must be in writing addressed to the Executive Director or his/her designate ("ED") of CIPA.

2. All complaints received by the ED will be forwarded to the Complaints Investigation Committee ("CIC") within 3 days of receipt of the complaint. The CIC shall have the authority to rule on the complaint as set out in this process.

3. The CIC will assign the complaint to one or more of its members who will assess and deal with the complaint within 14 days of the complaint being received from the ED as follows:

a) if the complaint is deemed not appropriate or is without merit, the CIC shall respond directly to the consumer in writing that the complaint is dismissed.

b) if the complaint is deemed appropriate or has merit, the CIC shall acknowledge receipt of the complaint to the consumer and shall send a copy of the complaint to the Certified Member.

4. The Certified Member receiving the complaint shall respond to the CIC in writing within 7 days of receiving the copy of the complaint from the CIC.

5. The CIC will:

a) review the Certified Member's response, if any;

b) seek additional information, if needed, from the ED, the consumer or the Certified Member;

c) prepare and provide a report to the consumer, within 10 days after the deadline for receiving the Certified member's response, with a copy to the Certified Member and the ED, which report shall include:

1) if the Certified Member has provided no response, a ruling that the membership of the Certified member in the corporation shall be revoked;

2) if the complaint, based on the initial or additional information received, is found to be without merit, a ruling that the complaint be dismissed and that no further action is required;

3) if the complaint, based on the initial or additional information received, is found to have merit, a referral of the complaint to the Certified Members Review Committee for adjudication.

6. The Chair of the Certified Members Review Committee, within 3 days of the receipt of the report, shall select one of its members to act as adjudicator. The adjudication shall be a document only adjudication unless the Certified Member, within 3 days of being notified in writing of the name of the adjudicator, requests a hearing.

7. If no hearing is requested, the adjudicator shall request the consumer to provide any comments on the report in writing within 7 days. Those further comments, if any, shall be provided to the Certified Member who shall provide any further comments to the adjudicator within a further 7 days. The Certified Member's further comments shall be provided to the consumer for final comments within a further 3 days and the consumer shall have a further 7 days to make those final comments to the adjudicator in writing.

8. Upon receipt of the final comments, if any, from the consumer, the adjudicator, within 10 days, shall consider all of the information provided and shall make a written ruling, with or without reasons:

a) to dismiss the complaint; or

b) to issue a reprimand to the Certified Member together with an order for the Certified Member to take such remedial measures as the adjudicator deems appropriate in the circumstances; or

c) to revoke the membership of the Certified Member in the Corporation; and

d) in addition to any other ruling, to levy a fine (to a maximum of $5000.00) against the Certified Member and/or to order that the Certified Member pay such costs associated with the process that the adjudicator deems appropriate in the circumstances.

9. If the Certified Member requests a hearing, the Certified member shall be responsible for all costs associated therewith including travel, accommodation and meals of the adjudicator in traveling to a location for the hearing that is convenient for the consumer. The costs shall be estimated by the ED and the Certified Member shall pay those costs to the Corporation, in advance, within 3 days of the ED providing the reasonable estimate of costs. If the Certified Member does not pay such costs in advance, the right to a hearing will be lost and the matter will proceed on a documents only basis. If a hearing is to proceed it must be set at a time that is no later than 30 days from the request for a hearing unless the consumer consents to a longer period and the adjudicator shall render a written decision within 10 days after the hearing is completed in accordance with subparagraphs a) to d) of paragraph 34 hereof.

10. The decision of the CIC and the adjudicator shall be final and binding upon the consumer and the Certified Member and the Corporation.

Canadian pharmacies servicing US patients strive to achieve the same level of patient care as any other pharmacy providing services to the Canadian population. To ensure a high level of care to the US patient Canadian pharmacies have incorporated rigorous policies and procedure. The following is a general outline of the process for a US patient to obtaining medications from a Canadian International Pharmacy:

1. **Registration with a Canadian Pharmacy**; typically requires three documents.

    a. A detailed patient profile; this document provides both demographic and medical (medical conditions, medication history, allergies) information that is utilized by Canadian pharmacists and physicians to provide optimal patient care.

    b. A customer agreement; this document outlines the relationship between the patient and pharmacy.

    c. A physical prescription from a US licensed physician; this document ensures that a US patient is receiving care from a primary care physician in the United States. The original prescription is either mailed by the patient or faxed by the US physician.

    A pharmacy will not process a prescription for a US patient unless all three documents are provided.

2. **Verification of information;** pharmacy staff verify demographic and medication information to ensure that all information is accurate and correct so the right medication reaches the patient.

3. **Authorization by a Canadian Physician;** the patient medical history and the US prescription are made available to the Canadian physician. The Canadian physician assesses all the information and determines which prescription to authorize. Under Canadian pharmacy regulations Canadian pharmacies can only dispense a prescription that is issued by a Canadian licensed physician.

4. **Dispensing medications;** since pharmacy practice is regulated at the provincial level, a licensed Canadian pharmacy follows standards set out by provincial pharmacy regulatory organizations for dispensing medications.

5. **Billing;** pharmacies use secure billing procedures to ensure patient confidentially. Any information that passes through an online connection does so with the same levels of encryption and security that online banking transactions occur with.

6. **Shipping;** methods of shipping require secure and traceable means and within appropriate temperature, light and humidity standards applicable to the item being shipped in compliance with the latest pertinent data.

Mr. BURTON. Are all of your comments in your written statement?

Mr. TROSZOK. Yes. I have submitted a——

Mr. BURTON. I want to send that to the FDA because I think that is important. Send that to the head of the FDA and to Mr. Thompson.

Mr. Hayes.

Mr. HAYES. Thank you, Mr. Chairman, committee members.

The Medicare Rights Center is the largest independent source of Medicare information and assistance in the United States. Day in and day out what we do is work with people with Medicare to assist them access needed health care. Tens of thousands of callers use our health lines annually and, no surprise to you members of this committee, the greatest and gravest unmet need of older and disabled Americans is the unavailability of affordable prescription medicine.

From the trenches from which we work in, Mr. Chairman, the unaffordability of prescription medicine is a national emergency you folks at least seem to recognize.

Today the importation of comparatively affordable medicine from Canada is literally saving the lives of people we work with. Of course, I think we all here know that easing access to lower-priced prescription drugs imported from Canada is not the comprehensive, ultimately the intelligent response this national emergency requires, but keeping this lifeline open is essential to the health security of hundreds of thousands of American citizens.

We at the Medicare Rights Center are staffed. We rely heavily on volunteers, are routinely in the heartbreaking position of being unable to assist callers help find the affordable medicine they do need. We do everything we can to advise consumers. We research State prescription programs, we look at veterans benefits, supplemental insurance programs, discount cards, free samples, private company programs, family foundations, mail order houses, Internet pharmacies—yes, even those that are not in the United States, and maybe we're lucky the FDA has taken off. We go to the kindness of strangers frequently to try to get medicine to people who need it, but too often we fail.

I think the committee really finds itself today legislatively in the same situation our volunteer counselors work in. We, like you considering this legislation to bring cheaper drugs from Canada, are doing what we can do with what we have, knowing what we have to work with is terribly inadequate.

Mr. Chairman, three quick points. One, Congress should amend the Prescription Drug Marketing Act to authorize individuals to import from Canada, whether by mail, by Internet, by visit, prescription drugs for personal use. Seems pretty clear it's vitally in the Nation's interest to take the discretion away from the FDA on how they enforce existing law.

Two, more significantly, Congress again needs to take the lead in authorizing clearly authority to reimport prescription drugs from Canada.

Three, I've got to say that those of us who try to keep somewhat away from politics and are working with folks in the trenches are so gratified to see a committee work as this committee is doing. I

think folks on both sides of the aisle here—maybe three aisles, almost—should be hugging each other, because it is such an unusual sight from the trenches to see this kind of tripartisan commitment to the public good. But there should be applause for the introduction of H.R. 847.

From our daily work assisting people find affordable drugs, we know that many Americans will go without medicine if their Canadian pharmacy is cutoff and they cannot find alternatives. Our experience, contrary to what I expected our friends from Glaxo to say, but what they do say on their Web site, our experience is that older Americans will not find an affordable alternative if the Canadian pharmacy route is cutoff from them.

Again, our experience, contrary to what GlaxoSmithKline speculates on, is that our callers, consumers have not faced dangers in purchasing drugs from Canada. The danger, as you folks have made quite clear, the danger they face is going without the medicines that doctors have prescribed.

So, to wrap up, four things we know: One, there is direct evidence that citizens of this Nation, real people, someone's parents, grandparents, and wives are going without the medication they need. We are not speculating on that evidence.

Two, more Americans will be able to afford more medicines that the doctors have prescribed if they are allowed to purchase the drugs reimported from Canada.

Three, there is absolutely no evidence of any person suffering negative effects or complications because their medicine was reimported from Canada.

And, fourth, ask any physician in America who treats an elderly population—the damage to our citizens who go without needed medication is palpable, painful, frequently deadly.

So, Mr. Chairman and committee members from all parties here, we thank you for your efforts to mitigate the damage being done to our people.

[The prepared statement of Mr. Hayes follows:]

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International Prescription Drug Parity

Testimony before the House Committee on Government Reform

Subcommittee on Human Rights and Wellness

Robert M. Hayes, President

Medicare Rights Center

April 3, 2003

Good afternoon, Mr. Chairman, Committee members. My name is Robert M. Hayes, and I am the President of the Medicare Rights Center.

The Medicare Rights Center ("MRC") is the largest independent source of Medicare information and assistance in the United States. Founded in 1989, MRC helps older adults and people with disabilities get good affordable health care. Day in and day out we work to assist people with Medicare access needed health care. Tens of thousands of callers use our help-lines annually, and the greatest and gravest unmet need of older and disabled Americans is the unavailability of affordable prescription medicine. From the trenches in which we work, Mr. Chairman, the unaffordability of prescription medicine is a national emergency.

Today, the importation of comparatively affordable medicine from Canada is literally saving the lives of Americans who otherwise would go without the medicines their doctors prescribe. Of course, we all know that easing access to lower-priced prescription drugs imported from Canada is not the comprehensive and intelligent response that this national emergency requires. But, keeping this lifeline open is vital to the health security of hundreds of thousands of American people.

The Medicare Rights Center

The Medicare Rights Center is a not-for-profit consumer service organization, with offices in New York, Washington, Baltimore, Iowa and New Hampshire. Its mission is to ensure that older and disabled Americans get good, affordable health care.

Through national and state telephone hotlines, casework and both professional and public education programs, MRC provides direct assistance to people with Medicare from coast to coast. MRC also gathers data on the health care needs of the elderly and disabled Americans that we serve. We share that data with researchers, policy makers and the media. Just one of MRC's services, its New York State Health Insurance Assistance Program, offers counseling support to one out of every 14 Medicare recipients in the nation. Each year, the Medicare Rights Center receives some 70,000 calls for assistance from people with Medicare. By far, the greatest number of callers are seeking help in finding ways to pay for medicines that their doctors have prescribed.

The Medicare Rights Center is supported by foundation grants, individual donations and contracts with both the public and private sectors. We are consumer driven and independent. We are not supported by the pharmaceutical industry, drug companies, insurance companies or any other special interest group.

Mr. Chairman, there is a national emergency facing millions of elderly and disabled Americans who cannot afford to pay for the medicine they need. I realize this is not news to you, not news to this Committee, not news to the Congress. I know that I do not have to tell this Committee that countless Americans will die prematurely this year for lack of needed medicine. I thank the tri-partisan membership of this Committee for its work to mitigate this national emergency. And I thank you, Mr. Chairman, for inviting the Medicare Rights Center to testify this afternoon on behalf of those people with Medicare who call our hotline desperate for help.

The Unmet Need For Prescription Drugs

As we know, all Americans – consumers, employers, leaders of state and local governments -- are struggling to keep up with the rising costs of prescription drugs. For older Americans, the situation is dire. The data is clear: Seniors are spending more than ever on prescription drugs.[1] This is not just because prescription drugs are playing a greater role than ever before in health care. The prices charged for prescription drugs have risen astronomically -- *at least in the United States*. Again, the data is clear: Prescription prices, *in the United States*, rose at more than six times the rate of inflation in 2001.[2] While the pharmaceutical industry has struggled, along with the rest of the global economy over the past two years, its return on investment has exceeded all other industries. According to *a Fortune Magazine* survey of Fortune 500 companies, in 2001, pharmaceutical companies had a return on revenue (indicator of profitability) that was eight times more than the median for all top performing industries. Pharmaceutical manufacturers' return on revenue in 2001 was 18.5 percent versus 2.2 percent for all Fortune 500 companies.[3]

It is fair to say that executives of the great multi-national drug companies have met their fiduciary duty to maximize shareholder return from their work. Generally, they have been richly rewarded for their efforts. But those same efforts have created increased hardship for the consumer. In 2003, the typical person with Medicare will spend nearly $1,000 out of her own pocket on prescription drugs and another $2,200 on health care costs that Medicare does not cover. That's 22 percent of her annual income.[4] Needless to say, millions of people will end up forgoing necessary medications. Obviously, the

hardship on the sickest 20 percent of seniors—more than eight million Americans—who are battling significant illness and disease can be insurmountable.

"Prescription Drug Benefit"

I have little doubt that everyone in this room, and just about everyone in the Congress, is in favor of adding a "prescription drug benefit" to Medicare. But we have to admit that few words in the English language carry less meaning on Capitol Hill than the term "prescription drug benefit." To some members of Congress, a prescription drug benefit means a comprehensive program that will make needed prescription drugs affordable to all elderly and disabled Americans. To some members of Congress, a prescription drug benefit means a modest extension of Medicaid. To the White House, a prescription drug benefit is a lure to privatize Medicare. To some experts, that White House prescription drug benefit is "the kind of proposal the pharmaceutical companies would write if they were writing their own bill."[5] To some leaders of the pharmaceutical industry, including representatives of that industry who are here today, a prescription drug benefit is any program that will preserve the pricing structure that has left American consumers paying the highest prices on the planet for prescription drugs.[6]

We at the Medicare Rights Center are often in the heart-breaking position of being unable to assist callers in need find affordable prescription drugs. We do everything we can to advise consumers – we research state prescription programs, veterans' benefits, supplemental insurance programs, discount cards, free samples,

private company programs, family foundations, mail order houses, internet pharmacies, the kindness of strangers, and just about anything else our creativity and diligence can uncover.

In the 1930's George Orwell wrote of the British tradition of tramping.[7] To secure a bed for a night, homeless men of that era were forced to move, to tramp from town to town, to demonstrate genuine need. That tradition seems to reflect public policy in the United States in 2003, not so much now for the nation's homeless poor, but for the elderly who live on a modest, fixed income. Need medicine? We say try welfare, collect discount cards, call your children, borrow from neighbors, beg your doctors for samples, cut pills in half, shake a tin cup to the multi-national corporations that have selected discount programs. We say, "We can't be sure, but maybe someone, something, somewhere, will help you." This forced march for older Americans, of course, often leads nowhere. It would be a tough march under any circumstances. It is an especially cruel march for men and women at their most vulnerable: they are old; they are needy; and they are sick.

Legislative Harm Reduction

I think it's fair to say that this Committee today finds itself, legislatively, in the same situation that our volunteer counselors work in. We do what we can with what we have, however inadequate. You are addressing, soberly and responsibly, how to bring affordable medicine across our northern border. I realize that no Republican and no Democrat and no Independent thinks this is any solution to the national emergency facing

older Americans. But the policies being considered by the Committee, like the patchwork efforts of our volunteer counselors, are worthy because they will reduce unnecessary human suffering, cut needless premature death. Scare tactics should not be allowed to undermine so decent a goal.

This is all prelude to stating the support of the Medicare Rights Center for Congressional action to allow the safe importation of drugs from Canada. Importation is a prudent, and in some cases, a life-preserving public policy. This support in no way lessens our regret that our federal government has failed, year after year, to enact a comprehensive drug benefit and to enforce market conditions that would drive the prices of prescription drugs paid by Americans down the levels paid by the rest of the developed world.

People Matter

That being said, allowing the re-importation of prescription drugs from Canada would suddenly, without adding a penny to President Bush's deficit, make many needed medicines affordable to United States citizens who would otherwise go without. Allowing personal importation from reputable, licensed Canadian pharmacies helps too. And stopping multi-national drug companies from bullying Canadian pharmacies away from U.S. customers helps too. Bit by bit, real people are helped. These are just two of the people who do benefit, who will benefit, from these policies. I use their names with their permission. I hope you, and others, will hear from them directly.

Frances Cardille is a 74-year-old woman who lives with her husband in Suffolk County, New York. She has been relying on a Canadian pharmacy for Evista, a brand-name estrogen replacement therapy, medication that she has been taking under doctors' orders for eight years due to severe bone loss. She was spending more than $200 for a 90-day supply of the medication at her local pharmacy; now she pays $77 for the same prescription. I do not know how much lost profit that costs Eli Lilly, the manufacturer of Evista. I do know what this found money means to the quality of life for the Cardille's who earn $25,000 annually -- with 75 year-old Mr. Cardille's income earned working as a janitor in a local supermarket. The golden years.

Then there is Vi Quiron, a 76-year-old retired shirt factory worker from Waterville, ME. She suffers from ovarian cancer and a gastrointestinal condition. She lives on a fixed income of $12,000 per year. Because she has no prescription drug coverage, once every few months, Ms. Quiron joins a bus trip to Canada organized by the Maine Council of Senior Citizens. There, she purchases her supply of Prilosec, medicine for severe acid reflux. The trip is a healthy social outing, but more important, by going to Canada, Ms. Quiron saves $2,000 per year on the cost of Prilosec.

Importation Laws

As you know, the Food and Drug Administration has traditionally allowed individuals in the United States to import a 90-day supply of pharmaceuticals for their personal use. Technically, the 1987 Prescription Drug Marketing Act ("PDMA") makes it illegal for anyone, other than a pharmaceuticals company, to import drugs into the U.S.

Congress should amend the PDMA, authorizing individuals to import from Canada – whether by mail, internet or visit – prescription drugs for personal use.

More significantly, Congress should take the lead in authorizing the re-importation of prescription drugs from Canada. As you know, the 106th Congress enacted the Medicine Equity and Drug Safety ("MEDS") Act, which established a program to allow pharmacies and wholesalers to import prescription drugs from abroad. Importation was only permitted once the Secretary of Health and Human Services ("HHS") certified that implementation of the act posed no additional risk to public health. There has been bi-partisan inaction by the executive branch on this certification process. Many claim that politics, not public health, stand in the way today of certification from Secretary Tommy Thompson.

Last July, the Senate passed a bill aimed at easing the re-importation of medicines from Canada.[8] It is similar to the MEDS Act, but as initially conceived covered only drugs from Canada and did not require the Secretary of HHS to certify expressly the safety of re-imported drugs. That bill, even as amended, stalled.

Whenever members of Congress can cross aisles and work together in the public interest, especially in the area of national health care policy, angels in the heavens applaud. There must be applause for the introduction of the *tri-partisan* Preserving Access to Safe, Affordable Canadian Medicines Act of 2003 (H.R. 847), which takes direct aim at the recent GlaxoSmithKline offensive against Canadian pharmacies that

ship needed medicines to customers in the United States. From our daily work assisting people with Medicare to find affordable drugs, we know that many Americans will go without needed medicines if their Canadian pharmacy is cut off, and they cannot find alternatives. Our experience, contrary to what GlaxoSmithKline says, is that older Americans will not find an affordable alternative. Also, our experience, again contrary to what GlaxoSmithKline says, is that consumers have not faced danger in purchasing medicine in Canada. The danger they face, without doubt, is going without the medicines their doctors have prescribed.

We hope that this Committee, and the Congress, will independently consider the large body of evidence concerning the safety of re-importing medicines from Canada. We do not discount legitimate safety concerns; we also do not discount the substantial political influence the pharmaceutical industry holds with the legislative and executive branches of the United States government. We urge that science, not the political power of special interests, be the decisive factor in allowing the re-importation of medicine from Canada.

We are not scientists, but we recognize the good work of groups such as the United Health Alliance and the Canadian International Pharmacy Association, which have developed reasonable safeguards to minimize any legitimate safety concern around the re-importation of medicines. We at the Medicare Rights Center do have a broad expertise in the needs of older and disabled Americans, and we understand the dire straits our clients face. Our work with clients is in the real world, and the consideration by the

Congress of the re-importation of drugs by U.S. citizens must be made in that same real world. Is drug safety absolute? Probably not, be it medicines re-imported from Canada or medicines mailed from Chicago. Can reasonable precautions be put in place? You bet.[9]

What we know for sure is that there is direct evidence that citizens of this nation, someone's parents, grandparents and spouses, are going without needed medication because they cannot afford it. And what we know for sure is that more Americans will be able to afford more medicines that their doctors have prescribed if they are allowed to purchase drugs re-imported from Canada. We know of no evidence of any person suffering negative effects or complications from medicine reimported from Canada. But ask any physician in America who treats an elderly population: the damage to our citizens who go without needed medicines is palpable, painful and frequently deadly.

We thank you for your efforts to reduce that damage.

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[1] National Institute for Health Care Management, "Prescription Drug Expenditures in 2001: Another Year of Escalating Costs," April 2002)(indicating that drug expenditures at retail outlets rose from $78.9 billion in 1997 to $154.5 billion in 2001).
[2] Id.
[3] "The 2002 Fortune 500, Top Performing Companies and Industries," Fortune, April 2002. From 1994 to 2001, pharmaceutical industry profitability ranged between 14 percent and 19 percent, while the median for all Fortune 500 firms ranged between 3 percent and 5 percent. Michael E. Gluck, Ph.D., "Federal Policies Affecting the Cost and Availability of New Pharmaceuticals," The Henry J. Kaiser Family Foundation, July 2002, p. 35. Available at www.kff.org

[4] In 2001, 40 percent of people with Medicare had an income at or below twice the Federal Poverty Level ($16,988 single, 12,430 couple in 2001. Henry J Kaiser Family Foundation, "Medicare Fact Sheet: Medicare at a Glance, February 2003. In 2003, the average elderly person with Medicare will $3,757 or 22.3 percent of their income on health care expenses. Maxwell, S., Moons, M. and Storeygard, M, "Modernizing Medicare Cost-sharing: Policy Options and Impacts on Beneficiaries and Program Expenditures", Urban Institute for the Commonwealth Fund, November 2002. Available at www.cmwf.org
[5] Mike Allen, Bush Plan a Boon to Drug Companies, Washington Post, A4, March 4, 2003 (quoting Bruce C. Vladeck).
[6] Americans pay $2 for a pill that costs the Italians, French and Canadians roughly $1" Id. at p. 22. The General Accounting Office has continually found that Americans pay more than their European and Canadian counterparts. *See* Prescription Drugs: Spending Controls in Four European Countries (GAO/HEHS-94-30, May 17, 1994); Prescription Drugs: Companies Typically Charge More in the United States than in the United Kingdom (GAO/HEHS-9429, Jan. 12, 1994); Prescription Drugs: Companies Typically Charge More in the United States than in Canada (GAO/ HRD-92-110, Sept. 30, 1992)
[7] George Orwell, *Down and Out in Paris and London* (1936).
[8] Greater Access to Affordable Pharmaceuticals Act of 2001.
[9] Testimony of Elizabeth Wennar, Ph. D., President, United Health Alliance, Examining Prescription Drug Reimportation: a Review of a Proposal to Allow Third Parties to Reimport Prescription Drugs, Hearing Before the United States House Committee on Energy and Commerce, Subcommittee on Health, July 25, 2002, available at http://energycommerce.house.gov/107/hearings/07252002hearing677/hearing.htm

Mr. BURTON. Let me just ask a couple of questions, and I won't take my full 5 minutes, which is unusual.

Mr. Hayes, you deal with the realities of life when you deal with these people. Are there people dying as a result of the problems that they can't afford prescription drugs?

Mr. HAYES. No question, Mr. Chairman.

Mr. BURTON. You wouldn't have any idea from your experience what the number might be?

Mr. HAYES. No idea. Obviously, we can only help so many people with our small crew of horribly paid staff and volunteers, many of them elderly, themselves, many of them who become volunteers in these trenches because they have experienced the same hardship. I think Congressman Sanders' idea to get the GAO to do some examination of this is vitally important and would be very useful.

Mr. BURTON. Well, I think many of us will join him in asking for that study. How big an area do you deal with?

Mr. HAYES. Nationwide.

Mr. BURTON. Nationwide. And so you have volunteers all across the country who feel as you do?

Mr. HAYES. We have callers from around the country.

Mr. BURTON. Callers.

Mr. HAYES. We have call answerers based mostly in New York. But this is a problem that is mitigated to some extent in some States where there is a State prescription drug program that helps some people.

Mr. BURTON. I know, but in many States they don't have that.

Mr. HAYES. Many they don't.

Mr. BURTON. And so as a result, people are suffering.

Mr. HAYES. Yes. And, of course, you'll hear from Glaxo and from any other drug company about all the alternatives there are. Believe me, we use them. We have no ideology against any pharmaceutical company, but it is similar to running from soup kitchen to soup kitchen to get a meal—it is so hard to access, and more often than not we can't help people find anything.

Mr. BURTON. Dr. Wennar, I just want you to answer one question. It is possible to use this kind of technology to make sure that the drugs being imported from Canada or any place as long as you've got a cooperating pharmacy, to make sure that they are absolutely safe?

Ms. WENNAR. Absolutely. And, I mean, on top of that you put an additional layer by requiring that they meet a set of standards, themselves.

Mr. BURTON. Yes.

Ms. WENNAR. Which includes a site visit, and then there is a list of standards with multiple elements under it that I would be more than happy to provide you with that whole listing.

Mr. BURTON. What I would like from you, all of you, to give us a list of things that you think could be done to make sure the importation of pharmaceuticals are safe. You give us a list of those, and we'll give it to the FDA, and we'll ask them to check that out because they say they can't find an answer, and we believe that maybe you do have some answers. If they look at your answers and say that they're not workable, we're going to ask them why. We'll

do our very best to work with you, and we'd like to continue to have this kind of dialog.

Ms. Watson, do you have any questions?

Ms. WATSON. Not really a question, but the models that have been mentioned here I would hope that we could maybe—well, I guess this piece of legislation does that. I would like to ask the authors of H.R. 847—and I haven't really looked at every line, but do you authorize the access and the labeling and the licensing through this legislation?

Mr. SANDERS. There are two separate issues. H.R. 847 deals specifically—is a response to what Glaxo did and what we say is that drug companies, not just Glaxo, cannot discriminate against Americans and limit supplies to Canada, and if they do that they are going to be fined heavily. But, to answer your question, in other reimportation language, bills that we have introduced, the issues that you have raised are dealt with.

Among many other things, we have built—I'll give it back to you, but we have built in a very strong regulatory mechanism to make sure that all product that comes into this country is FDA approved and is safe.

Ms. WATSON. Is that in addition to this bill?

Mr. SANDERS. Yes.

Ms. WATSON. It's in other bills?

Mr. SANDERS. Yes.

Ms. WATSON. I would like the panel to respond if the bills that have already been introduced meet your needs of making these drugs accessible across the border.

Ms. WENNAR. Well, I think there is a litany of bills that are out there that are trying to serve multiple purposes. I mean, obviously in the ideal world we'd like to see one comprehensive bill that could serve multiple purposes. The reality—I'm going to get back, and maybe I'm going to sound like the FDA here, but safety is a major concern of ours and quality is a concern. Let's not confuse counterfeiting, although it is a component of this. Counterfeiting, as Mr. Gutknecht eloquently pointed out, exists in every country in the world, including the United States. We are not attempting to solve all of the potential counterfeiting problems. What we are trying to do is assure the highest level of safety that we can and quality as it relates to something that is being brought back in. And again we're just talking about Canada, but the same technology can be applied, and certainly this technology we're talking about right here in terms of the seals that would go around the bottle or on a labeling is saying that once it left the manufacturing site in this condition—and this optical technology is so inexpensive in terms of how you assess it by simply rotating it, and it is very easy to do. It doesn't require huge resources. This is a first stage effort of saying that you have done something at that manufacturing level when it leaves there. That's the first step.

The second thing is that we're talking about the pharmacies actually meeting a set of accreditation standards just like hospitals in the United States are required to do now. I will point it out again—every component of health care with the exception of this one is required to meet some set of accreditation standards.

Ms. WATSON. Would you yield for a minute?

Ms. WENNAR. Yes.

Ms. WATSON. Are the bills that are out there doing what you're asking? Then let's have a bill introduced that does this.

Ms. WENNAR. I have not seen specific language that would require any mail order pharmacy to meet a set of standards.

Mr. SANDERS. If the gentlelady will yield, last year we introduced a bill which for, in a sense, political and practical considerations limited the reimportation from Canada, which has built in it very, very strong regulatory and safety safeguards. This year that bill has already been introduced in the Senate and will be introduced in the House.

Ms. WATSON. Mr. Chair, if I may on this issue?

Mr. BURTON. Sure. Yes.

Ms. WATSON. When that bill comes over here to the House of Representatives, why not amend it to put in the provisions that you are describing if they are not already enumerated? We can do that. We can prepare them and have them ready to amend into the bill. Then it could go into conference and we'll come out with——

Ms. WENNAR. And what this does do is very simply it makes the FDA—I should say Customs' job much easier, because now if they—I believe one of the envelopes that's floating around, in addition to it being secure this way, on the cover of that shipping and handling package there is a non-counterfeitable seal that would be applied that's simply rotated by the Customs officer, and if the seal doesn't change optically in terms of the color it should be not allowed into the United States. Very simple.

Mr. GUTKNECHT. If the gentlelady would yield, I am working on that portion of the bill because I think that is a critical point, but if I could just make this point, Mr. Chairman, just real briefly, the problem we have confronted for the last 4 years is that we have come up with a number of ideas, but what we are dealing with here is a agency who clearly does not want to do this. And no matter what we may put in statute, if they don't want to do it—in fact, it is on the books today that they have to allow personal importation, and yet they are finding every excuse possible not to enforce the law that's on the book—in fact, in my opinion to misinterpret the law that is on the books. So whatever we put in law will be very difficult to get the FDA to implement if they're not willing to at least listen to what we and the vast majority of Americans are saying.

Ms. WATSON. Would you yield?

Mr. GUTKNECHT. It's your time. I'm sorry.

Ms. WATSON. Why is it that, along with the amendments that you've already been working on, that we could not put in a provision directing the FDA to do this, and if it is not done by a certain date there are consequences, whatever that might be?

Mr. GUTKNECHT. I think that is an excellent idea. As a matter of fact, we may have to put at the end of this bill this year, assuming we can get it to a floor vote on the House and in the Senate, we may have to put a line at the very end that says "and we really mean it." [Laughter.]

Ms. WATSON. We'll work with you on that.

Mr. BURTON. I suppose you could put a criminal penalty on there. If they don't comply with the law, then the bureaucrats are liable.

Mr. TROSZOK. May I just make a comment regarding the Canadian political system as reacting to the current laws? In February our organization took Glaxo to the Competition Bureau, the Federal Competition Bureau, because Glaxo has—just to be on the record, Glaxo has imposed the ban to Canadian pharmacies that sell prescription medications to U.S. patients, so that ban is on as of January 21st.

We took Glaxo to the Competition Bureau. The Competition Bureau came back and said, "You have a case in every single circumstance with the exception of the legality." And the Competition Bureau dropped the case because they talked to the FDA and were told that this is an illegal act. So I think it also has to be——

Mr. BURTON. The FDA told them it was an illegal act?

Mr. TROSZOK. Yes, they did.

Mr. BURTON. The law doesn't say that.

Judge, did you have any questions?

Mr. DUNCAN. Well, thank you, Mr. Chairman. I had some other meetings and so I don't have many questions, but I will say that we had a hearing that got into some of these things before the Government Reform Committee just a few days ago. Mr. Hubbard testified and they had an official from the Federal Trade Commission who testified, and he said in response to a question that I asked that they had not received any complaints, not one, at the Federal Trade Commission from people who had gotten prescription drugs over the Internet. You know, sometimes you can get a little more with a carrot than with a stick, and I actually introduced a bill that I knew wouldn't really go any place but I thought would start the conversation at least maybe, to try to come up with some type of tax break for a pharmaceutical company that would certify that they were selling their drugs at the same price in this country as in any other country.

I think, though, that the chairman a while ago got into the area where probably something really could be done on this, and that is we put some provision in the law when we set up the prescription drug plan that no company can participate unless they will certify that they are selling those drugs to the government or the prescription drug plan at the lowest price that they're selling it any place else, something to that effect.

But I appreciate your testimony today. I've read over as much as I could here in just a few minutes, and I'm sorry I didn't get to hear it all in person.

Thank you, Mr. Chairman.

Mr. BURTON. That's a great idea, and we'll see if we can't get an amendment to that effect on the floor with a bunch of us speaking on it.

Mr. Sanders.

Mr. SANDERS. I'll be brief because we have some votes. I just want to thank our panelists. Without exception, the testimony was excellent.

Mr. Chairman, Mr. Hayes told us that in the real world people are suffering and dying because they can't afford prescription

drugs. Dr. Troszok—we thank you very much for coming south—has told us about the high standards of the Canadian pharmaceutical industry and their willingness and desire to cooperate with the U.S. Government in making sure all of the safety standards that we require are met. And Dr. Wennar, who comes from Bennington, VT—you forgot to mention that, Beth—has done just an outstanding job starting off small scale in Bennington and spreading all over this country, and because of Dr. Wennar's work God knows how many Americans now are receiving medicine that they require at reasonable prices. We thank you all very much, and her innovative ideas in terms of safety are great.

The conclusion that I reach, Mr. Chairman—I think you've said it and Mr. Gutknecht has said it. We've all said it. This is a problem that can be easily solved if there is the will to solve it, and we have got to continue to work together, because, as Mr. Hayes has indicated, the stakes are enormous. People are dying today and they are suffering because this institution, our Congress, has not acted. And I pledge to work with all. Let's all work together in a nonpartisan way, and if we do we will succeed.

Mr. BURTON. Very good.

Mr. Gutknecht.

Mr. GUTKNECHT. Mr. Chairman, we do have a vote, and I do want to thank the witnesses. This was excellent testimony. I wish we had time, especially for Dr. Wennar. She has testified before. We have met several times. The program that they have going on is really the model that I would like to see implemented around the country and I think could be expanded upon.

This is one of the most frustrating issues that I have ever been involved with, and I always tell people I feel sometimes like the little boy who came in and asked his mother a question and his mother was busy and she said, "Go ask your Dad." And the little boy said, "Well, I didn't want to know that much about it." The more you learn about what is happening and the pernicious nature of the way pharmaceutical drugs are priced around the world, it is really shameful. And it seems to me that, working together with people in the private sector, that there has to be a better way to come up with a formula so that at least we can have average prices. You know, there is no excuse for the world's largest market paying the world's highest prices.

And if I could just say also, we subsidize this industry in three separate ways. Mr. Sanders mentioned through the tax code we are incredibly generous in terms of allowing them to write off their expenses. Second, we subsidize them in the amount that we spend on basic research. This year this Federal Government will spend over $21 billion taxpayer dollars on basic research, much of which will go to benefit the pharmaceutical industry. And then, finally, we pay as American consumers virtually all of the cost for the other research that's done, and that is being used by consumers all around the rest of the world.

I want to thank our excellent panels. I want to thank you for having this hearing. This is a very important first step. It is a bipartisan issue. It is an issue whose time has come, and ultimately I am confident that some time during this Congress we are going

to move this ball forward and allow Americans to have access to world-class drugs at world-market prices.

Mr. BURTON. Well, let me just make a suggestion. Individual bills may or may not succeed, but we are going to have the prescription drug bill on the floor for discussion and debate. We need to go to the Rules Committee, ask for an open rule so we can amend that, and then try to put something in there that will deal with this problem so people can get the lowest prices on these drugs. So that's going to be the opening that we can get to if we really work at it.

With that, thank you for being here. We'd like to have all your suggestions so we can write to the FDA.

We stand adjourned.

[Whereupon, at 4:05 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[Additional information submitted for the hearing record follows:]

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April 30, 2003

The Honorable Dan Burton
Chairman
Subcommittee on Human Rights and Wellness
U.S. House of Representatives
2185 Rayburn House Office Building
Washington, DC 20515-1405

Dear Chairman Burton:

JP Garnier has asked me to respond to your letter of April 17.

We understand and share your concerns about assuring access to prescription medicines for patients in the U.S. We do not want a lack of insurance coverage or financial means to put a patient at risk by either not filling a prescription or filling it through illegal, potentially unsafe means. Accordingly, we do not believe that having patients rely on illegal cross-border Internet sales is a viable "solution" to providing safe and affordable access. Our actions reflect this belief. Secretary Thompson, the Food and Drug Administration (FDA), and the US Customs Service agree, and have made statements to Congress, that prescription medicines dispensed to US patients from foreign pharmacies are illegal and pose significant risks.

GlaxoSmithKline (GSK) and its heritage companies have provided patient assistance programs for years to low-income patients without drug coverage. GSK's patient assistance programs helped more than 400,000 patients last year by giving away products worth $168 million. We are in the process of enhancing and expanding the programs, including expanding the eligibility requirement to $25,000 (single) or 250% of the federal poverty level (multi-person household). For our oncology products, the income eligibility ceiling is even higher -- up to 350% of the federal poverty level.

More recently, we pioneered a consumer-savings program, the Orange Card℠, for Medicare beneficiaries of modest means without prescription drug coverage. Subsequent to its introduction in 2001, we joined with six other companies to offer the Together Rx Card™. More than 711,000 beneficiaries have enrolled and have saved an estimated $87 million since the programs began. Incidentally, patients using either card are able to realize a net price on GSK medicines that can be comparable to prices advertised by Canadian Internet companies, and still have the protection and peace of mind that come with filling prescriptions at a trusted, accountable local pharmacy.

While I know you are primarily concerned about American patients, GSK's efforts to assure access to our medicines are not limited to the U.S. In fact, last year GSK invested more than $350 million in global community outreach programs, including product donations and charitable contributions.

As a percentage of pre-tax profits, that amounts to more than four times the average given by the top 250 companies in the U.S. Our global programs include donating treatments to protect people at risk for Lymphatic Filariasis, also known as elephantiasis, a disease affecting 120 million people in 80 countries; and providing access to HIV/AIDS medications at preferential prices through extensive programs in developing countries.

In response to your specific questions, we provide answers below.

Question: Why did you decide not to appear at the Subcommittee hearing on April 3, 2003?

We have clearly and publicly stated our position on the cross-border sale of prescription medicines over the Internet and the reasons for our actions to curtail the illegal practice. In our judgment, our appearance at the hearing would have been a diversion from the more important issue -- developing solutions for assuring safe access to medicines while preserving the incentives to develop new ones.

We are continuing to work toward viable solutions for providing safe and affordable access to medicines to Medicare beneficiaries and low-income, uninsured patients that assure them access without putting them at risk.

In spite of the lower prices in Canada, does your company still make a profit from your Canadian pharmaceutical sales? What is your profit margin in Canada?

Because the extensive cost of pharmaceutical research and development is largely "sunk" by the time a medicine is marketed, we are able to sell our medicines in Canada for a profit. However, that perspective overlooks something quite crucial: artificially constrained prices, such as those prevailing in Canada, are not sufficient to fund the robust investment in research upon which we and the patients we serve depend. Last year, for example, GSK alone invested more than $4 billion in the search for new medicines -- that is four times more than was invested in Canada on research and development by the entire pharmaceutical industry. (Canada Rx&D). We could not make this level of investment if we relied solely on markets like Canada. Not surprisingly, the U.S. is the worldwide leader in the development of new medicines. In 2001, eight out of ten new medicines were developed in the U.S. (Scrip Magazine Jan. 22, 2003).

GSK does not report profitability on a country-by-country basis. As reported in ValueLine Investment Surveys, GSK's global net profit was 18.5 percent in 2002. That's slightly more than half of Microsoft's net profit (36.6%), and is comparable to Coca-Cola (22.5%) and Weight Watchers (18.1%).

How do your Canadian pharmaceutical prices compare to your prices in European Union countries?

In Canada, a Canadian government body, the Patented Medicines Prices Review Board, reviews the prices of patented medicines to establish a national "maximum". To establish a maximum price, the Board takes the median price from a list that includes prices from the U.S. and six countries in Europe -- France, Germany, Italy, Sweden, Switzerland, and the UK. The US price

used is a straight average of the wholesale acquisition cost, (i.e., the "list price" to wholesale customers), and the price set under the Federal Supply Schedule. Most of the other countries in the comparison are price controlled, single-payor systems.

Since the Canadian "maximum" price is the median of the benchmark prices, by definition, the Canadian price will always be lower than half of the benchmark prices and higher than the other half.

The table below provides a few examples (wholesale prices are provided in US dollars at current exchange rates).

Drug Name & Dosage	Canada	UK	France	Germany
Advair/Seretide diskus (50/250 mcg) – 60 doses	$59.20	$54.82	$43.65	$51.03
Avandia (4 mg)	$133.17/100 tablets	$148.03/112 tablets	$117.39/112 tablets	$116.52/112 tablets
Paxil/Seroxat (20 mg) per tablet	$1.07	$0.83	$0.64	$1.02

Please let us know if you want information on specific countries.

For generic medicines, however, which account for almost 50 percent of all prescriptions in the U.S., prices in the U.S. tend to be lower than in Canada and other price-controlled markets – a market aberration of price controls. (Patricia M. Danzon, "Making Sense of Drug Prices," Regulation, Vol 23, No. 1:56-63 (2000)).

Canada's price control system, however, does not mean patients have better access to medicines. Under the Canadian system, seniors (aged 65 and older) and low-income patients on welfare receive prescription drug coverage under Canada's Medicare system. Many breakthrough medicines are not covered for patients under Canada's Medicare system. For example, though our breakthrough treatment for diabetes, Avandia®, was approved in Canada more than three years ago, it still is not covered under Canada's Medicare system in most provinces. Fosamax®, a leading treatment for osteoporosis, and Vioxx®, a leading treatment for arthritis, are only available on a limited basis in several provinces (neither of these is marketed by GSK). Three new treatments for Alzheimer's disease, Aricept®, Reminyl®, and Exelon℠, available in the U.S. and approved in Canada, are only available to Medicare patients in Canada on an extremely restricted basis in several provinces. (None of these medicines are marketed by GSK.)

Medicines under patent are not the only treatments that may be cheaper in Canada. Though US Medicare pays more than three times more for a hip replacement than the cost in Canada, the reason people aren't crossing the border to have a hip replaced in Canada is that US Medicare covers these procedures for US patients.

Is there any country in the world where your prices equal or exceed your U.S. prices?

We supply products to 191 markets around the world, including 28,000 different finished packs a year. Different regulations and market conditions mean different labeling, manufacturing, and packaging standards. Because of these differences among the products sold in different countries, making pricing comparisons is extremely difficult. Straightforward apple-to-apple comparisons are not possible. However, there is no question that prevailing prices in the U.S., where the market is relatively free of artificial constraints, tend to be higher than in many countries.

Price comparisons are also significantly complicated by differences in the healthcare systems around the world and how they pay for medicines. For example, frequently the price comparisons that are reported often ignore the widespread variations in rebates and discounts available. For the U.S. free-market system, competition drives prices down through discounts, rebates, and bargained-for contractual terms. Accordingly, published "list price" in the U.S. will overstate the actual price that GSK is paid by insurers, hospitals, the government, and other payors. In countries that set prices, the "list price" is the actual price or very close to the actual price that the government pays GSK. Thus, a comparison between those two prices may reflect a greater difference than actually exists.

Just looking at GSK's "list prices" in the U.S. and other countries shows that though the U.S. often has higher list prices for medicines, this is not always the case. The table below provides some examples.

Drug Name & Dosage	US	Canada	Japan	UK	Germany
ReQuip (2 mg) – per tablet	$1.06	$0.75	N/a	$1.53	$1.70
Agenerase (150 mg) – per tablet	$1.22	$1.26	N/a	$1.30	$1.00
Valtrex (500 mg) – per tablet	$3.21	$1.97	$4.26	$3.26	$2.51

Is your company acting alone in blocking drug shipments to Canada, or are you serving as a stalking horse for the rest of the industry?

GSK did not block shipments to Canada. In fact, GSK continues to supply medicines to the Canadian market for the legal sale to patients in Canada. We acted in the best interest of patients based upon our understanding of the safety risks and legal/business concerns to curtail the illegal sale of medicines from Canada to patients in the U.S. We acted completely independently of other pharmaceutical firms. We do not know, nor would it be appropriate for us to discuss, the plans of other pharmaceutical companies with respect to cross-border pharmaceutical sales from Canada.

How much does your company spend annually on drug promotion and advertising (all kinds) compared to expenditures for research and development?

Last year, GSK invested more than $4.3 billion in the search for new medicines. In contrast, we spent $2.9 billion promoting our products in the U.S. The promotion figure includes free samples we provide to healthcare providers, direct-to-consumer and other advertising, and the salaries and expenses associated with our professional field representatives who call upon healthcare providers.

Some media accounts have erroneously reported the "Sales, General & Administrative Expenses" line in a company's financial statement or annual report as promotional spending. Promotional spending is only a part of that figure. For GSK, "Sales, General & Administrative Expenses" includes promotional spending and a wide array of other expenses ranging from salaries and benefits of employees in our Human Resources, IT, Legal, and Finance departments to basic operational expenses like utility bills, computers, and office supplies.

How much does your company spend to promote Together Rx, the program designed to help low income consumers?

Over the two-year period 2002-2003, the seven pharmaceutical companies who participate in the Together Rx will spend about $24 million promoting the card. This amount does not include the cost of having 35,000 sales representatives, including approximately 10,000 GSK representatives, promote the program.

In addition to working with doctors, nurses, and pharmacists to help identify and inform eligible patients, we are involved in several innovative outreach activities. For example, we recently have partnered with Meals on Wheels to include copies of applications on meal trays. We also continue to work with Members of Congress in reaching out to constituents who can benefit from the Together Rx program, including staffing senior health fairs sponsored by Members in districts across the U.S. Currently, more than 20,000 Indiana residents are Together Rx cardholders; more than 2800 live in your district. We will be glad to work with you, as we have with other Members of Congress, to make certain that all of your constituents who can benefit get an application and enroll.

Also, of the more than 400,000 low-income, uninsured patients helped by the GSK patient-assistance programs last year, greater than 11,000 live in Indiana.

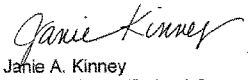
Why should American consumers, and only American consumers, bear the cost of the pharmaceutical industry's research and development?

The fact is that the U.S. is one of the few relatively free markets in the world, and Americans do subsidize the discovery and development of new medicines for the rest. It's not fair, and we are making efforts to change it.

In the meantime, the fact remains that the sales from medicines today are what fund our efforts to find tomorrow's medicines. Including GSK's $4.3 billion contribution, pharmaceutical companies

invested $30 billion last year in the search for new medicines. Because of the free market environment in the U.S., the vast majority of pharmaceutical research and development is done here. Other countries anxious to attract this type of investment look to the U.S. as the gold standard for pharmaceutical research and development. Without such a robust investment, US patients will continue to wait, potentially in vain, for better treatments for Alzheimer's disease, cancer, and the many other diseases for which answers are currently limited.

Sincerely,



Janie A. Kinney
Vice President, Federal Government Affairs and Public Policy
GlaxoSmithKline

Testimony
of the

American Pharmacists Association

On International Prescription Drug Parity

Submitted to the Government Reform Committee Human Rights & Wellness Subcommittee

April 3, 2003

APhA

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The American Pharmacists Association (APhA) appreciates the opportunity to provide our perspective on the critically important topic of illegal, personal importation of prescription medications. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians.

Although prescription medications have proven to be a valuable tool in our health care system, it is important that the safety net that exists to assure that the medications are safe and effective is maintained. This statement addresses patient safety issues associated with personal importation of medications.

Patient Safety Issues

It's critical to keep in mind that there is one overriding reason for the myriad of laws and regulations that help assure that Americans receive safe and effective medications and represent "what the doctor ordered" — Patient Safety. The current U.S. regulations were put in place after several critical incidents resulted in patient harm. When patients were harmed by contaminated or ineffective medications, Congress took action to protect patients, to protect our citizens. Those actions included requiring evidence of safety and effectiveness, controlling the production and distribution of products, and other efforts to limit the presence of counterfeit and contaminated medications. Current regulations protect American consumers from unsafe products.

In the U.S., the manufacturing, distributing, and dispensing of all prescription medications are subject to extensive regulation and control. Consumers may not understand the risks they face when they receive a prescription medication from outside of the U.S. system — they may be receiving a contaminated product, an inactive product, a product not recognizable by American pharmacists or doctors (possibly different strengths or name), a product that is not manufactured, distributed or regulated in the country where they are purchasing the drug, or simply, the wrong product. And once a product leaves the U.S. regulatory system, the patient loses access to legal recourse if they are harmed by the product.

While some products from foreign countries may be safe and effective, some may not, and consumers must understand these risks. Unless the prescription medication has stayed within the

confines of our drug delivery regulatory system, there are NO assurances that their products are safe, effective, or have been produced under U.S. quality control requirements that protect against contamination. And even with the comprehensive U.S. system, counterfeit products have penetrated our system. A recent example of counterfeit penetration was reported on by the *St. Petersburg Times* in late February. The report cited the shipment of 11,000 boxes of counterfeit Epogen and Procrit products (anemia drugs often given to cancer, AIDS and kidney failure patients) — counterfeit products here in the U.S. The criminals involved realized a $28 million profit. The risk of counterfeit products is real.

Not only do imported drugs directly impact patient health, but imported drugs and their questionable quality create a situation for health care providers that's best described as "working in the dark". Physicians and pharmacists have no way of knowing what a patient is taking because of the differences in names and physical appearances of foreign drugs, even those from Canada or Europe. Pharmacists' ability to identify drug-to-drug interactions is hindered to the point of nonexistence without knowing the drug's content and strength. This "blindness" removes a critical role of the pharmacist as the medication expert on the health care team, and compromises the ability of pharmacists to improve medication use and advance patient care.

Furthermore, some foreign websites offer prescription drugs without any direct contact with a prescriber. This practice bypasses yet another part of the U.S.'s safety net. Medications have become a critical aspect of patient care. But prescription medications are only safe and effective when patients understand how to use them appropriately, and for what side effects they should watch. Direct interaction between the prescribers, pharmacists and patients is critical to ensuring appropriate medication use. To remove such a basic component of our health care delivery system's safety net seems diametrically opposed to the "pro patient safety" environment we are all working to achieve.

Pharmacists are not alone in expressing concern with illegal importation. Secretary of Health and Human Services Tommy Thompson, in response to a 2001 legislative proposal that would have allowed manufacturers and pharmacists to import medications, expressed strong concerns with importation, "I do not believe we should sacrifice public safety for uncertain and speculative cost savings…Our drug approval and monitoring system, overseen by the FDA, is what ensures that the American consumer has the safest and most effective pharmaceutical products in the world. It would be short-sighted to compromise that system."[1]

Legal Issues

There seems to be a general confusion regarding current importation law. Importation by parties other than the manufacturer is illegal. Generally, the Food and Drug Administration (FDA) has exercised its enforcement discretion and allows individual patients to import small amounts of prescription drug, when the product is NOT commercially available in the U.S. These very limited circumstances are addressed in the FDA's "Coverage of Personal Importations"

[1] US Department of Health & Human Services, Press Release, July 10, 2001, "Secretary Thompson Determines That Safety Problems Make Drug Reimportation Unfeasible", http://www.dhhs.gov/news/press/2001pres/20010710.html

enforcement guidance document[2]. The document states that the FDA may use a more lenient, permissive approach in the following situations:

> 1. when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; or
>
> 2. when a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

In the background accompanying the guidance document, the FDA explains that there are several reasons for regulating the importation of medications, "Because some countries do not regulate or restrict the exportation of products, people who mail order from these businesses may not be afforded the protection of either foreign or U.S. laws." The key to the FDA's stance: protecting the American public.

Storefront operations in many communities across the country are facilitating the illegal personal importation of medications. These businesses are not only violating federal law, but also State Pharmacy Practice Acts that require pharmacies and pharmacists practicing in the state to be licensed by the State Board of Pharmacy. State Boards of Pharmacy are not licensing these operations due to the illegal nature of the business practice. These storefronts are both illegally practicing pharmacy and facilitating dangerous — and illegal — activity. Boards of pharmacy are beginning to work with the FDA to crack down on these risky practices.

Most recently, the FDA and the Arkansas Board of Pharmacy took enforcement action against a storefront operation, RX Depot, Inc, for illegally obtaining prescription drugs from Canada. On March 27th, the Oklahoma State Board of Pharmacy and the Oklahoma Attorney General's Office filed a petition for injunction seeking to stop Rx Depot from violating state law—illegally operating an unlicensed pharmacy. The state's action was supported by the FDA. Finally, the Alabama Board of Pharmacy was recently successful in obtaining a temporary restraining order against a storefront pharmacy, Discount Drugs of Canada, claiming that the storefront was performing functions and activities that constitute the operation of a pharmacy. The judge granted the temporary restraining order on March 20th and it will likely remain in effect until further order of the court. APhA applauds these actions by State Boards of Pharmacy and the FDA to protect consumers from potential harm.

Addressing Seniors Access to Prescription Medications

Clearly, as the profession who makes providing safe and effective medication therapy their priority on a daily basis, pharmacists are supportive of efforts to enhance patients' access to

[2] FDA, Office of Regulatory Affairs, Regulatory Procedures Manual, Subchapter Coverage of Personal Importations, http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html

prescription medications. But undercutting the regulatory system that tries to assure patients receive safe and effective medications is not the way to address the access problem. Importation may offer short-term savings, but creates the potential for long-term costs in patient harm.

APhA recommends direct, immediate action to help patients access medication through the U.S. healthcare system. Our country needs a pharmacy benefit in Medicare that provides access to the critical medications patients need every day. In the interim, consumers should work with their pharmacist and prescriber before making any changes in their drug therapy regimen. Generic medications are cost-effective alternatives to brand-name products — even brand-name products imported from other countries — and pharmacists can provide guidance on using generic medications as well as accessing assistance programs. The most expensive medication is the one that doesn't work — or worse, causes harm. Patients should use pharmacists as a valuable resource to make the best use of their medications and to get the most value from their money.

Conclusion

Importation creates safety hazards by circumventing the current medication safety safety net. We should allow the FDA to continue its work to keep patients safe by critically reviewing manufacturing and distribution practices that assure medications that American patients receive are safe, effective, and exactly "what the doctor ordered".

Some might observe an irony in Congress' consideration of changes to the medication safety laws, at the same time an overwhelming number of Members of the U.S. House of Representatives voted in favor of a voluntary error reporting system to improve medication use and health care. Undercutting the current safe, medication distribution system could negate any positive effects that an error reporting system might create.

APhA thanks you for the opportunity to provide comments on this important issue. We look forward to working with the Committee to develop a safe and effective system of providing prescription medications to all Americans.

Statement to
The Subcommittee on Human Rights and Wellness
Committee on Government Reform
U.S. House of Representatives

Hearing on
International Prescription Drug Parity

April 3, 2003

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The American Society of Health-System Pharmacists (ASHP) is pleased to submit this statement for the record of the Subcommittee on Human Rights and Wellness' hearing on international prescription drug parity. ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, long-term care facilities, home care, hospice, health maintenance organizations, and other components of health care systems. ASHP believes that the mission of pharmacists is to help people make the best use of medicines. Assisting pharmacists in fulfilling this mission is ASHP's primary objective.

ASHP would like to express its deep concern over ongoing efforts to open the United States market to prescription drugs from foreign sources.

Patients in the United States, because of high prescription drug costs, the lack of adequate prescription drug insurance coverage, and the resulting inability to obtain affordable medications, are increasingly going to sources that are outside the United States regulatory system to purchase their medications. This practice is illegal under current law and presents a significant public safety risk.

Under the federal Food, Drug and Cosmetic Act, it is illegal to import prescription drugs into the United States for personal use. The law clearly bans anyone other than the manufacturer of a product from reimporting US-made products and considers foreign versions of US-approved product as unapproved drugs. Despite the clarity of the current law, many believe a "personal use exemption" makes it legal to buy a 90-day supply of prescription drugs from foreign countries. This is a gross misinterpretation of an extremely limited exception intended to allow patients with life-threatening diseases for which potentially effective treatments are not yet available in the United States to access these "experimental" medications.

ASHP strongly concurs that something needs to be done to ensure that Americans have access to affordable medications. While laws permitting the importation or reimportation of medications from Canada are a well-meaning attempt to ensure access to lower cost medications, the safety issues outweigh the potential benefit.

The purchasing of medications from unknown and illegal sources via the Internet or other means is compromising the United States medication distribution system and placing patients at risk. In short, patient safety is at risk because the integrity of these products is not checked by our regulatory system and cannot be ensured. The following describes three common potential problems with imported or reimported products:

> **Pharmaceutical products will degrade if not kept under appropriate environmental conditions.** Degraded, subpotent products lose effectiveness and result in treatment failure. There is also the likelihood that some products degrade into toxic substances that could cause adverse effects.
>
> US-manufactured pharmaceutical products are packaged and labeled to guide handlers and users on the environmental conditions under which the products

must be stored, transported, and repackaged to reasonably ensure that active drug components will remain within standards of purity and potency up to the expiration date. Transport through high-temperature and high-humidity conditions is known to accelerate degradation. Pharmaceutical products reimported from tropical locales, in particular, would be suspect.

Pharmaceutical products could be significantly subpotent as a result of deliberate dilution of active ingredients. A repackaging operation could remove the contents from capsules, mix the removed powder with additional fillers, then recapsule resulting in, for example, a 250 mg strength being reduced to 50 mg. If this were an antibiotic, the patient would continue to suffer from an infection and the use of a subpotent strength could increase the development of drug-resistance. Oversight and other controls on the handling of pharmaceutical products outside the U.S. would be necessary to reduce likelihood of deliberate adulteration for profit.

Pharmaceutical products could be adulterated with other active ingredients or toxic substances. The dilution or replacement of the labeled ingredients with other bioactive ingredients could exacerbate the patient's disease and cause other adverse effects. Several incidents have been reported on the discovery of potent drugs or toxic substances found in imported pharmaceuticals. Again, oversight and other controls would be necessary to reduce this hazard.

Even medications obtained from a country with high standards such as Canada, create huge risks. Canadian drugs, like all foreign drugs, are outside the realm of the United States regulatory system and there is no way to verify where they have been, the conditions in which they have been stored, and whether they have been tampered with or contaminated. In fact, in many cases, it is impossible to tell if Canada is even the true country of origin.

In addition, foreign dispensers may provide patients with incorrect, contraindicated medications or inadequate directions for use.

Lawmakers and appropriate agencies should enforce, and, in regard to Internet pharmacies, strengthen, current federal and state law to maintain the integrity of the United States drug supply. In a Board-approved policy subject to ratification by our House of Delegates in June 2003, ASHP opposes the "reimportation of pharmaceuticals except in cases where the Food and Drug Administration determines it would be necessary for the health and welfare of United States citizens."

ASHP hopes congressional attention will focus on more constructive ways to ensure patients access to affordable medications. The addition of a prescription drug benefit to Medicare, for example, would be such a constructive step.

ASHP appreciates the opportunity to submit this statement for the record.

Statement on

International Prescription Drug Parity

before the

United States House of Representatives
Committee on Government Reform
Subcommittee on Human Rights and Wellness

Thursday April 3, 2003

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Mr. Chairman, and Members of the Subcommittee. The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to participate in this hearing on issues relating to imported prescription pharmaceuticals. NACDS is a national trade association that represents more than 200 chain pharmacy companies that operate nearly 35,000 community retail pharmacies. Our members dispense almost 70 percent of all outpatient retail prescription drugs in the U.S.

NACDS wishes to correct some common misunderstandings about prescription drugs that are imported from foreign countries. Commercial importation of prescription drugs for a consumer's personal use is clearly illegal. Companies that facilitate mail order drug importation do not comply with federal and state laws. These laws exist because drug importation schemes are unsafe. Rather than threaten public safety by encouraging illegal drug importation schemes, NACDS supports alternative approaches to providing American consumers access to safe and affordable prescription drugs.

Legal Issues Relating to Drug Importation

It is illegal to import prescription drugs into the United States for a consumer's personal use. If a drug was originally manufactured in the U.S., then it is illegal for anyone other then the original manufacturer to "reimport" the drug back into the U.S. If a drug was originally manufactured outside the U.S., then the drug is almost certainly not approved or properly labeled for use in the U.S. For these reasons, the federal Food and Drug Administration has repeatedly stated that "virtually every shipment of prescription drugs from Canadian pharmacies to consumers in the U.S. violates the [Federal Food, Drug and Cosmetics] Act."[1]

Despite this clear law, foreign companies that facilitate illegal drug imports mislead consumers about the legality of their actions. The importing companies' websites often say the FDA has created a "personal use exemption" that makes it legal for consumers to buy a 90-day supply of prescription drugs from foreign countries. The truth is that there is no *exemption* that makes mail order importation legal. The FDA has said it will not enforce the import prohibition when

[1] *See, e.g.*, FDA "warning letter" to Rx Depot, Inc. (March 21, 2003); FDA letter to The Kullman Firm (Feb. 12, 2003); FDA letter to The Manitoba Pharmaceutical Association (Jan. 17, 2002).

consumers with deadly diseases import unapproved drugs. But this FDA enforcement guidance, entitled "Coverage of Personal Importations," applies only in extremely limited circumstances where the imported drugs are not advertised in the U.S. and no treatment for the disease is available in the U.S. First adopted in 1954, the guidance was last modified in 1988 in response to concerns that certain potentially effective treatments for AIDS patients were not available in the U.S. but were available in other countries. The FDA enforcement guidance specifically states that it does not apply to international mail order shipments, such as those advertised by Internet pharmacies. The FDA has explained that "this policy is not intended to allow importation of foreign versions of drugs that are approved in the US, particularly when the foreign versions of such drugs are being 'commercialized' to US citizens. It does not change the law, and it does not give a license to persons to import or export illegal drugs into the United States."[2]

The illegal importers also mislead consumers by claiming that the Medicine Equity and Drug Safety Act (known as the "MEDS Act") allows personal importation of prescription drugs. The MEDS Act would have allowed importation of prescription drugs by certain professionals only if the Secretary of the Department of Health and Human Services concluded that importation was safe. But the MEDS Act never went into effect because both the present and former Secretaries of HHS – one a Republican and the other a Democrat – concluded that it was impossible to guarantee the safety of imported drugs.[3]

Shipping prescription drugs from other countries to U.S. consumers also violates state laws. For example, many state laws require companies that provide prescription drugs to consumers within the state to be licensed by the state. Yet companies that facilitate illegal drug importation are not properly licensed by the state boards of pharmacy.

Because numerous federal and state laws prohibit importation of prescription drugs, the FDA and state boards of pharmacy have begun cracking down on companies that facilitate illegal

[2] *See* FDA letter to The Kullman Firm (Feb. 12, 2003);
[3] *See* HHS Press Release, "Secretary Thompson Determines That Safety Problems Make Drug Reimportation Unfeasible" (July 10, 2001), available at www.hhs.gov/news.

importation. The FDA recently sent an enforcement letter to one such company.[4] Boards of pharmacy in Oklahoma, Florida and other states are investigating and bring enforcement actions against illegal importers.

NACDS applauds these recent enforcement activities by federal and state authorities. NACDS members operate in full compliance with federal and state laws to assure the safety of their patients. In recognition of the law, and in consideration of patient safety, chain pharmacies do not participate in illegal drug importation schemes. Specifically, we neither support nor encourage the illegal conduct of large foreign pharmacy operators who are profiting from selling potentially harmful and unregulated drugs in the U.S. NACDS urges the FDA, Members of Congress, state attorneys general, and state boards of medicine and pharmacy to enforce existing laws and regulations and stop this growing practice that has serious potential patient care implications.

Patient Safety Issues

Drug importation is illegal because it is unsafe. Allowing foreign pharmacies to import drugs into the U.S. dramatically increases the risk of sneaking counterfeit, adulterated and misbranded drugs across the border. Internet pharmacies may advertise that their drugs come from Canada, but the truth is consumers really cannot know whether those drugs are actually counterfeits from Vietnam, China, India or some other country.

Local community pharmacies are perhaps the most accessible and trusted providers in the entire health care system. It is estimated that 95 percent of Americans live within five miles of a retail community pharmacy. Thus, the vast majority of Americans are never far from a highly trained health professional who can provide medications and advice on a wide range of health care issues. Convenient access to community pharmacies makes them a critical part of society's health care safety net.

The United States has the safest drug distribution system in the world. Federal and state authorities ensure that American pharmacies, wholesalers and manufacturers satisfy stringent

[4] *See* FDA "warning letter" to Rx Depot, Inc. (March 21, 2003).

safety standards. But when consumers get their drugs from foreign sources they lose contact with their local community pharmacies. The drug safety net meticulously maintained in the U.S. is completely bypassed by illegal importation schemes. The drugs purchased from foreign companies may well be counterfeit, of impure quality, or simply not the drugs that they are supposed to be.

The FDA has strict guidelines on the manufacturing of prescription drugs here in the United States. Foreign-imported drugs do not have the important safety and quality checks that are built into the current U.S. community-pharmacy based distribution system. When drugs are mailed into the U.S. from foreign countries there is no way to ensure they are prepared, packaged, transported or stored in compliance with federal and state standards. Prescriptions shipped to U.S. residents may be subject to extreme heat or cold. These temperature extremes may result in an ineffective or unusable product. The potential for counterfeiting drugs is high. No licensed pharmacist is available to consult with the patient about the drug.

In 2001, the FDA surveyed drugs mailed into the U.S. and found "serious public health risks"[5] associated with "many" of the drugs. The risks included "drugs of unknown origin or quality" and drugs dispensed without a prescription. Some of the intercepted drugs were controlled substances. Others had been withdrawn from the U.S. market due to deadly side effects. Both the past and present Secretaries of HHS – one Republican, one Democrat – formally declared that HHS could not guarantee consumers' safety if importation is allowed.

As Secretary Thompson has said, "Opening our borders to reimported drugs potentially could increase the flow of counterfeit drugs, cheap foreign copies of FDA approved drugs, expired and contaminated drugs, and drugs stored under inappropriate and unsafe conditions."[6]

Furthermore, not all prescriptions needed by patients are available through foreign sources. In these cases patients would have to seek services from their local pharmacy provider. It is also

[5] Testimony of William Hubbard, FDA Senior Associate Commissioner for Policy, Planning and Legislation, before the Senate Special Committee on Aging (July 9, 2002).
[6] *See* HHS Press Release, "Secretary Thompson Determines That Safety Problems Make Drug Reimportation Unfeasible" (July 10, 2001), available at www.hhs.gov/news.

common for patients not to disclose to their health care provider all of the prescriptions that they are taking. Knowing that many of these drugs are obtained through questionable sources there is a tendency for some patients to withhold critical medical information from their pharmacist. This could result in the dispensing pharmacist's inability to recognize why dispensed medications are not working, or worse yet, may lead to an inability to detect a possible life threatening drug interaction. The consumer could be subject to increased health risks resulting in illness, an inability to work, impairment, or possible hospitalization. Clearly, quality of care is compromised by the use of imported pharmaceuticals.

Companies that facilitate illegal imports are well aware of these safety risks, so they make consumers sign long and onerous waiver forms. The foreign pharmacies don't want to accept the same responsibilities as local community pharmacies because they are vulnerable to serious liability. They know that what they are doing is unsafe and illegal, so they make consumers promise that they will never sue them if the consumers are injured by their foreign drugs. They know their foreign drugs may be adulterated or subpotent, so they make consumers promise not to return their drugs for a refund. They also know the U.S. government may seize their illegal drug shipments at the border, so they force consumers to agree not to demand a refund if the drugs never arrive. The forms routinely make consumers waive many other rights, such as the right to privacy, the right to consult a qualified pharmacist, the right to child proof packaging, and any warranties that the drugs are safe and effective. If consumers read the fine print and they will see how much they lose when they buy drugs from foreign pharmacies.

Helping Seniors Obtain Prescription Medications

NACDS members certainly sympathize with those patients who struggle to afford expensive prescription medications. But the solution is not to violate the law by encouraging unsafe drug importation. Instead, NACDS supports American solutions that do not promote unsafe and unscrupulous foreign companies over licensed U.S. pharmacies.

Private sector solutions already exist in the U.S. that offer prescription drugs at low prices, many of which are competitive with prices available from Canada. Drug manufacturers already offer

discount cards and subsidy programs with significant savings, such as the TogetherRx Card, the Pfizer For Living Share Card and the LillyAnswers Card.

As we have in the past, NACDS pledges to work with Congress in the coming months to fashion a Medicare drug coverage program that will help provide vital prescription drugs to our nation's seniors. We will also continue our ongoing efforts to inform seniors about existing drug manufacturer programs that provide significant discounts off drug prices. Working together, Americans can provide affordable access to prescription drugs without relying on dangerous importation schemes.

Conclusion

Illegal importation of drugs from foreign countries is growing, and is reaching a crisis level in terms of the implications for pubic health and security. Lawmakers and the appropriate agencies should enforce existing Federal and state laws to stem the tide of these illegal products. Obtaining drugs from international sources is neither safe nor reliable. We encourage law enforcement agencies to close down companies that aid and abet the illegal importation of drugs from foreign countries.

NACDS appreciates the opportunity to submit this statement for the record.

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