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PRESCRIPTION DRUG REIMPORTATION

HEARING

BEFORE THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

NOVEMBER 20, 2003

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

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PRESCRIPTION DRUG REIMPORTATION

THURSDAY, NOVEMBER 20, 2003

U.S. SENATE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Committee met, pursuant to notice, at 9:35 a.m. in room SR–253, Russell Senate Office Building, Hon. John McCain, Chairman of the Committee, presiding.

OPENING STATEMENT OF HON. JOHN MCCAIN, U.S. SENATOR FROM ARIZONA

The CHAIRMAN. Good morning. Today's hearing focuses on the debate over prescription drug importation.

This Committee held its last hearing on this issue just over 2 years ago. As I think back to that hearing, I must say, I'm disappointed that, to this day, our laws still do not give American consumers the right to import prescription drugs. To be clear, we're not talking today about just any drugs. Rather, we're talking about prescription drugs that have had their safety and effectiveness certified by the U.S. Food and Drug Administration. Nevertheless, FDA-approved prescription drugs remain an exception to the free flow of trade between the United States and the rest of the industrialized world.

This trade problems is stoking the fire of America's prescription-drug price crisis. The prescription drug prices paid by our sick, elderly, and uninsured are significantly higher than those of other industrialized countries, like Australia, France, and Switzerland. As a result, millions of our citizens travel across the border to Canada each year to purchase prescription drugs. Others purchase imported pharmaceuticals over the Internet. In all, Americans spend hundreds of millions of dollars on imported pharmaceuticals, not because they don't want to buy prescription drugs in the U.S., but because they simply can't afford to.

I fully agree that demand for lower prices should not lead us to sacrifice the health and safety of our citizens. That's why any legislation that permits the free importation of pharmaceuticals must contain safeguards that protect American consumers from tainted or counterfeit prescription drugs. But those who oppose importation must begin to engage in a dialogue to tell us what additional or alternative safety measures they believe will work. They must stop repeatedly telling us only that there's nothing we can do to implement an effective importation system that protects both the health and the pocketbooks of American consumers.

Indeed, it seems to me that most Americans, and especially those in need of prescription drugs to treat serious illnesses, want us to stop listening to the naysayers and start working on a reasonable solution to the ever-growing problem of excessive prescription drug prices in this country. To that end, I have sponsored S. 1781—co-sponsored—the Pharmaceutical Market Access Act of 2003, with several of my colleagues, including Senator Dorgan and Snowe.

Though the Act is likely not the cure-all for problem of sky-rocketing prescription drug prices in this country, it's the type of legislation that would allow our citizens greater access to the pharmaceutical markets of other industrialized countries, while still maintaining the safety of our prescription drug supply. The act would do so by permitting American consumers to import FDA-approved prescription drugs from Canada, European countries, and other industrialized nations, while requiring safety measures such as anti-counterfeiting technology for prescription drug packaging that is virtually identical to the technology used to secure U.S. currency.

I hope our witnesses today will engage in a constructive discussion about how best to strike a balance between affordable prescription drug prices and a safe prescription drug supply.

Before we proceed any further, I want to note my disappointment, but not surprise, that the Pharmaceutical Research and Manufacturers of America, which has repeatedly spoken out against the liberalization of our prescription drug importation laws, and, by the way, has a very restrictive clause in the Medicare prescription drug benefit—they've succeeded again—declined to appear today. What a surprise. I find it extraordinary that an organization tasked with speaking for several major pharmaceutical manufacturers on this issue, and has spent roughly $8.5 million in lobbying expenses this year, couldn't make the time to share with us the views of the companies that it represents.

[The prepared statement of Senator McCain follows:]

PREPARED STATEMENT OF HON. JOHN MCCAIN, U.S. SENATOR FROM ARIZONA

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I thank the witnesses who did accept our invitation and I look forward to hearing their testimony.

The CHAIRMAN. I thank the witnesses who did accept our invitation, and I look forward to hearing their testimony. And first I'd like to hear from Senator Dorgan and Senator Wyden and Senator Lautenberg, if they have opening statements.

STATEMENT OF HON. BYRON L. DORGAN, U.S. SENATOR FROM NORTH DAKOTA

Senator DORGAN. Mr. Chairman, first of all, I know we have a lengthy hearing, so I will try to be brief, but I do want to make a couple of comments that are important to this subject.

First of all, the subject is drug reimportation. The fact is, we import a substantial amount of prescription drugs in this country. It's done by the manufacturer of the prescription drug. Lipitor is manufactured in Ireland and shipped to this country. Prevacid is manufactured in Japan, Nexium in Sweden, and sent into this country. So there's a lot of importation of drugs going on. It is just that the pharmacists and the licensed wholesalers are prevented from reimporting, and consumers are allowed to reimport a personal amount for personal use, a very small amount.

But the issue of safety has been raised, and I want to make a couple of points with some bottles here in which the same pill is put in the same bottle made by the same manufacturer and sent to two countries.

And this perhaps demonstrates it better than any way I know. This is Celebrex. And you can see, the bottle is shaped the same, it's an identical bottle. They've reversed the coloring on it. But the only difference—this is an FDA-approved drug produced at an FDA-approved facility, and it is the same pill in the same bottle made by the same company, 79 cents per tablet in Canada, $2.22 in the United States. The only difference between these two tablets are the price. It is identical in every other way.

Lipitor. As you can see, it is the same container, same pill made by the same company, put in the same bottle, sent to Canada for $1.01 per tablet, the U.S. $1.86 per tablet. Or Vioxx, same bottle, same shape, reverse the color just a bit, and it's the same pill, put in the same bottle, made by the same company, FDA-approved. The U.S. consumer pays $2.20 per tablet; the Canadian consumer, 78 cents per tablet. The only difference is the price. The U.S. consumer pays the highest prices in the world.

Now, the pharmaceutical industry has aggressive supporters here on Capitol Hill, and we have an uphill battle. Let me compliment my colleague, Congressman Sanders and Congressman Gutknecht, for the aggressive fight they have waged in the Senate, and my partner here in the—in the House, I should say—and my partner in the Senate, Senator Stabenow, and Senator McCain and so many others who have worked on this issue. But it has proven to be a steep hill to climb.

And we're going to have testimony today about this subject. One person who will present testimony is Lew Lubka, from Fargo, North Dakota. He is in the audience, and he actually went to Canada with me one Friday morning when it was snowing, and we went to a one-room pharmacy in Emerson, Canada, five miles north of the North Dakota border, and what we discovered is, the same pill five miles apart, between a Pemina, North Dakota, pharmacy and a pharmacy in Emerson, Canada. It was identical pills, but dramatically different prices. Unfair to the American consumer.

So let me make one final point. I, along with my colleagues, including Senator McCain and Senator Stabenow, have introduced legislation that has passed the House of Representatives, and we are very disappointed by what it appears will be included in the Medicare prescription drug bill on the reimportation issue. It looks like the pharmaceutical industry wins there. So we will have to then try to move the bill that's already passed the House here in the Senate, and we are intending to try to do that, with all the aggressiveness we can, on behalf of the American consumer, who now pays the highest prices in the world for prescription drugs, and it is wrong, and it's unfair, and it has to change.

I, too, Mr. Chairman, am terribly disappointed that the Commissioner of the FDA is not here to answer. He's been the biggest supporter the pharmaceutical manufacturers have to try to prevent the American consumers from accessing decent prices. And I'm also disappointed that PHRMA is not with us this morning.

But, nonetheless, I appreciate the Chairman calling this hearing on this very important subject.

The CHAIRMAN. But I've never been to a fundraiser that there isn't a PHRMA representative there. I'm sorry——

[Laughter.]

The CHAIRMAN. Senator Wyden?

STATEMENT OF HON. RON WYDEN,
U.S. SENATOR FROM OREGON

Senator WYDEN. Thank you, Mr. Chairman. And I, too, appreciate your holding the hearing.

And you and Senator Dorgan and all of our colleagues at the table have done a lot of work in this area. And I think it's very

timely that this hearing be held now, because my understanding is, with respect to drugs overseas now, we're starting to see the same problems there we've seen everywhere else, that the prices are starting to go up, the wait that seniors face for their medicine is increasing. And it seems to me that as we look at this issue of drug importation, and particularly the developments in recent days, we also focus on the fact that there really is no substitute for what's going to help seniors contain costs, and that is bargaining power. Until there are steps taken, either in this legislation that we're going to vote on in the next few days, or some other piece of legislation, to give seniors bargaining power in the marketplace, I don't think we're going to see any real change with respect to the price of pharmaceuticals.

My understanding about the legislation that we're looking at now, not just in the area of drug reimportation, but with respect to what's done in managed-care plans, what's done in private plans, there still is not yet the bargaining power that seniors are going to need with respect to actually holding costs down.

I think we understand what a disgrace it is that in the richest country in the world, with all of this talent in the healthcare arena, we have seniors traipsing throughout the world trying to find affordable medicine.

So put me down on record as being for any kind of cost-containment strategy that is safe and that promotes more affordable medicines for seniors. But I think we ought to be looking at this issue now, because my understanding, just in the last couple of days, from seniors is, when they are looking to Canada and other parts of the world in the last few days they have seen price increases in those areas, they have had to wait longer for their drugs, and I think this reinforces the question of doing this job right. And the way you're going to do it right is by creating bargaining power for seniors in the marketplace.

And I wrap up by——

The CHAIRMAN. Which is prohibited in the Medicare——

Senator WYDEN. Correct.

The CHAIRMAN.—bill.

Senator WYDEN. I wrap up by way of saying, almost 30 years ago, Mr. Chairman, when I was co-director of the Oregon Gray Panthers, I did what Senator Dorgan is eloquently doing today, which is, I brought prescription drug bottles. And at that time we were working for generic drug pricing. And through your leadership and Senator Schumer's and others, we've made a little bit of headway there.

But I think we ought to understand that we have a long, long way to go in this fight, and I look forward to hearing from our witnesses today.

The CHAIRMAN. Senator Lautenberg?

STATEMENT OF HON. FRANK R. LAUTENBERG, U.S. SENATOR FROM NEW JERSEY

Senator LAUTENBERG. Thank you, Mr. Chairman.

I look at the material that our friend from North Dakota produced, and it looks—the bottles look the same, and—apart from perhaps some coloration on one package or another. The question

is exactly what's in the package. I would suggest that, just to be sure—because one of the concerns, one of the criticisms, is that there have been, in the past, incidents where a drug sold under one name does not have the same content or the same quality. And I would suggest to the Senator from North Dakota that, just to put a total cap on this, is perhaps to have a laboratory test these, make sure the ingredients are identical and to make sure that we get what we see.

Senator DORGAN. If I might just say to the Senator from New Jersey, that was part of the Senate bill that was passed, and those protections are in the reimportation legislation.

Senator LAUTENBERG. Well, they are now, but what we're looking at, at the moment, doesn't—hasn't passed the same quality test. It's required. But what—the bill is——

The CHAIRMAN. We have witnesses, Senator Lautenberg. Would you complete your opening statement, and then Senator Snowe is here, so we can get to the witnesses?

Senator LAUTENBERG. Listen, while all Americans are affected by the high cost of prescription drug, this burden falls largely on the senior citizen population, and nearly 14 million seniors have no insurance that provides for them to get the prescription drug benefits. So they're forced to pay full freight.

Additionally, 50 million Americans under the age of 65 also lack prescription drug coverage. With drug prices increasing 15 percent in 2001, the seventh straight year of double-digit increases, seniors and working-class Americans are forced to make impossible choices between the medications they need and food and shelter.

Now, I'm concerned, as the Chairman or anybody else is, about the fact that prices can be substantially lower in Canada for the same prescription drugs sold here in the United States. And we know the reason for this price. And I assume that my colleagues, who were, to use the expression used by the Senator from North Dakota, aggressive about this. And we should be aggressive. Included in that framework of aggression is price controls. Now, if that's what we're looking for here as a substitute for the free market, where most of the development of these new products is done, and with lots of failures along the way, then we have to step up boldly and say so.

In Canada, the price of a newly patented prescription drug cannot exceed the highest price of an existing drug used to cure or treat the same disease. And drug price increases generally cannot exceed increases in the Canadian CPI.

The system is good for Canadians, whom we are basically subsidizing. It's our drugs that they're taking. They develop few new drugs of their own. There's no economic incentive to do so. American pharmaceutical manufacturers develop 45 percent of all new drugs worldwide, and it can take up to 15 years, as much as $500 million, to get a new drug to market.

I want to be clear here. I agree that drug prices in the United States are too high. The products are too good, the longevity has improved substantially. I'm one of those who's, I hope, a shining example. I don't think that it's the same prescription—I don't think it's right that the same prescription drug can be found for retail

prices that are 30, 40, even 50 percent less in some European countries.

What's going on here is that these countries get a free ride. They benefit from the new drugs that are developed here, while they leave American consumers to bear the financial burden of developing and testing the drugs. But I don't think that the reimportation, even if it's limited to Canada, is necessarily the best way to reduce the burden on American consumers. What works for a country of 30 million people isn't necessarily the same prescription for a country of close to 300. Canada simply doesn't have a system in place to handle large cross-border trade in pharmaceuticals and to be able to guarantee their safety.

If we want to reduce prescription drug prices in this country, then Congress should develop the legislation, have an honest debate on the issue, instead of an ad hoc backdoor policy where the risks sometimes outweigh the benefits.

As Wednesday's *New York Times* reported, "Internet pharmacies have recently sprung up that claim to be based in Canada but do business from another country using a Canadian domain name." Now, I don't know whether there's a network of intrigue that we're looking at here, but I think we have to make sure that we ferret it out.

Americans looking for cheaper drugs abroad should not be gambling with their health. We had an opportunity to fix the problem of high drug costs for seniors by expanding Medicare to include a prescription drug benefit and then using the enormous bargaining power of the Federal Government to negotiate volume discounts, but we didn't do that. Instead, Congress is poised to adopt a haphazard prescription drug plan that contains significant gaps in coverage and doesn't do an awful lot to bring the prices down, even though it will cost us $400 billion.

So I regret that we missed an opportunity to do something that would have made, perhaps, this hearing unnecessary. We must get on with the price differential, and I want to do something about it, as well.

Thank you.

The CHAIRMAN. Senator Snowe?

STATEMENT OF HON. OLYMPIA J. SNOWE,
U.S. SENATOR FROM MAINE

Senator SNOWE. Thank you, Mr. Chairman. And I appreciate the fact that you're holding this hearing to focus on this most critical issue that's facing so many Americans. And it's a problem for which a solution is long overdue. And so I appreciate your leadership, and I think that the Congress does have a responsibility to address this issue, as I know Senator Dorgan has done so much in the past, Senator Wyden, on this issue, and passing this legislation for the last 3 years in two consecutive Congresses, and yet we have not been able to implement this legislation because it's predicated on the Secretary of Health and Human Services safety certification requirements. And as the prescription drug medication conference report is pending before the Senate, it'll include similar provisions. But we have yet to overcome the hurdles of those—safety certification. And I think it's unconscionable, I think it's unreasonable

that we have been able to surmount these hurdles in order to make sure that our consumers, our seniors, have access to affordable medications.

The fact of the matter is, our America's seniors are desperate enough to have to travel across the borders. That is true for Maine seniors, who have taken busload after busload to go to Canada to access affordable medications. Because, otherwise, they have no access to prescription drugs that they so desperately need, and otherwise would be out of reach. It's not only a matter of quality of life, it can be a matter of life and death.

And it was interesting, in the papers the other day, as we're all familiar with the charts, but they showed a survey in Maine to low-cost providers, and they compared drugstores, one in Maine and a number in Canada, as well. For 15 drugs, it was $804,000. The lowest price in Canada was for $355,000, 50 percent less, and that's the problem. And so albeit that we're going to have a prescription drug benefit as part of the Medicare program, it will do nothing to address the cost. So it's no wonder that more than 70 percent of Americans want reimportation, they want the ability to access those lower-priced medications, because we now know the facts, that drugs sold in other industrialized nations are selling for far less than they're selling here in the United States. In fact, the National Institutes of Health did a survey on the top 21 most important drugs, and 15 were found to have been developed using knowledge and techniques from federally funded research.

The fact of the matter is, America's investments in philanthropy has been shared worldwide. The one thing that hasn't been shared are lower-priced medications. We are paying the highest prices in the world. Americans are bearing a disproportionate burden for the research and the development making these new medications and innovative medications available to consumers worldwide, and yet they're bearing the highest price in prescription drugs.

Now, people say importation—reimportation isn't safe. I cannot believe, in America, we can't develop innovative techniques to ascertain the safety standards that are necessary to meet the requirements under the legislation and the laws that have passed previously in the current pending legislation in the Medicare conference report. I cannot believe that the FDA cannot meet those standards or the challenges involved in that legislation.

We can't develop anti-counterfeiting packaging? We mandated, in 1992, pedigree requirements so that you can have the bar codes to track the medication. I cannot believe that the FDA hasn't been working diligently and vigorously within the government, with consumers, to make sure that we could meet those standards when Congress has passed this legislation time and time again. Yet FDA is spending more time in Canada convincing the government not to sell medications here in the United States, and scaring seniors, essentially trying to shut down the borders, and yet they're not investing the appropriate time to meet the standards within the law and meet the intent of Congress that has passed this legislation on two different occasions, that has become law.

So I think we do have a responsibility. Reimportation of drugs isn't a problem, it's one of a number of solutions, and I think we have to address not only the issue of providing a benefit to Amer-

ica's seniors, but we also have an obligation to address the costs that are associated with prescription drugs that can make all the difference for the life of a American senior and American consumer.

So, Mr. Chairman, I appreciate your efforts here today, and hopefully this will be the beginning of developing, I think—and facilitating a process by which we can solve this problem. Government should be helping to serve America's seniors, not being an impediment to preventing their access to something that they clearly depend on and need.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator Snowe.

We had a hearing a few weeks ago, you know, on these dietary supplements, and it's been 9 years since the passage of that bill, and the FDA still has not written the regulations associated with it. So placing our trust in the FDA is, I would say, somewhat misplaced.

I want to welcome our colleagues from the House and the Senate here today. Senator Rick Santorum and Senator Debbie Stabenow and Representative Gil Gutknecht and Representative Bernie Sanders are here. We'll begin with Senator Santorum.

Welcome, Senator Santorum.

STATEMENT OF HON. RICK SANTORUM,
U.S. SENATOR FROM PENNSYLVANIA

Senator SANTORUM. Thank you, Mr. Chairman. I appreciate the opportunity to be here and to share my perspectives on this very, very important issue.

I know a lot of people here believe that the reimportation of prescription drugs from Canada will solve what ails the American healthcare system. I would argue that you, by doing so, would be attempting to treat the symptoms. You will not cure the disease. And I would argue that you will kill many patients in the process.

Foreign drug importation may seem like a straightforward and attractive remedy to prescription drug access. It, in fact, will create a host of serious healthcare consequences. Number one, it will import, potentially import, foreign price controls into this country. Two, it will decimate the research and development of pharmaceutical products in this country. And I know there are a lot of people on this panel who hate the tariffs that have been imposed on steel, and we do so much around here to help save an industry. We have an industry here in the pharmaceutical industry, which is one of the most competitive industries in the world, that imports—I mean, exports pharmaceutical products all over the world, and so the answer here is to try to somehow knock it on its heels. I don't think that's necessarily a good thing for this country or for our economy.

Reimportation undermines the FDA's authority to regulate drugs and opens up U.S. borders to diverted and counterfeit drugs from foreign sources. That, to me, is not necessarily a prescription for better healthcare in this country. The side effects are all too predictable and much worse than the perceived disease itself.

The proponents of foreign drug importation claim they have discovered a miracle cure for American healthcare, and what they're doing is basically selling snake oil to the American public. While

the problem of affordable access to prescription drugs is real, particularly in the elderly, they are better and safer ways, and effective ways, to solve this problem, more so than simply opening up borders to cut-rate foreign drugs.

In fact, the best way to do it is something that we're considering this week, which is to pass a Medicare drug benefit. This will assure seniors affordable access to safe and the best prescription drugs in the world. This means access to drug products that FDA has stamped with their approval, and it comes with the ironclad assurance that they're safe, authentic, and effective, which is something that reimported drugs could never be claimed to be.

What Congress should focus its attention on, candidly, is the international drug price disparities that have given rise to this debate in the first place. I agree with everybody here that it's unfair for Americans to pay more for their medicines than the rest of the world, but the answer is not to adopt what the rest of the world has done, which is price controls, and import them into this country. What we should do is insist that other countries pay their fair share. This is a trade issue. And we should be out there aggressively trying to work, through our trade offices and through here in the Congress, to get the rest of the world to pony up and to bear their cost that we bear here in America, which has to do with the research and development of new drugs.

While Canada is, by no means, a third-world country, many of the drugs that are funneled through Canada come from third-world countries with significant counterfeit problems. A recent five-part series in the *Washington Post,* my favorite newspaper, highlights the threat posed by counterfeiters. And if you've not read this series, I urge you to do so. While America's drug supply remains the safest in the world, it is under constant attack from well-funded, highly organized and technologically savvy foreign and domestic counterfeiters, some connected to organized crime, and some connected, perhaps, to terrorist organizations. Under current law, these counterfeiters face significant getting their products into commerce. But if we open up the borders to Canadian drugs, we will, in fact, increase the risk of these counterfeit drugs coming into this country. Not a positive thing for the health and safety of our population.

The lesson here is that we should be focused on strengthening protections, not opening up our borders to new assaults on the safety and health of the American people.

We recently strengthened the protections regarding imported food, which I know some Members of this Committee were very strongly in favor of. It's inconceivable, while we're doing that, that we're going weaken our borders when it comes to something that is critically important and something that can be counterfeited and tainted very easily, which is prescription drugs.

The price of drugs in Canada is lower than in the United States purely and simply because Canada has price controls. I find this an incredible argument that this is a fair trade or free trade issue, when what the free trade is, is to import drugs that have price controls on them. There hasn't been an increase in prices in Canadian drugs in 8 years. Eight years, they've controlled prices and haven't increased those levels. This is free trade? Allowing price-controlled

drugs into this country? Manufacturers that refuse to meet these price controls, what happens to them? Well, they can have their license revoked to sell their product up there. In other words, they can have their product stolen, they can have a compulsory license, have their patent stolen, and have it produced in Canada. This is free trade? This is what we want to condone by the Canadian government and other governments by taking the drugs and having them reimported back into this country? I don't think this is a free trade argument. This is trying to use the bullying tactics of the Canadians to beat drug companies up in this country to lower their prices. Importing cheap prescription drugs from Canada means importing price controls and all that comes with it, long lines, drug shortages, and the decimation of research and development.

The drug industry is the most vibrant, innovative, and productive in the world in this country, in part because the market-based system permits it to recoup its massive costs in research and development in spite of the subsidies that are received by getting research done through the Federal Government, which the gentlelady from Maine talked about. It costs roughly $1 billion to bring a new drug to market. Someone has to pay those costs, or those drugs are simply not going to be produced. And the fact is, the Canadians are not paying that cost, which is obviously one of the issues that we need to address.

I would say two things in closing. Number one is the safety issue. And I know people seem to dismiss this, but the fact is, you have two Secretaries of Health and Human Services under two different Administrations that says it not safe, DEA, U.S. Customs—the FDA's described the present situation as "buyer beware," and we want to make this more of a common thing in this country? I just find completely unacceptable for the health and safety of the people in this country.

And, finally, I would just say that anyone who believes that the pharmaceutical industry, if reimportation were put in place to this small country of Canada—they sell drugs up to Canada basically in sufficient numbers to meet the demand in Canada. Now, if we're going to have reimportation, which means Americans are now going to be able to buy drugs in Canada, do you think the drug companies in the United States are going to produce enough drugs to supply all the drugs through Canada, back to the United States? Well, the answer to that is, of course they won't. They're going to produce enough drugs in America to sell to meet the market in Canada. Well, what will that meant to the—what drugs, then, will become—do you think the Canadian government is going to give these good quality American drugs to be sold back into the United States? Of course they won't. They'll save those for their own people. So what are we going to get reimported? Nothing will be reimported back to this country. We will get imported drugs from third-world countries, because Canada simply doesn't have the ability to manufacture them in their country. So we'll get third-world counterfeit drugs coming through Canada with a stamp of approval from the Canadian government, when they haven't inspected them in the first place. This is not reform. This is a safety boondoggle for a lot of folks who are not necessarily looking out for the best

interest of the American public, and something that we should not countenance and support.

We should go out and aggressively go after countries who fix prices, who don't pay their fair share. That's the answer to the problem.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator Santorum. I know you have other responsibilities, so I—I know that Senator Dorgan would love to——

Senator DORGAN. Well, Mr. Chairman——

The CHAIRMAN.—discuss this with you. But——

Senator DORGAN. Mr. Chairman, surely Senator Santorum will not leave now. We do have questions.

Senator SANTORUM. I'd be happy to stay for questions.

Senator DORGAN. Yes, I would hope he would. I think he's talked about killing patients and so on, and I certainly want to ask him about "killing many patients." So if he has the time, I think it would be helpful to our Committee to allow us to ask him a few questions.

The CHAIRMAN. I would ask if it would be possible for Senator Santorum. Look, this is an emotional issue. I think we all realize it. But I think it would be fair to the other Members if they could give their statements. I know your time is limited, Senator Santorum, but I think it wouldn't be appropriate if we engaged in a debate with Senator Santorum and not allowed our other colleagues to make their statements. Would that be agreeable to you, Senator Santorum, or——

Senator SANTORUM. If I could run, for a few minutes, while these folks—I have something I have to do, and I'll be—I can come back if that's——

The CHAIRMAN. Thank you.

Senator SANTORUM.—okay with the Chairman.

[The prepared statement of Senator Santorum follows:]

PREPARED STATEMENT OF HON. RICK SANTORUM, U.S. SENATOR FROM PENNSYLVANIA

Mr. Chairman, I appreciate the opportunity to lend my perspectives on legislative proposals to legalize the importation of prescription drugs from Canada. Some believe that this is the right prescription for all that ails the American health care system. You hear it in city hall; you hear it in the statehouses; and you even hear it by some here on Capitol Hill. They argue that the way to fix the problems of access to the miracle cures of the 21st century-and many of these medicines truly are miraculous -is to open up the floodgates to cut-rate, priced-controlled medicines from Canada.

Although the proponents of foreign drug importation have the best of intentions, unfortunately their solutions treat the symptoms instead of curing the disease. While foreign drug importation may seem like a straightforward and attractive remedy to the health care issues affecting this country, it will in fact create a host of serious healthcare problems that could plague the country for years to come. These include: (a) importing foreign price controls; (b) decimating the incentives for research and development; (c) undermining the FDA's authority to regulate drugs; and (d) opening the closed U.S. drug distribution system to diverted and counterfeit drugs from foreign sources. These "side effects" from foreign drug importation are all-too-predictable and much worse than the original disease. The proponents of foreign drug importation claim they have discovered a miracle cure for the American healthcare system; in fact, they are selling nothing more than the legislative equivalent of snake oil.

Before buying this foreign drug importation cure-all, we need to step back and get a second opinion. We need to ask ourselves why we are having this debate in the

first place. Are we so desperate for solutions that we're willing to wager the health and safety of the American public on a risky, unproven foreign drug importation scheme?

The answer has to be "Absolutely Not!" While the problem of affordable access to prescription medications is real, particularly for the elderly, there are better, safer and more effective ways to solve this problem than simply opening up our borders to cut-rate foreign drugs. In fact, the best way to solve this problem is for Congress to pass a Medicare drug benefit for our seniors. A Medicare drug benefit will ensure that seniors have affordable access to the best prescription drugs in the world, through private sector competition working in concert with the group purchasing power of social health insurance. This means drug products that have the FDA's stamp of approval; that come with an ironclad assurance of safety and effectiveness; that seniors know are authentic and will work.

In addition to passage of a meaningful Medicare prescription drug benefit, improving affordable access to prescription drugs requires that we work aggressively to minimize international drug price disparities that have given rise to the idea of foreign drug importation in the first place. We all agree that it is unfair that Americans can pay more for their medicines than Canadians. The answer to this very real and legitimate concern lies in working to *eliminate* foreign price controls on drugs, *not* in importing them. We must also more stringently defend patent holders' intellectual property rights in our trade negotiations and other international policy initiatives. We can and should insist that other countries pay their "fair share" of the costs of developing new medicines, by working to open their markets so as to allow competition and free trade to work across borders. For far too long, the American public has been forced to shoulder the financial burden of researching and developing new drugs. It is high time that we bring to an end this "free ride" which directly results from foreign price controls.

It's not good enough for Congress to say to our seniors: "We'll give you access to prescription drugs—but only to drugs that have been funneled through Canada." While Canada is by no means a Third World country, many of the drugs that are funneled through Canada come from Third World countries or countries with significant counterfeiting problems. A study conducted by Prudential Financial, for instance, indicates that Canada recently increased its prescription drug imports from Pakistan by 196 percent; from Argentina by 171 percent; and from South Africa by 114 percent. In addition, studies have found that approximately one-third of the Internet websites claiming to be from Canada are not actually located in Canada. In many cases, the medicines are in fact from China, India, Mexico, Nigeria or Pakistan. Yet under the various foreign drug importation schemes now being considered, these are some of the drug products that very likely will be dispensed to our American seniors.

Given the increased threat to the integrity of the American drug supply, now is not the time to open up a huge new supply channel for the counterfeiters. A recent five-part series in the *Washington Post* highlights the threat posed by counterfeiters, and if you have not read this series, I urge you to do so. While America's drug supply remains the safest in the world, it is under constant attack from well-funded, highly organized, and technologically savvy foreign and domestic counterfeiters, some connected to organized crime and some connected, perhaps, to terrorist organizations. These counterfeiters are ruthless, and prey upon the weakest and most vulnerable elements of society in order to make a quick buck. Because of the protections in current law and the unflagging efforts of the FDA and Federal and state law enforcement officials, these counterfeiters face significant hurdles getting their products into legitimate commerce. Yet if foreign drug importation is authorized, these counterfeiters will have a field day, and Canada will become a massive entry point for diverted and counterfeit drug products of all kinds. Indeed, if the counterfeiters had a trade organization, you can bet they would be pulling out all the stops lobbying for foreign drug importation.

The lesson from the *Washington Post* series and the recent anti-counterfeiting activities by FDA is that we should be focusing on *strengthening* the protections around our borders, *not* opening them up to new assaults. We recently strengthened the protections regarding imported foods. It is inconceivable that a few months later we would consider doing exactly the opposite with respect to imported drugs.

This is all the more true given the realities we face in a post-September 11th world and our ongoing war against terrorism. With the distribution of anthrax contaminated letters through the Postal Service to the U.S. Capitol complex and several news media offices in 2001, terrorist use of biological weapons has become a reality. It does not take a great leap of imagination to envision the increased potential for terrorist attacks on our pharmaceutical supply were we to let our guard down on drug safety: attacks that could cause catastrophic harm to patients, enor-

mous economic damage our second-to-none health care industry, and could threaten confidence in our Nation's public health system.

Some may argue that the critical difference between food and drugs is price, and that the lower prices charged in countries like Canada simply are too attractive to pass up. And if price really is the driver, we need to understand why the price of drugs in Canada is lower and what the ramifications of that are. And if we take a critical look at that, it becomes clear, I think, that the price of those low Canadian drug prices simply is too high for American patients to pay.

The price of drugs in Canada is lower than in the United States because-pure and simply—Canada imposes price controls. Unlike the United States, Canada does not permit market-based pricing. Instead, Canadian authorities set a maximum price for each drug. Manufacturers that refuse to abide by the set maximum price face the threat of having their patent rights revoked. Thus, manufacturers have little or no recourse to fight Canadian price controls.

But while Canadian patients may pay a marginally lower price for their prescription drugs than Americans, they pay a much higher societal cost. Price controls on prescription drugs have decimated the Canadian drug industry. Just a few years ago, Canada had a vibrant and innovative research-based prescription drug industry. Today, that industry is mostly gone and the research and development activities have dried up. The meager Canadian drug industry that remains mostly churns out generic copies of existing drugs.

In addition, the Canadian health care system keeps a lid on costs by rationing goods and services. Long lines at the doctor's office are routine. Patients may wait months to see a specialist or for needed medical procedures. Many drug products that are available in the United States simply are not available in Canada.

Consequently, when the foreign drug importation proponents talk about importing cheap prescription drugs from Canada, we must remember that that is not all we will be importing. We also will be importing Canadian price controls and all that comes with it, including long lines, drug shortages, and the decimation of research and development. The U.S. drug industry is the most vibrant, innovative and productive in the world, in part because market-based pricing permits it to recoup the massive costs of research and development. If we turn our back on the free market and instead seek to import Canadian price controls, we also undoubtedly will be importing not only the fate of the Canadian drug industry, but also the "price" that Canadian citizens pay in terms of diminished access to the newest and most effective medicines.

Given these economic realities, it is curious that some proponents of foreign drug importation have characterized this as an issue of "free trade." In fact, foreign drug importation from countries with price controls is the *antithesis* of free trade.

Finally, foreign drug importation is the wrong medicine for America because, plain and simply, it just is not safe. This is not just merely one opinion, but the consistent view of the FDA, two Secretaries of Health and Human Services from both Democratic and Republican administrations, the U.S. Customs Service, and the Drug Enforcement Administration. Moreover, the Canadian authorities have stated for the record that they cannot or will not ensure the safety of drug products exported to the United States. That, they claim, is not their job. And the FDA does not have the resources or manpower to police every shipment offered for import. Thus, drug importation presents a situation where nobody is minding the store. Or, as the FDA has described it, it presents a situation of "Buyer Beware." While this may be an acceptable way to buy other goods and services, it is not an acceptable way to purchase prescription drugs. And it certainly should not be an acceptable policy for providing greater access to prescription drugs for American citizens.

The most sensible, direct and safe method of ensuring that Americans have a fair deal on prescription drug prices is to pursue trade and other international policy initiatives aimed at tearing down foreign price controls. Clearly, it cannot be maintained that importing the price controls of other countries and removing the tools and authority that currently exist for the FDA to protect our medicine supply is a viable, long-term solution to achieving international drug price "parity."

Some may have forgotten the fact that just over 20 years ago, a series of Tylenol cyanide murders in the Chicago area had consumers, pharmaceutical manufacturers and regulatory agencies in a state of national panic about the safety of over-the-counter drugs. Since then we have made great strides in strengthening the Federal drug safety standards that protect the American public from counterfeit and/or adulterated drugs. All Americans have come to depend on our current controls that assure the safety, strength, quality, and purity of medicines. We cannot afford to turn back the clock; now more than ever, we must stand strong and uphold the regulatory standards that have made our drug supply the safest in the world.

As responsible elected officials, we have an obligation to focus on the real issues at hand, and resist the temptation to foist upon the American public short sighted, seemingly "free lunch" solutions to prescription drug access. Despite its noble purported intentions, foreign drug importation is, in the final analysis, a snake oil approach that raises more questions than it answers. We need a real cure for the problem of affordable access to prescription drugs. It should start with passing a meaningful Medicare drug benefit. And it should continue with a dogged resolve to eliminate foreign drug price controls, so that Americans do not continue to shoulder the burden of researching, developing, and bringing to market new, innovative and lifesaving medicines.

Thank you again for this opportunity.

The CHAIRMAN. Obviously, we'd appreciate it.

And I also would remind my colleagues, we have two other panels following this one.

Senator Stabenow?

STATEMENT OF HON. DEBBIE A. STABENOW, U.S. SENATOR FROM MICHIGAN

Senator STABENOW. Well, thank you, Mr. Chairman. I very much appreciate the opportunity to be here, and I, too, would love the opportunity to debate Senator Santorum line by line, in terms of his testimony. And I realize that there are many opportunities for the Committee to ask questions today.

I want to first thank you for your leadership as it relates to the issue of closing patents and putting more generic drugs onto the marketplace. I'm pleased to be a cosponsor of the legislation, that we originally passed in the Senate, that actually, on a bipartisan basis, would make a real difference. I'm very concerned about what appears to be watering down of that legislation in the final Medicare bill. But I thank you for your leadership and for all of my colleagues on the Committee who have been involved in the issue of reimportation, particularly Senator Dorgan, who has, I know, been a leader, far beyond my time in the Senate, and Senator Snowe. And I would only say that my first legislation, my first bill I introduced in coming to the Senate in 2001 was on this issue.

I believe we have two important challenges in front of us. One is a real Medicare prescription drug benefit, and the other is lowering prices for everyone. And if we were to pick the one that would make the difference the quickest, it would be this issue. Even the bill in front of us on Medicare does not take effect til 2006, has a very large price tag, although I would argue it is nowhere near what our seniors deserve or need. But if we, frankly, instead of that, simply today pass the legislation that has already passed the House, we would be doing a major service for the people of this country. It would cost very little. It could help beef up the FDA to address the issues that Senator Snowe talked about, in terms of bringing the safety issues together. Certainly, in the United States of America, we have the capacity to design a system that, frankly, is already designed for the pharmaceutical industry, who brings back drugs every single day across the border. We just want others to have the same benefit from this.

But if we simply took away this prohibition, we would not only help seniors in this country, we would help every business, large and small, every worker. When I sit down with those in my state who manufacture automobiles and look at their numbers, at least

half the cost of their explosion in healthcare premiums is as a result of the explosion in prescription drug prices.

So this is a real issue for business. It is a real issue for every senior and every consumer. And, in fact, this year, the Medco Health 2003 Drug Trend Report found that prescription prices will rise, this year, anywhere between 14 and 17 percent. They predict next they will rise another 18 percent, and the next year another 18 percent. We are talking about an explosion in prices that businesses and seniors and any consumer cannot sustain. That's why I believe this issue is so critical.

We know that if we simply pass the House bill that has already been passed by my colleagues on a bipartisan basis, that all taxpayers and consumers would save some $40 billion by doing that. I am very concerned that, not only in the legislation in front of us now coming to the floor on Medicare do we not see these provisions, but it's even worse, because they are prohibited from doing what Senator Wyden has talked about, which I totally agree with, which is the leverage, the group purchase, to be able to bring the price down. The bill in front of us doesn't allow that, has specific language to prohibit that kind of group leverage. So we have the worst of the worst in the bill coming before us, a poor benefit, and a new group of consumers, a new group of customers for the industry, locked into the highest prices possibly in the world. There is only one group that benefits by that, Mr. Chairman, and it's certainly not the seniors of this country.

I've taken many bus trips. From Michigan to Canada, it's only 5 minutes across a bridge. It's astounding to see the differences. We all know the differences in prices. Senator Dorgan has already spoken about the differences. I would just share one thing. Last month, in the town of Howell, Michigan, which is about 60 miles away from Detroit in the border, the Senior Center took a group to Canada, and it was interesting to note that one couple flew up from South Carolina to visit their daughter, who lives in Howell, Michigan. And the savings from just one of the drugs that they purchased in Canada paid for their trip, their flight, to come up and be able to join their daughter and go to Canada.

You know, there's a lot of talk about the free marketplace, and I want to mention just one of the price differences and why I don't think this holds water, when we talk about some of the comments of our colleague, Senator Santorum. Let me give an example of Tamoxifen. We've all heard this before. But right now Tamoxifen is one of the drugs to battle breast cancer. It's about $340.77 in the United States. When we took the seniors to Canada, they received it for $39.19. Now, eight times more expensive. Does the marketplace work for this? Can a breast cancer patient who's diagnosed today say, "You know, I think I'll wait. I don't think I'll take Tamoxifen, which I need to possibly save my life. I think I'll wait and take it another time when the price is better"? Of course, they can't do that. This is not like buying an automobile or a pair of tennis shoes or a new shirt. You can't just say, "I can't afford it today. I'll do it tomorrow." These are life-saving medicines, and the marketplace works differently. When someone says, "You're got to pay $340.77 for your Tamoxifen, because you have breast cancer," you're going to do everything in your power to find that $340 a

month, because it is critical for your health and possibly your life. So this is different, and I believe we need to look at it differently and have a sense of urgency about what it is we're talking about.

I would simply add one more thing, and that relates to what we're really talking about here. And, Mr. Chairman, I will submit my full testimony for the record. I know we have other colleagues here. But let me say that this is not an issue about the Internet or about mail order. And I do think we have some issues with Internet and mail order that need to be address, in terms of where drugs are coming from.

Reimportation is about allowing the local pharmacists at the local pharmacy to be able to do the same thing that the pharmaceutical companies do every single day, to bring back drugs, to have a business relationship with the pharmacist or the wholesaler in Canada. Right now, every single day, every single day, there are prescription drugs coming across the border from Canada into Michigan. The only difference is, they're being brought across by the industry and not by the licensed pharmacist. The FDA sends inspectors to the countries where these product lines are made. They inspect them, they make sure there's a closed supply chain, and they make sure it's safe. They can do exactly the same thing if we choose to give our seniors lower prices and licensed pharmacists the same ability to do that.

We also know that there is ample technology available, both in the Senate bills that we have talked about, as well as the House, to address the issues of safety.

Mr. Chairman, I would just say, in closing, this is not an issue of safety. This is an issue of competition and the fact that the prescription drug industry does not want to be in a position to have to lower their prices to American consumers. And shame on us if we can't get this right. We help subsidize making the drugs, we give tax credits and tax deductions for the development of the drugs, we give up to a 20-year patent in order to protect them so they can recover their costs, and what do we get at the end of that? The highest prices in the world. That is not a good deal for us, Mr. Chairman. And I hope, with your leadership and the leadership of the Committee, that we will change that.

[The prepared statement of Senator Stabenow follows:]

PREPARED STATEMENT OF HON. DEBBIE A. STABENOW,
U.S. SENATOR FROM MICHIGAN

Chairman McCain, thank you for convening today's hearing on the rising cost of prescription drugs. I also want to thank my colleague and committee member, Senator Dorgan, for his work. You both have been leaders in trying to reign in the high cost of medication through generics reform and market access.

The timing of this hearing is obviously fortuitous because Congress is considering whether to add a prescription drug benefit—a flawed benefit in my opinion—to Medicare.

I am sure that we all agree that prescription drugs need to be more affordable and accessible—not just for Medicare beneficiaries but for all Americans. The Medco Health 2003 Drug Trend Report found that prescription drug costs will rise somewhere between 14 to 17 percent this year for health plans. And the report estimated that these costs will rise 18 percent in 2004 and again in 2005.

Unfortunately, the Medicare conferees missed a great opportunity to bring prescription drug relief to American families. The nonpartisan Congressional Budget Office estimated that a reimportation provision similar to the House Bill HR 2427 would save *all payers* some $40 billion.

This failure is just one of the reasons why I oppose the present Medicare bill, and I urge the members of this Committee to do the same. If we defeat this conference report, we can start over and get a good Medicare RX benefit, more competition and lower prices for all Americans and continue our successful Medicare system.

I know what a difference a reimportation provision would have on people's lives. For years, I organized several bus trips to Canada. As you know, Canada is just a short trip over a bridge or through a tunnel for many residents of Michigan. What I discovered on my bus trips was almost unbelievable.

With just a short drive across the border, U.S. citizens can substantially reduce the cost of their medications by purchasing them in Canadian pharmacies. The difference in price for medications was absolutely shocking. A price study I conducted, comparing the price of several drugs purchased in the U.S. to the Canadian prices, confirmed what we saw happening on our bus trips—the price of the same drug purchased in Canada is substantially lower than the average U.S. price.

Just last month, the City of Howell organized a bus trip to Canada, a trip that made national news. From Howell to Windsor is a distance of about 60 miles. Sixty miles for affordable FDA-approved prescription drugs.

How much did people save? One couple from South Carolina had planned a visit to their daughter in Howell *around this bus trip!* They saved enough money on one of their prescriptions to pay for their airfare.

How much are people saving? Here are a few price comparisons that the Alliance for Retired Americans put together in August of this year:

- Zocor: a drug to reduce cholesterol is $129.99 in the U.S. and $67.72 in Canada. That is nearly a 50 percent savings.
- Prozac: a drug to treat depression $302.97 in the U.S. and $140.60 in Canada, that's over 50 percent savings.
- Celebrex: a drug for arthritis pain is $85.99 in the U.S. and only $44.76 in Canada. Vioxx: another arthritis drug is $90.99 in the U.S. and only $44.16 in Canada. In both cases, the arthritis drug is about half the price in Canada.
- Finally, Tamoxifen: an important drug in the battle against breast cancer, is a $340.77 in the U.S. and only $39.19 in Canada. Tamoxifen in the United States is eight times more expensive than the same drug sold in Canada.

People are desperate for affordable medications because they are rising two-and-a-half to three times the rate of inflation. There is no way that our health system, our citizens, and our Nation can continue to endure these double digit increases year after year.

As many of the witnesses will agree, these cost escalations are a huge financial burden on all Americans: from our senior citizens on fixed incomes, to working families without insurance, to small businesses with high health plan costs, to hospitals struggling to stay afloat, to cities and states.

States and cities are already leading the way in developing policies and strategies to safely reimport drugs: from New York City to Springfield, Massachusetts, from Maine to Minnesota. I am very excited by the work that Minnesota Governor Pawlenty (PAUL-lent-e) has done at looking at lowering prescription drugs, and I look forward to working with him in the future.

It is unfortunate that the Federal Government has done little to help Americans with this growing problem. The Food and Drug Administration's recent about-face decision to consider legal action against states and localities that are trying to reduce their drug costs is mind-boggling. The FDA should be working toward affordability and accessibility, not bullying our citizens and our states.

Opponents will tell you that Americans have to swallow the bitter pill of high prices if they want safety and innovation. This is a false choice for our Nation and our world—we can achieve both.

Accomplishing our shared goal of affordability and accessibility is no easy task. Health care defies traditional economics of supply and demand. Unlike other economic goods, we do not choose when we need to purchase prescription medicine. Access to prescription drugs are very often a matter of life and death.

Giving Americans access to FDA-approved prescription drugs—often American-made—that are sold for lower prices in other countries will reduce the price of drugs in the U.S.

Note that pharmaceutical manufacturers are the only groups legally allowed to bring drugs from other countries into the U.S. Presently, the FDA sends out inspectors to countries all over the world to inspect and approve production lines that produce drugs that will be brought into the U.S.

Such reimportation occurs now when either the drugs are manufactured only outside our Nation or the manufacturer cannot meet existing demand due to a domestic

shortage. The drug manufacturers have a complete monopoly on the reimportation of prescription drugs. Doctors, pharmacists, patients, and employers should have the same opportunity to purchase FDA-approved drugs from other countries at lower prices just as pharmaceutical manufacturers do.

We need to set up a system that allows pharmacists, patients, and providers to use the global marketplace to find the lowest priced drugs. Such a system should include only countries that have safety standards that are as strong as those set by the FDA as appropriate for reimportation. And there should be mechanisms in place to ensure the supply chain is closed and the authenticity of reimported drugs.

Harnessing existing technology can help us address safety concerns and create such a system. In fact, there is technology already being implemented that tracks shipments, and this same technology can be used by the pharmaceutical industry. Anti-counterfeiting protection can be used on the seals and labels of drugs to guarantee authenticity.

As aforementioned, pharmaceutical manufacturers are reimporting drugs now and able to ensure their safety and security through a closed supply chain. Surely, we can do the same by using existing—technologies to protect drug shipments and help make prescription drugs available to everyone at lower prices.

Thank you for your time and consideration. By working together, we can improve our Nation's health.

The CHAIRMAN. Thank you very much, Senator Stabenow.

Thank you, Congressman Gutknecht, and thank you for all of your hard work on this issue.

STATEMENT OF HON. GIL GUTKNECHT,
U.S. REPRESENTATIVE FROM MINNESOTA

Mr. GUTKNECHT. Well, thank you, Mr. Chairman. I am so happy to be here today, and I am so happy that you're having this hearing.

One of my mentors in this subject is a gentleman by the name of Dr. Steve Schondelmeier, and he is a professor of pharmacology at the University of Minnesota, and he teachers pharmacology, he is a pharmacist, he has studied this issue for more than 15 years. And one of my favorite quotes from Dr. Schondelmeier is this, "A drug that you cannot afford is neither safe nor effective." And what we have in America today is really the worst of all worlds for consumers. As my colleague from Michigan just said, literally what we do is we grant these long-term exclusive franchises, and then we hold American consumers captive, and the results are absolutely predictable.

And I'm one who doesn't necessarily say shame on the pharmaceutical industry. It really is shame on us. Because ultimately the FDA works for us, and we have a responsibility and an obligation and, more importantly, an opportunity to do something about it.

And I'm so glad that you have co-sponsored this bill. We hope that it will move through the Senate. Now, we are considering legislation, as has been mentioned, in the House and Senate that would essentially just transfer the responsibility of paying for most of these drugs from the consumers of the drugs to the taxpayers, and some say that that's the answer. Well, I'm not convinced it is, because I think we've asked the wrong question.

I think from the very beginning on this debate about prescription drugs for seniors, we have framed the issue around coverage. Ladies and gentlemen, if you go out and meet with real seniors, and many of you have, you know that the issue isn't so much coverage, it's affordability.

And Senator Stabenow pointed out Tamoxifen. I want to come back to that. But I also want to mention that I happen to believe that markets are more powerful than armies, and, at the end of the day, markets work. And the reason we have the situation today is because we don't allow markets to work.

Now, it's interesting, because Representative Sanders and I agree on very few issues, but we agree on this. And what I have always said is that this is not a matter of right versus left, because we have some of the most conservative Members of the House and some of the more liberal Members of the House who both agree on this issue. So it's a matter of right versus left. It really is a matter of right versus wrong. And it is wrong to hold American consumers captive so that they have to pay, by far and away, the highest prices in the industrialized world.

Now, the issue that's continuously raised by the FDA and the other critics is safety, but I hope you'll take an objective look at this basic issue of safety, because when you do, you will find out that it really is a bogus issue.

Now, we know, for example, that the CDC and other government agencies keep incredibly good records. We know how many people have died from taking drugs from other countries. We also know from studies that at least a million Americans—in fact, that number may well exceed five million Americans—are currently buying their drugs from other countries. In some respects, that's a tragedy in and of itself. I represent Rochester, Minnesota, home of the Mayo Clinic. Every day, thousands of people come from all over the world to get their healthcare here in the United States. But, tragically, Americans must go to other countries to get affordable prescription drugs.

When we talk about safety, though, we keep records. We know how many people have died from taking drugs from other countries. It's a nice round number. It's easy to remember. It's zero. We know that you are more likely to become seriously ill from eating raspberries from Guatemala, by the government's own statistics, than you are from taking prescription drugs from Canada. We know today that five people in Western Pennsylvania have died from green onions from Mexico. And yet we know of no one who has died from taking prescription drugs from Canada or Mexico. And so the safety argument, I think, is widely and wildly exaggerated.

But the important part about the bill that you are cosponsoring is, it will make the safety even safer, because we're, for the first time, going to require counterfeit-proof, tamper-proof packaging. That technology exists today. And we have, and we can show you, some of that technology. And you've got some great witnesses that can talk about that, as well.

One of the other arguments is about counterfeiting. But remember this, Members, no one counterfeits one dollar bills. The reason we have counterfeiting is because of the expense of the drug. And, interestingly enough, I think the FDA would admit that most of the counterfeiting that we see happening today is happening inside the United States. It's not happening somewhere else and being brought in.

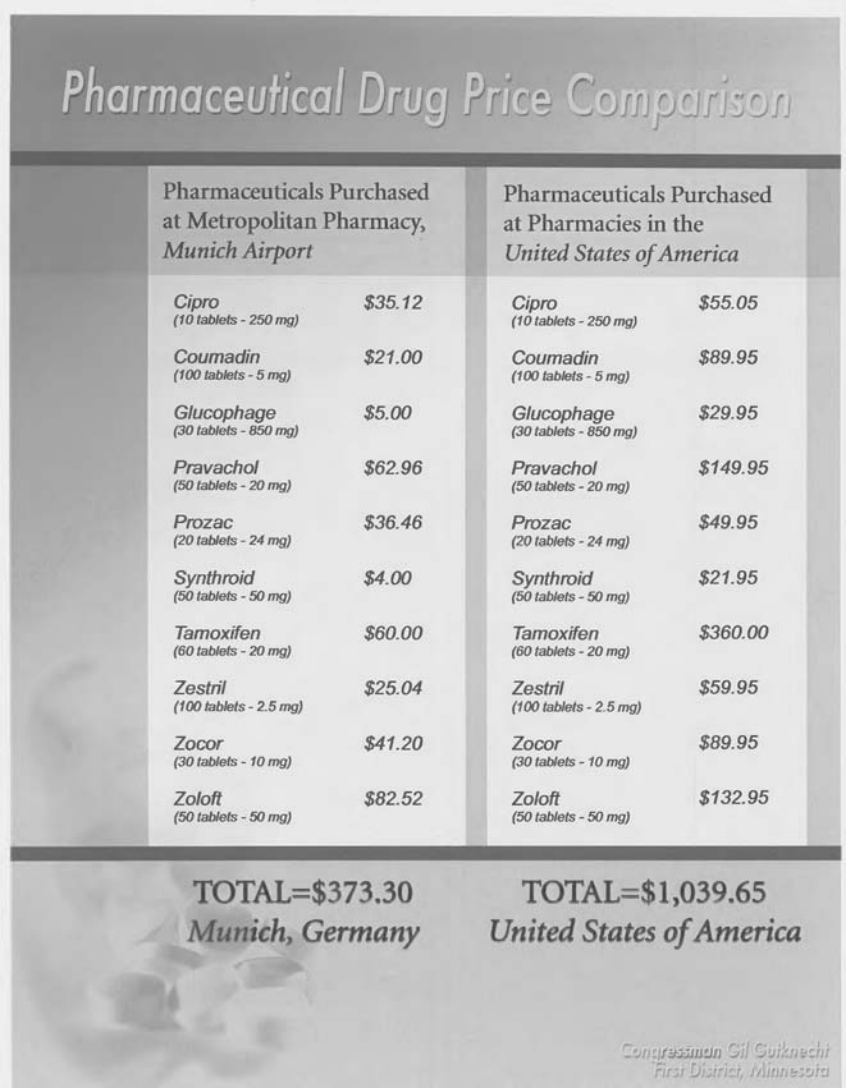
The other argument that was raised is about free trade, and these countries might steal patents. Well, Members, you need to understand that every country has to sign, before they're permitted into the WTO, what is called the TRIPS agreement, where they literally pledge that they will not steal intellectual property rights. And I'm one who believes in intellectual property rights.

Finally, I want to talk a little bit about how we subsidize this industry. And I'm not here to bash the pharmaceutical industry. As I said earlier, it's not shame on them, it's shame on us. But do understand that we subsidize this industry in three separate ways. First of all, we subsidize them through the research that we do with taxpayers' dollars. This year, we will fund the NIH, the CDC, and other groups that do research in the United States, to the tune of about $27 billion. Much of that information is available to the pharmaceutical companies free of charge.

The second way we subsidize them is in the tax code. The pharmaceutical companies who talk about how much they spend on research neglect to mention that they deduct every penny of that research from their Federal taxes. More importantly, they also quality, in many cases, for research and development tax credits. Over the last 10 years, they've taken advantage of $28 billion in those tax credits.

But, finally, we subsidize the pharmaceutical industry in a very important third way, and that is the price that we pay for prescription drugs. I have, and I think we've made available to you, and you've got all the charts, you can see this chart—this is a chart of ten of the most commonly prescribed prescription drugs. And when I was in Germany, in May—in fact, we stopped at the Landstuhl Hospital there—but on our way home, we stopped at the Munich Airport pharmacy. And most of you travel quite a bit, and you probably realize that if you want a bargain, you don't go to the airport to buy things. But on our way out of town, we bought ten of the most commonly prescribed drugs. And I would invite you to look at that chart. And the total for those ten drugs bought in Germany was $373.30. We came back to the United States and priced those same ten drugs at a pharmacy here in Washington, D.C. The total was $1,039.65.

[The chart referred to follows:]



Mr. GUTKNECHT. The one that really sticks out is the drug that Senator Stabenow mentioned, Tamoxifen, one of the most amazing drugs ever developed in the United States. But here's the interesting thing. That drug was developed at the expense of the American taxpayers. We literally took the development of that drug through Phase II trials, and the reward for the American consumer? Well, we pay about $360 for that drug. It's available in Germany for about $60.

Now, I'm not saying that we shouldn't pay our fair share for the cost of research and development. Clearly, America is a blessed country. We ought to pay our fair share. We ought to pay more, for

example, than the people in sub-Saharan Africa. But I don't think American consumers and taxpayers ought to have to subsidize the starving Swiss, and that is what is happening today.

And one of the ways you can change the arithmetic and the entire pricing structure of these pharmaceuticals is to open markets. Now, let me say, it is not my vision that American consumers will go to Canada or Germany or wherever to buy their drugs. Because, ultimately, once you open markets, they will be forced to adjust their prices here in the United States downward.

You're going to hear later from someone who's called a "parallel trader." And ultimately that's what we're looking for, is so that pharmacists, whether it be in Arizona or Montana or wherever, will be able to buy their prescription drugs wherever they can get them the cheapest. If they can buy them from a pharmaceutical supply house in Munich, Germany, cheaper, then they ought to have that right. That's called parallel trading. It happens every day in Europe. And let me just say something to you, Members. The Europeans are not intrinsically smarter than we are.

So, again, this is not about shame on them, it's about shame on us, it's about basic fairness. It's not right versus left, it's right versus wrong. We have an opportunity to change it.

I thank you very much for this hearing. I look forward to the hearing, and I will do everything in my power to help you get this bill passed through the Senate.

Thank you very much.

[The prepared statement of Mr. Gutknecht follows:]

PREPARED STATEMENT OF HON. GIL GUTKNECHT,
U.S. REPRESENTATIVE FROM MINNESOTA

Chairman McCain, committee members, thank you for the opportunity to speak this morning about what may become the greatest reform of healthcare in America. I believe in markets, Mr. Chairman, and the value of markets is what this committee will weigh throughout this hearing.

I am the author of the Pharmaceutical Market Access Act, HR. 2427 which passed the House of Representatives by a vote of 243–186. I am delighted at the introduction of S. 1781, the Senate companion bill. It is a pleasure to be with so many supporters today.

In this testimony I want make a couple clear points about the legislation. First, and most fundamentally, Mr. Chairman, this bill is *not* about importation and it's *not* about re importation. This is about permitting free enterprise to function. This is about allowing Americans their basic right to access markets. Secondly, I will describe how this legislation is the greatest enhancement in pharmaceutical marketing safety in nearly a decade.

Perhaps it is a surprise to many that I do not associate with the words importation or re importation. When I use the words, "pharmaceutical market access", it is in order to best articulate the intent and affect of the proposal. If America's pharmaceutical supply were manufactured only within our national borders, I might use the term "re-importation". The nation's pharmaceuticals are not manufactured only within our borders. If the ultimate benefit from this bill would be greater opportunity for consumers to fill their scripts in foreign pharmacies, I might use the word "importation". That is not the ultimate benefit of the proposal.

American pharmacists, wholesalers and individuals should be allowed to access pharmaceuticals markets. They should be allowed to seek the best price available. That is elemental to the practice of free enterprise. Yet such access is illegal for retailers, wholesalers and individual consumers of pharmaceuticals. That's right, the United States Congress explicitly prohibits Americans from seeking a product anywhere outside our borders. In other words, pharmaceutical manufacturers are saddled with absolutely no incentive to price their product competitively to American consumers. What incentive would any manufacturer have to competitively price their product if they existed in a government-sanctioned captive market? None. In-

deed, such an environment exists for no other product in the American market. In a recent memo, the American Law Division of the Congressional Research Service confirms, no other statute exists restricting the importation of a product. Heavy chemicals? Americans may import them. Munitions? Americans may import them.

Ironically, such market restrictions exist for all consumers of pharmaceuticals, but not manufacturers. Pharmaceutical manufacturers import billions and billions of dollars worth of their product every year. A senior can fill their scripts in an American pharmacy and receive drugs manufactured in China, India, Brazil, Turkey or at least 61 other countries. Naturally, this fact nullifies the myth that Americans consume a medicinal product made within our borders—leading to the myth of "re-importation". These manufacturing facilities, approved by Food and Drug Administration (FDA) inspectors, allow manufacturers to reap the benefits of the global market place. In the form of cheap labor, technological specialization and other commercial concentrations, pharmaceutical manufacturers exercise their rights to free enterprise.

Americans deserve access to markets. America deserves a government that is willing to deal with the complexities of permitting the practice of free enterprise. American consumers deserve the right to go to their local pharmacist for the best price. Consumers should not be driven to shopping in Canada or other countries. The Pharmaceutical Market Access Act makes way for a new era where consumers can find the best deal at the local pharmacist they trust.

In creating a system of commerce, both interstate and global, governments must guard the safety of their citizens. Our country participates in global commerce on a scale and in a volume never imagined by any other society in history. The sheer tonnage of products imported into this country would defy the credulity of this committee. Nonetheless, we import everything from tomatoes to nuclear fuel rods and we do it safely.

Many opponents of the Pharmaceutical Market Access Act, claim that it is a dangerous measure that will plunge America into a pharmaceutical safety crisis. The FDA Commissioner himself has often expressed concerns about the safety of the Act. He and other opponents observe that counterfeiting problems are on the rise. They recognize a problem but they offer no other solution than the status quo. Maintaining a status quo does not resolve the problems that plague a status quo. Irresistibly, such a response falls short of the fiduciary responsibility vested in opponents like Commissioner McClellan.

In fact, the growing counterfeit problem has only been met by the FDA with, what I call "malignant neglect". Not since 1994 has the FDA implemented any rules or regulations for the marketing of prescription drugs. Rules issued in 1999 have been postponed every year since and are currently postponed until April of 2004. Moreover, to my knowledge, the FDA has not come to the Congress to request any change in statute. The Internet sales of pharmaceuticals, for instance, are *completely* unregulated. It is the wild west.

FDA officers often site great cases of pharmaceutical fraud over the Internet. I am certain we will hear again from the FDA official here today. But the FDA has not regulated Internet pharmaceutical sales, nor has FDA requested any congressional action. Such actions illustrate why I view their stewardship of our pharmaceutical marketing regulations as "malignant neglect."

Mr. Chairman, the Pharmaceutical Market Access Act sets forth a stout framework for allowing pharmacists, wholesalers and individuals to access 25 pharmaceutical markets abroad. Pharmacists and wholesalers must provide thorough paperwork to the Secretary of Health and Human Services for the imported product. The chain-of-custody is paramount to the security of all imported goods. The documentation of that chain is primary to this program for importing prescription drugs. According to the Act, the FDA may suspend the importation of any drug if it is suspected of violating requirements. Furthermore, anyone knowingly frauding the system may be criminally punished with 10 years in prison or fined $250,000. I recognize the problems in the pharmaceutical markets, and this legislation is packed with solutions.

Perhaps the legislation's greatest addition to pharmaceutical marketing safety provisions is a requirement for anti-counterfeit packaging. Long used throughout the world and voluntarily used domestically by pharmaceutical manufacturers, such secure packaging acts at the core of safety concerns. The technology described in the bill must meet standards used by the U.S. Treasury for currency. And the Secretary of HHS may approve additional packaging technologies. This packaging provision again sets this legislation apart from the FDA's neglect. Though Congress has been working on pharmaceutical market access legislation for over five years, only last month, October of 2003, did the FDA hold a public meeting for packaging technology.

The FDA can attain pharmaceutical marketing safety beginning with this legislation.

Mr. Chairman, this proposal stands ready for the American people now. I pray that the Senate will debate this bill and help put it on the President's desk as soon as possible.

The American people deserve their right to a market. All Americans deserve relief to sky-rocketing pharmaceutical costs. Access to markets works, Mr. Chairman. As Ronald Reagan said, "Markets are more powerful than armies."

News from U.S. Congressman Gil Gutknecht, First District, Minnesota

FOR IMMEDIATE RELEASE: November 5, 2003

CRS CONFIRMS RX MARKET CONCERNS

Gutknecht says industry needs incentives to keep Rx pricing competitive

Washington, DC—First District Congressman Gil Gutknecht today released a memorandum from the Congressional Research Service (CRS) confirming that pharmaceuticals are not subject to the same market standards as all other products.

"I must ask my colleagues why Congress has eliminated market incentives to keep pharmaceuticals affordable," Gutknecht said. "In 1988, Congress granted the pharmaceutical industry the right to price pharmaceuticals without the force of markets. Nobody wins when pharmacists are charged whatever manufacturers demand. And they have no choice but to pass the cost onto the consumer. American consumers and businesses are suffering the sad results of government-sanctioned monopoly pricing."

The CRS memorandum concludes that, "Even other heavily regulated industries, such as chemicals, pollutants, and munitions are not apparently subject to statutory provisions. . ." like those for pharmaceuticals which exclude the industry from international competition.

"Congressional lawyers have confirmed that this statutory favoritism is unprecedented in American law," Gutknecht concluded "It is time for the Senate to pass H.R. 2427, the Pharmaceutical Market Access Act. Americans deserve access to world market pharmaceutical prices."

Gutknecht is Chairman of the House Agriculture Committee's Subcommittee on Department Operations, Oversight, Nutrition and Forestry, Vice Chair of the House Science Committee, and a Member of the House Budget Committee.

Memorandum October 30, 2003

TO: Honorable Gil Gutknecht
Attention: Brandon Lerch

FROM: Todd Tatelman
Legislative Attorney
American Law Division

SUBJECT: Re-importation of Products

This memorandum is in response to your request regarding statutory language that expressly limits there-importation of products to the manufacturer of the product, as is the case with respect to pharmaceutical importation.[1] We have been unable to locate any statutory provisions similar in language and structure to the one in the Food, Drug and Cosmetic Act. However, there does appear to be a trademark statute as well as a military firearms statute that have a similar effect on certain imported goods.

Statutory Language

The Food, Drug and Cosmetic Act. Section 3 of the Prescription Drug Marketing Act, amended the Food, Drug and Cosmetic Act to expressly prohibit the importation of prescription drugs "which [are] manufactured in a State and exported. . ." unless the "drug is imported by the manufacturer of the drug."[2] The only exception to this rule provides that the Secretary of Health and Human Services may "authorize the importation of a drug. . .if the drug is required for emergency medical

[1] 21 U.S.C. § 381(d) (2000).
[2] *Id.*

care"[3] This language was added to the Food, Drug and Cosmetic Act by Congress in 1987 to address two specifically articulated threats to American public health. The first concern was the emergence of "foreign counterfeits, falsely described as re[-]imported U.S.-produced products" entering the drug distribution system.[4] The second expressed concern was that the "proper storage and handling of legitimate pharmaceuticals cannot be guaranteed by U.S. law once the drugs have left the boundaries of the United States."[5] A general exception was given to drug manufacturers to protect existing business practices as they related to obtaining the return of their products for reasons such as recalls, damages, or general unsuitability.[6] In addition, the Congress provided the limited emergency exception to be decided on a case-by-case basis.[7]

Other Statutes. As indicated above, our research has uncovered no other statues that contain language similar to that of section 38l(d). Even other heavily regulated industries, such as chemicals, pollutants, and munitions are not apparently subject to statutory provisions limiting re-importation of the product to the original manufacturer. The only statute that even appears to produce the same result is found in section 42 of the Trademarks Registration and Protection Act, which prohibits the importation of merchandise that "shall copy or simulate the name of [ ] any domestic manufacturer . . . or which shall copy or simulate a trademark registered . . . or shall bear a mark calculated to induce the public to believe that the article is manufactured in the United States. . . ."[8] The law is similar to section 3 of the Prescription Drug Marketing Act in the sense that it restricts the re importation of goods initially manufactured in the United States, however, unlike the re importation restriction on prescription drugs, the trademark statute does not contain an exception for the original manufacturer of the product. In addition, where the prescription drug statute was motivated by specific safety concerns, the trademark statute was designed in part to protect the investment of time, money and labor on the part of the trademark owner.[9] In other words, the concerns of Congress in enacting the trademark statute were economic rather than rooted in public safety. Furthermore, the statutory language receives much of its force from judicial interpretations and the development of trademark case law.[10]

The other relevant statute is contained in the Arms Export Control Act. Section 38 of the Arms Export Control Act requires regulations to be promulgated that "prohibit the return to the United States for sale in the United States of any military firearms or ammunition of United States manufacture furnished to foreign governments. . . ."[11] This provision is limited to military firearms and specifically does not apply to firearms that "have been so substantially transformed as to become, in effect, articles of foreign manufacture."[12] This statute, unlike the prescription drug statute, makes no mention of "re-importation," nor does it distinguish between re-importation by the product's original manufacturer and re importation by other citizens.

Conclusion

Based on our research, it appears that there are no other statutory provisions that are similar in language, structure or intent to Section 3 of the Prescription Drug Marketing Act. The closest are provisions in the Trademarks Registration and Protection Act and the Arms Export Control Act. Both these statutes, however, are substantively different from the strict prohibition against re-importation of prescription drugs and are similar only in the sense that they restrict the overall importation of trademarked goods and military firearms.

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[3] *Id.* at (d)(2).
[4] H.R. Rep. No. 100–76, at 2–3 (1988), *reprinted in* 1988 U.S.C.C.A.N. 58.
[5] *Id.*
[6] *Id.* at 58.
[7] *Id.*
[8] 15 U.S.C. § 1124 (2000).
[9] S. Rep. No. 1333 at 1 (1946), *reprinted in* 1946 U.S.C.C.A.N. 1274.
[10] *See, e.g., Summit Tech. Inc.* v. *High-Line Medical Instruments Co. Inc.,* 922 F.Supp. 299 (C.D. C.A. 1996) (citing in reference to 15 U.S.C. § 1124 *Lever Bros. Co.* v. *United States,* 877 F.2d 101 (D.C. Cir. 1989) and *Societe Des Produits Nestle* v. *Casa Helvetia,* 982 F.2d 633 (1st Cir. 1992)).
[11] 22 U.S.C. § 2278(b)(l)(A) (2000).
[12] *Id.*

POLL ANALYSES

GALLUP NEWS SERVICE, *September 2, 2003*

7 in 10 Americans (71%) say Congress and the president should make it legal for Americans to buy prescription drugs from Canada and other countries outside the United States. Just 28% disagree.

Q: As you may know, many Americans now buy prescription drugs from Canada, even though the practice is illegal, because the drugs are cheaper there than in the United States. Do you think Congress and the president should -- or should not -- make it legal for Americans to buy prescription drugs from Canada and other countries outside the U.S.?

	Yes, should make it legal	No, should not	No opinion
2003 Aug 25-26	71%	28	1

Harris Interactive/ Wall Street Journal Online, *October 9, 2003*

20 million Americans have sought pharmaceutical market access

7% (nearly 20 million!!) of Americans have bought prescription drugs from a pharmacy in Canada or another country. Almost 5 million more Americans than in 2002.

ABC News, *October 13, 2003*

Some people say it should be legal for Americans to buy prescription drugs from Canada, Europe, and other industrialized countries because they're less expensive. The U.S. Food and Drug Administration says it should be illegal because imported drugs may be less safe and effective. What do you think - should it be legal or illegal for Americans to buy prescription drugs from Canada, Europe, and other industrialized countries?

Legal	Illegal	No opinion
69%	29%	2%

Quick Bullets on Safety Provisions of HR 2427and the Senate companion bill, S. 1781

Fact: The Pharmaceutical Market Access Act allows pharmacists, wholesalers and individuals access to ***only*** FDA-approved drugs from FDA-approved facilities. These prescriptions may be purchased in the following FDA-chosen countries: the European Union, Australia, Canada, Iceland, Israel, Japan, Lichtenstein, New Zealand, Norway, Switzerland, and South Africa. Note: Mexico is NOT included.

Fact: The legislation *raises safety standards in two ways.* First, It requires all pharmaceutical manufacturers to use of state-of-the-art technology to strengthen America's commitment to maintaining the safest pharmaceutical drug market in the world. All drugs distributed within the US must utilize the same counterfeit-proof technology utilized to secure our currency. Second, the bill contains language written by the legal team at FDA that requires wholesalers to test each pharmaceutical shipment, unless the packaging uses counterfeit-resistant technology. This represents the greatest enhancement of drug safety standards in over a decade.

Fact: *There have been **zero** reported deaths from Americans taking imported pharmaceuticals.* Today, Americans are more likely to be harmed by counterfeit or tainted drugs from within the United States. Worse yet, thousands of Americans become ill or die from food borne illnesses each year, yet no one suggests banning the importation of food.

Fact: According to the Kaiser Family Foundation, n*early 30 percent of all Americans seniors who are prescribed drugs do not fill their prescriptions because they cannot afford to.* An unaffordable drug is neither safe nor effective.

Fact: *Facts are facts.* Our domestic pharmaceutical supply is manufactured throughout the world. From at least 949 FDA-approved facilities throughout the world, pharmaceutical manufacturers import their product for sale in the United States. If foreign manufacture were such a threat to safety, the FDA wouldn't allow any party to benefit from the global market. Today, only manufacturers reap the benefits of a global market.

"Facts are stubborn things." –John Adams

Foreign Facilities inspected for approval by FDA since 1995

(949 Facilities in 65 countries)

Argentina
Australia
Bahamas
Bulgaria
China
Czech Republic
Finland
Germany
Hungary
Ireland
Italy
Jordan
Macau
Mexico
Niue
Poland
Republic of Korea
Russia
Slovakia
South Africa
Sweden
Taiwan
United Kingdom
Austria
Belgium
Brazil
Canada
Croatia
Denmark
France
Haiti
India
Israel
Japan
Latvia
Malta
Netherlands
Norway
Portugal
Romania
Singapore
Slovenia
Spain
Switzerland
Turkey

THE WALL STREET JOURNAL. ONLINE

November 18, 2003 12:15 p.m. EST

HEALTH

[FDA allows dangerous imported food. Americans allowed to access markets.]

Hepatitis Scare Spurs Scrutiny Of Food Imports

Regulators Focus on Handling Of Produce Before It Enters U.S.; Should You Get Vaccinated?

By BETSY MCKAY
Staff Reporter of THE WALL STREET JOURNAL

MORE COVERAGE

• **The Daily Scan:** Hepatitis A Outbreak Prompts Rumors, Fears[2]

PERSONAL JOURNAL ONLINE

[3] See our revamped Personal Journal section[4] with new features and online-only columns, tools and stories, along with the entire contents of the print edition.

As the toll from the largest outbreak of hepatitis A in U.S. history tops 500, frightened consumers may be wondering if something has gone wrong in the way the restaurant industry handles food.

Three people have died and 510 have been sickened so far after eating at a Chi-Chi's chain restaurant in a mall outside Pittsburgh. The outbreak follows similar restaurant-based hepatitis A outbreaks in other American cities earlier this year. For a nation that spends 46% of its food dollars in restaurants, the source of prepared food and how it is handled is no small issue.

Health officials say the public shouldn't be overly worried: Dining out is generally safe, and cases of hepatitis A as well as several other food-borne illnesses actually are on the decline. But the outbreaks have drawn attention to the nation's increasing reliance on imported produce. The severity of the Pennsylvania outbreak also is rekindling debate over whether children or food-service workers should routinely be vaccinated against hepatitis A.

One lesson is already clear: Watch out for green onions.

As with three other hepatitis A outbreaks over the past two months, green onions, found in everything from salads to salsa, are a suspected culprit in the Pittsburgh case, though the source there has not been definitively established. The hepatitis A virus is so similar in all other recent outbreaks that both raw and lightly cooked green onions are strongly suspected to be behind all four, says Robert Brackett, the director of food safety and security at the U.S. Food and Drug Administration. Chi-Chi's parent company, Prandium Inc., of Irvine, Calif., has closed the restaurant where the sick people ate but says it doesn't know yet what went wrong. "We don't know who is responsible," a Chi-Chi's spokesman said.

over →

WARNING SIGNS

Some common symptoms of Hepatitis A

- Fatigue
- Loss of appetite
- Nausea
- Jaundice (yellowing of the skin and eyes).
- Abdominal discomfort

See three drugs[1] in the development pipeline for treating hepatitis C. (10/09/03)

Health officials are particularly concerned about fresh produce generally, which is often eaten raw or not cooked heavily enough to neutralize germs it may carry. While fresh produce was responsible for only two or three outbreaks a year in the 1970s, that number has climbed to 15 or 16, says Robert Tauxe, chief of the food-borne and diarrhea diseases at the Centers for Disease Control and Prevention. "Fresh produce eaten fresh -- that's the real challenge," he says.

A salmonella outbreak that sickened 450 people the summer of 2002 was caused by domestically grown tomatoes. But imported produce is also an increasing worry. It makes up a growing percentage of the U.S. food supply, yet has been found in some recent cases not to be grown and handled according to U.S. government standards. The green onions connected with a recent Tennessee outbreak of hepatitis A, came from Mexico, according to the FDA, which monitors food imports. Cantaloupe imported from Mexico and other overseas products have been behind outbreaks in recent years of salmonella and other food-borne illnesses.

Grocery shoppers will often find a tag on fruits and vegetables stating the country of origin. But determining where produce served in a restaurant came from may be more awkward. The FDA has banned cantaloupe imports from offending farms and importers over the past two years and issued "import alerts" on other suspect produce. Now it is working on tracking the green onions to the source, along with the CDC.

In the meantime, the FDA has advised consumers to avoid green onions while eating out if they're worried, and at home to boil or saute them thoroughly. The National Restaurant Association has recommended that the 300,000 individual restaurants run by its 60,000 members follow FDA advice and remove green onions or cook them. Chi-Chi's has removed green onions from its menu.

Hepatitis A, a viral infection of the liver and the most common form of hepatitis, is normally transmitted when a person puts in the mouth something that has been contaminated with the stool of an infected person. That might be contaminated food or water, but it isn't clear how many of last year's 8,795 reported hepatitis A cases were attributable to food contamination. The hepatitis A virus can remain viable on a piece of food or other inanimate surface for months, but only 3% to 4% of cases a year are definitively linked to food. Most are thought to be contracted sexually or through other close contact.

While U.S. restaurants are required to adhere to strict sanitary measures, violations still occur. As recent hepatitis A outbreaks in Tennessee, Georgia, and North Carolina have shown, sometimes food can be tainted before restaurant employees even take it out of its box.

In the U.S., an estimated 76 million persons contract food-borne illnesses each year. Food contamination can occur along any point of the agricultural process, from contaminated soil to improper handling by distributors, says Anthony Fiore, a medical epidemiologist with the

Customers at the Beaver Valley Mall's foodcourt eat lunch

CDC. An outbreak of an unusual diarrhea-causing disease in the U.S. in 1996 was traced to imported raspberries from Guatemala, which officials think may have been contaminated by unclean water, workers or birds.

The FDA, which recently increased the number of inspectors it has at U.S. borders, doesn't plan major changes to how it monitors imported foods as a result of the outbreaks. Currently, imported foods are electronically screened to help the FDA track what types are coming into the country. Suspect produce is pulled aside for closer inspection. "We monitor them well," says Dr. Brackett of the FDA. Since problems are relatively rare, the FDA zeroes in aggressively on the cases it discovers, he says, sometimes banning farms and suppliers until they correct the problem. New bioterrorism legislation that takes effect in December and requires advance notice of arriving products will help the FDA keep track of imports, Dr. Brackett says.

Chi-Chi's, which operates 100 Mexican food restaurants in the Midwest and Eastern U.S., has been in bankruptcy proceedings since October. Company spokesman David Watson wouldn't comment on the outbreak's impact on the chain's sales, which totaled $42.5 million during the second quarter. The Chi-Chi's restaurant linked to the outbreak has been temporarily closed, but other outlets remain open.

The Pennsylvania outbreak is renewing debate about whether vaccination against the disease should be made routine for children, who are the biggest carriers of the disease but frequently have few symptoms. Hepatitis A is one of the most frequently reported vaccine-preventable diseases in the U.S., but the vaccine, available since 1995, isn't given routinely nationwide. Supporters say however few cases there are on the whole, the vaccine is an inexpensive way to prevent the deadly and costly outbreaks that do occur.

After a person has been exposed, shots of immune globulin, antibodies can neutralize the virus up to 14 days. But routine preventive vaccination is currently conducted only in parts of 11 states where hepatitis A rates are highest. CDC officials are studying what role it has played in reducing rates of hepatitis A overall in recent years. Currently, three to four cases are reported per 100,000 people nationwide, compared with a national average of 10 cases per 100,000 people between 1987 and 1997, the CDC says.

Opponents of routine vaccination say it's not necessary because hepatitis A isn't common in the U.S., and long-term studies haven't been done on the vaccine to determine its efficacy.

John LaBella, a Pittsburgh pediatrician, says that while he has given some shots of immune globulin to offer temporary protection in the current outbreak, he says he doesn't normally promote the hepatitis A vaccine. Other vaccinations are more crucial, he says.

--Scott Kilman contributed to this article

Write to Betsy McKay at betsy.mckay@wsj.com[5]

URL for this article:
http://online.wsj.com/article/0,,SB106910721875432900,00.html

Hyperlinks in this Article:

The CHAIRMAN. Thank you, sir.
Congressman Sanders?

STATEMENT OF HON. BERNARD SANDERS,
U.S. REPRESENTATIVE FROM VERMONT

Mr. SANDERS. Mr. Chairman, thank you very much for holding this important hearing, and for your work and Senator Dorgan and Senator Snowe and Senator Stabenow. Thank you very, very much for all that you have done fighting for consumers in this country.

Mr. Chairman, as the first Member of Congress to take American citizens over the Canadian border, this is an issue that has obviously concerned me for a very long time. Because the state of Vermont borders on Canada, many of our people, for years, have purchased safe, affordable medicine in Canada. And like many of my friends here, I will never forget the first trip that I took, where women who were fighting for their lives against the killer disease of breast cancer, women who do not have a lot of money, were able to purchase safe Tamoxifen at one-tenth the price that they were paying here in the United States of America.

And I'm glad Senator Santorum is back. He used the word "killing people." Well, Senator, we have a study that we have asked the CRS to ask how many thousands of Americans have died because they cannot afford the outrageously high prices that the pharmaceutical industry is shoving down our throats. How many millions of Americans have seen a deterioration in their health? There are studies done by the Kaiser Foundation which suggest that 25 percent of senior citizens in the United States of America are either skipping doses or not taking the medicine that their doctors prescribed because of the outrageously high prices. You talk, Senator, about people dying. Well, I want to know, how many thousands of people are dying because they're being ripped off by the greediest industry in the United States of America?

Now, one of the exciting aspects of this whole issue is, we have brought together a very strong tripartisan coalition in the House of Representatives, Gil Gutknecht, Dan Burton, Jo Ann Emerson, some of the Republicans who have played a great role, we have Democrats, I am in Independent. And we have stood up to the pharmaceutical industry. We have stood up to the hundreds of millions of dollars that this industry has thrown into Congress. We have stood up to the 650 paid lobbyists. We have stood up to their campaign contributions. And what we and the American people are asking the U.S. Senate, will you also have the courage to stand up to the most profitable, the most powerful lobby in the United States of America?

Senator, I know that you have been concerned, in your years in the Senate, about the power that money has over the public process, and I applaud you for your efforts. I would like to introduce to the record some information by the Center for American Progress, which was prepared by the Center for Responsive Politics, talking about millions and millions and millions of dollars in campaign contributions that have gone into the people who are sitting in the conference committee right now on this Medicare conference, the people who have done the most outrageous act by put-

ting language into a bill which says that the U.S. Government cannot negotiate lower prices on prescription drugs. Beyond belief.

The question that we are dealing with, therefore, today, Senator, is not just a healthcare issue, and I agree with what these people have said. The issue even goes deeper than that. The issue is whether the U.S. Congress is any longer capable of standing up for ordinary people or whether it will continue to succumb to the power of big money.

Now, let's deal with the two issues that the pharmaceutical industry so aptly represented by Senator Santorum today. You don't need the pharmaceutical industry here. Senator Santorum has given their line. Let's talk about the two issues.

The issue of safety. We had, in our Subcommittee, William Hubbard, who is a senior official at the FDA and one of the leading critics of reimportation, working with the drug industry. And we asked Mr. Hubbard—we said, "Well over one million Americans, over one million Americans, are purchasing their prescription drugs from Canada." That number is—you know, it is growing every day. "How many of those people have they made sick or have died?" And the answer was, to the best of his knowledge, he did not know of any.

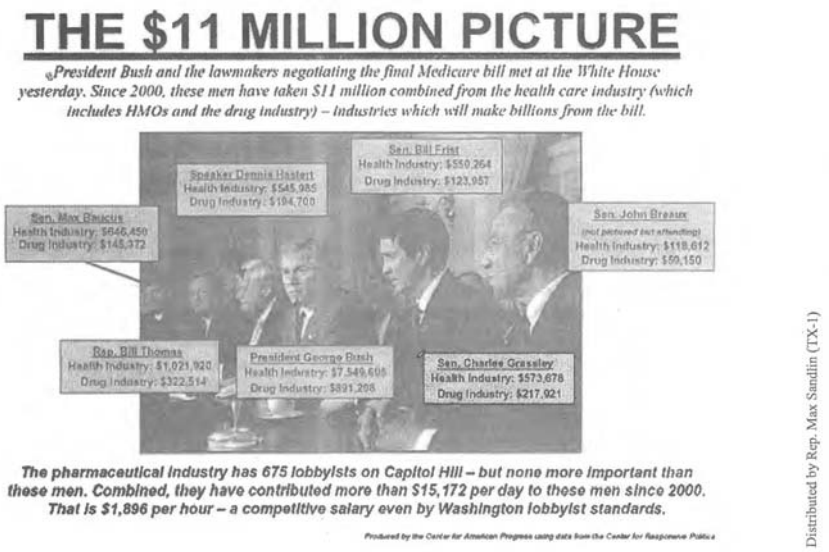
Senator Santorum and others, the industry, has said, "Price controls. We don't want to import price controls." Well, this is an amazing remark. As everybody in this room knows, we have lost millions of decent-paying manufacturing jobs in this country because China is selling us every product in the world. Now, we can't get safe, affordable, FDA-approved medicine from our neighbors in Canada because we're importing price controls, but we can import slave labor from China, we can import 20 cents-an-hour labor from China, we can import the fact that anybody who tries to form a union in China goes to jail, we can import billions and billions of dollars of those products, but somehow, as Senator Snowe indicated, we just cannot, through the United States of America, our government, the FDA, regulate a handful of factories and plants through the kinds of efforts that we have put into this legislation to make sure that that product is safe. I think anyone who looks at that for one moment understands that that is absurd.

Senator Santorum said, "Gee, those terrible Canadians. In 8 years, they have not had to experience an increase in the cost of prescription drugs. What an awful country. How terrible can they be to their consumers?" Well, I would suggest that if the American people would know that we had the courage to stand up to the industry—and, by the way, let's talk about this industry—this is the most profitable industry in the United States of America. This is an industry struggling, no doubt, that was able to pay $150 million in compensation to the CEO, I believe it was, of Bristol-Myers. This is an industry so struggling that it could spend hundreds of millions of dollars trying not only to bribe this institution, but legislatures all over the country.

Senator we have an opportunity to do something important. Let's do it.

Thank you.

[The information referred to follows:]



The CHAIRMAN. I mentioned to my colleagues, I've been on this Committee for 17 years, and very rarely do we have opening statements that generate so much interest.

[Laughter.]

The CHAIRMAN. It's usually sort of a pro forma affair.

[Laughter.]

The CHAIRMAN. Could I—but not in this case. We do have two other panels waiting. We've already been in for an hour. All members of this first panel do have other things to do, but I know that there is a desire here for a back and forth. So could we compromise and say we could use 10 minutes for Q&A back and forth?

We have—the Governor of Minnesota is waiting to testify, and I think it would be a bit discourteous for us to extend this too much longer. So if you'd set it for 10 minutes, and I'll ask Senator—first ask Senator Santorum if he's like to respond to any of the comments that were made, and then perhaps Senator Dorgan, Senator Wyden, and Senator Snowe would like to have an exchange with members of the panel.

Senator Santorum?

Senator SANTORUM. Well, Mr. Chairman, I know you're short on time. I would just say, in response to the Senator from Vermont, the point I was making is that—and to all the Senators and Congressmen—that I agree that we're paying too much for drugs here and that we are underwriting the world's cost of research and development. I admit that freely. The question is, what do we do about it? And I would suggest that what we need to do is to not import what the other countries have done, which is price fixing and price controls, which I can't imagine that—most Members here would recognize that we shouldn't go out and set price controls artificially low, below the reimbursement, to make these drugs, you know, profitable for any company to want to produce. In fact, the information I received, when it came to the question of all this un-

derwriting that the Federal Government does for these pharmaceutical products, that, "Scholars at Tufts examine 284 new medicine approved in the U.S. in the 1990s. They found that 93 percent originated from the pharmaceutical industry with no government support, 7 percent split between government, academic, and nonprofit sources."

So the idea that the government is funding all this research and that all we should be doing is recouping our money, I mean, it's just—the facts don't bear that out.

There is an enormous amount of risk in producing new drugs. Most of them fail. Most of them don't come to market. And the question is, do we want to have a vibrant drug industry? I don't think a drug industry that's profitable is a bad thing. I think it's a good thing. It produces more drugs.

I think we're all here for the same reason. We all want to have lower-cost drugs here, and we want the other people around the world to be able to, sort of, pay their fair share. The question is, how do we get there? I would argue this doesn't get us there.

The CHAIRMAN. I would just make one comment, very quickly. We all know that the Veterans Administration and DOD currently use their market share to negotiate lower prices for drugs. Why in the world, if we're interested in lower prices for prescription drugs, would we put a prohibition in that Medicare can't use its market share to negotiate better prices for drug companies? I mean, it makes no sense. It authenticates Congressman Sanders' argument of the power of the pharmaceutical companies. There's no reason—if we're going to prohibit Medicare from doing it, then let's prohibit Department of Defense and the Veterans Administration from doing it. Why in the world would we do such a thing if we're interested in lower prices? Now, this has nothing to do with reimportation, it has to do with giving government the power to negotiate lower prices.

Senator SANTORUM. Well, since I don't represent the pharmaceutical industry, contrary to what everybody says—I just what I think——

Mr. SANDERS. You could have fooled me, Senator.

Senator SANTORUM.—is in the best interest of American consumers and an industry that I think is a very important industry in this country. I agree with you, I don't know why we did—I wasn't on the conference, so I can't speak for the conferees and why they did that.

The CHAIRMAN. Thank you.

Senator Dorgan, real quick?

Senator DORGAN. Mr. Chairman, I'll just—I want to ask Senator Santorum a question, because as is usually the case, he has sparked my interest with his language. Two points, and both in the form of questions. I'll be very quick.

One of the inconveniences of globalization is that when you trade with other countries, you inherit whatever those other countries are doing. In this case, with Canada price controls. And I won't ask the Senator from Pennsylvania to demonstrate today, but I will be that on his person, his shoes, his shirt, his necktie, his cuff links, or his handkerchief, somewhere he has something that he's purchased from China, and is, therefore, giving comfort in importing

the retirement pay for Jung Ju Min, a noted communist leader. Does that make him uncomfortable? No. Part of globalization is, you inherit and import all that which other countries are involved in.

So let me, finally, make this point. The Senator from Pennsylvania said that this will kill many patients. Quote/unquote, "kill many patients." We have millions of Americans who are now importing drugs. Name one patient that it has killed. Just one.

Senator SANTORUM. When I say will "kill many patients," I mean in the future, because new drugs will simply not be developed, and those cures that will save lives in the future simply won't be available for people to take. You list all these wonderful miracle drugs. Companies don't produce miracle drugs to lose money. I mean, let's just be honest about this. I mean, you make it sound like all we're going to is, we're going to beat back these horrible drug companies that produce life-saving therapies, and we're going to make sure that they don't make any money, and they're going to go and continue to make drugs. I mean, this is just—I mean, it doesn't make any sense. Let's be honest about this.

Senator DORGAN. Well, Mr. Chairman, if I—your support for the pricing strategy of the drug industry is eloquent, but wrong. The fact is, those manufacturers are not selling drugs at a loss in Canada. Would you agree with that? They're not selling drugs at a loss in Canada, because if it were a loss, they wouldn't sell in Canada. Because they're selling drugs in Canada at a fraction of the price here, but still making money in Canada, suggests to me they are overpricing prescription drugs in this country, and that's the issue.

Senator SANTORUM. And I would be happy to respond to that. I would say that, first off, as you know, to sell a drug in Canada, you have to get approval to sell a drug in Canada. And you do know that. You have to get approval by the government. And, of course, if the government doesn't—if you don't accept the price the government is willing to pay, you can't sell your drug there. If you don't accept the price the government's going to pay, and you don't sell your drug there, the government has the ability to steal your patent and have that drug manufactured in that country. So it does provide a little incentive for you to cooperate when it comes to selling your drug.

So I would agree with you that, no, they do not sell it at the price they do here, because they have certain extraordinary circumstances to deal with. But they probably do make a profit, in that they sell it for more than what it costs for them to manufacture it, and, therefore, it adds somewhat to the profitability. But it doesn't underwrite the billion dollar cost that it takes to research and develop this drug.

And I agree with the Senator from—I mean, I—we're in agreement that we need to do something about that. Canadians should pay more, Germans should pay more, for underwriting the cost of research and development of new drugs. That's the issue. It's not that—they're not paying their fair share, and we are paying too much. I agree with you.

The CHAIRMAN. Senator Snowe?

Senator STABENOW. Mr. Chairman, I'd like to just add one comment.

The CHAIRMAN. Could we just go to Senator Snowe and then Senator Wyden, and then we'll have responses—and Senator Boxer——

Senator SNOWE. I'll let Senator Stabenow——

The CHAIRMAN.—who's short of stature, evaded my gaze.

[Laughter.]

The CHAIRMAN. And then we'll respond, real quick, if we could, because we really are—we're doing what we usually do on the floor, although perhaps not very well.

Senator Snowe, real quick.

Senator SNOWE. I'll let Senator Stabenow respond.

The CHAIRMAN. Senator Stabenow?

Senator STABELOW. I just wanted to throw in one comment. We keep talking about research costs. According to the latest numbers, the industry is spending two and a half times more on advertising, marketing, and administration than research, and so it's very important to look at where they put their dollars. We can do this and not affect research in this country, I'm absolutely convinced.

The CHAIRMAN. Congressman Sanders?

Mr. SANDERS. Senator——

The CHAIRMAN. Briefly.

Mr. SANDERS. Senator Santorum, you said you just don't know, you can't understand how that language ended up in the bill which prohibits the government from negotiating. So I hope that you will——

The CHAIRMAN. Congressman Sanders——

Mr. SANDERS. My question is, I hope that you will tell us now that you want to get that language out so the government can negotiate with the pharmaceutical industry.

Senator?

Senator SANTORUM. I haven't seen the language. I'll take a look at it, and if it's not—comports with what I think are best practices, then I would be for removing the language. But I haven't looked at it yet. I haven't seen the bill.

The CHAIRMAN. Congressman Gutknecht, did you want to say anything? Real quick.

Mr. GUTKNECHT. Well, just real quickly, Mr. Chairman. We have actually asked PHRMA, and we've asked all the experts at FDA, how many countries have ever expropriated a patent from a company for refusing to deal with their regimen of working on controlling prices. And the answer is zero. Its never happened.

The CHAIRMAN. Senator Snowe?

Senator SNOWE. Thank you, Mr. Chairman.

I want to thank all of the testimony from the witnesses here today. I think they made some excellent points. Senator Santorum was the one exception.

[Laughter.]

Senator SANTORUM. I thought you were complimenting me.

Senator SNOWE. I know.

The CHAIRMAN. Aren't you glad you came this morning, Senator Santorum?

Senator SNOWE. Exactly. When you were referring to the counterfeiting, I mean, primarily that was focused here in this country in domestic distribution, I might add, with respect to the issues in a series that focused on that particular issue. There's no question,

if we can do it with 20 dollar bills in preventing counterfeiting, I think we certainly can do it when it comes to life-saving medications.

I think one of the issues here today—and Senator Stabenow raised the point about the rising prices of prescription drugs, 16 to 18 percent a year. That's seven, eight times the rate of inflation. I mean, the cost of prescription drugs are not declining over time, which you expect would. But not. And that's the issue. Because they don't have any competition. And we would have competition by bringing those drugs across the border. There is competition, as we'll hear later from—about parallel trading and opening markets. But that's what we're facing in this country, 16 to 18 percent a year. And it's not just been 1 year. That's not an exception. It is the norm. That is the pattern. And what accounts for such skyrocketing increases when it comes to the cost of prescription drugs? I mean, how long can you recover your investments? So these prices normally should be declining over time, and are not.

And I'd like to have you or other members of the panel to speak to that issue.

Senator SANTORUM. Well, I would just say, with respect to competition, as you know the competition is—once the patent expires, you have generics who go in and compete, and that is one way. But the patent protection is——

Senator SNOWE. Making that more difficult, too.

Senator SANTORUM. Actually, we've made it easier under this bill that—for generics to be able to compete. At least that's what I've been told is in the underlying Medicare bill. And I agree with that. I think that we should have competition. At the same time, patents are there for a reason. They're there for companies to be able to protect their intellectual property so they can get reimbursement and recoup the expense. I mean, generic manufacturers aren't inventing Tamoxifen. I mean, they're basically waiting til the patent expires, and then they're going to produce it and sell it a lot less. Why? Well, they can sell it a lot less, because they don't have any research and development costs into it, other than the fact of what it takes to make it, but not invent it.

And so the question is, are we going to reward companies for doing what we want them to do, which is to invest in research and technology and develop new life-saving, quality-enhancing drugs? And I would argue that we need to. At the same time, that cost should be borne, not just by Americans, but by the rest of the world, and that's the issue that I think we need to focus on, not trying to take the pricing structure, which is artificially low around the world, and impose it here in America. By doing so, I mean, just let me assure you, the number of drugs in this country that are going to be produced are going to dramatically decline. And that may be OK. I mean, that's a tradeoff, and it's a tradeoff that I know some people are willing to accept. And if you advocate for that, I have no problem advocating for that, if that's what you want to do, but understand the cost and the benefit that's going to be incurred when you do that.

The CHAIRMAN. Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman.

As you all heard me say, I think this ball game's about bargaining power for seniors, and that's what Senator Snowe and I had in our bill 4 years ago, to basically give seniors bargaining power, like Members of Congress have. And I want all of you, because you've been very eloquent, to kind of give me your response to an example of how the Canadian situation is going to affect bargaining power. And I want to be very specific.

Somebody that I've used for a lot of years for counsel on prescription drugs told me yesterday that he ordered Lipitor, in the United States, from Canada on August 31. It arrived on October 17. He got a 90-day supply for $255, or about 2.83 a pill. But because the order took so long, he had to go out and buy a 60-day supply in the United States, at $259. So, in effect, he got a third more from Canada for roughly the same price.

And my question for all of you is, Canada's got a pretty small population. If we have millions of people in the United States ordering their drugs from Canada, the Canadians are going to serve their citizens first. What is this going to do for our joint goal of trying to get more bargaining power for the consumer? That's what we've always felt this was about. That's what Senator Snowe and I have been trying to do for 4 years. And because you all are the experts in it, just walk me through what the Canadian situation will do with respect to the key issue——

The CHAIRMAN. And walk him through——

Senator WYDEN.—of bargaining power.

The CHAIRMAN.—walk him through briefly, please, beginning with you, Congressman Sanders.

Mr. SANDERS. We understand—and Senator Santorum referred to it, in a different context—that the industry will do everything it can to sabotage our ability to lower prices in this country. And one way that they are doing it is trying to limit supplies to Canada. In our legislation, we are very clear that it is against the law for them to do that, that, in fact, they will have to not discriminate against American citizens. And if people in Canada, the pharmacists in Canada, want the medicine, they will get the medicine they need. So it would be against the law for them to sabotage the effort.

The CHAIRMAN. Congressman Gutknecht?

Mr. GUTKNECHT. Part of the reason that the bill we passed in the House and the bill before the Committee here includes 26 countries—which, incidentally, we didn't make up; those were 26 countries that was given to us by the FDA saying they had similar regimens to ours relative to the safety of drugs. And you will later hear, in this hearing, from a parallel trader. Ultimately, we're not—I don't believe we're talking just about Canada. And, more important long term, we're not talking about mail order. We want to open up markets so that your local pharmacist can get the same price.

Can I come just briefly back to a point that Senator Snowe made, because I think it's very intuitive. Because you were really talking about intellectual property rights. And the argument that's made is, that if we open up markets and force competition here in the United States, they'll lose intellectual property rights, people won't do research. If you step back just for a moment and compare that

to the technology industries, I mean, Intel lives and breathes on intellectual property rights, just like the pharmaceutical companies. We don't give them the same protections. They understand that if they don't invest in new technologies and new innovations, they're going to be out of business. But they don't get the same kind of protections that the pharmaceutical industry.

Incidentally, and we've got the CRS report, no other industry gets the protections that the pharmaceutical industry does.

The CHAIRMAN. Senator Stabenow?

Senator STABENOW. Thank you, Mr. Chairman.

I think that's a very important point. No one else gets the same protections that we're talking about here.

Senator Wyden, I think that as we look at this, and particularly if it's beyond just Canada, as Representative Gutknecht was indicating, what we're going to see is a shift in the markets. I mean, if the pharmaceutical industry isn't just able to stop it by manipulating supply, what you will see is a shifting and a changing in all of this, in terms of prices. And the competition can't help but bring prices down in the United States.

Again, we're not talking about mail order Internet, we're talking about going to the local pharmacy, having the pharmacist there be able to do business with pharmacists in other places for safe, FDA-approved drugs.

One other quick point, and that is, we keep talking about, well, there's competition when the patent runs out and—from generic drugs. In the last 5 years, the FDA has approved patents, and over 65 percent of them have not been for new life-saving drugs. They have been for what's called a standard drug or often called a "me-too drug," meaning the packaging is changed, the daily dose becomes a weekly dose, or some other change is made to keep the patent going to stop competition. So we have the industry—the most highly subsidized, most highly profitable in the world—doing everything they can to stop competition—by continuing patents, by stopping competition, and putting more than two and a half times more into aggressive marketing and advertising now for on purchasing rather than on life-saving research. I'm all for investing in research, doing everything we can to partner with the industry to do that, but we've seen an industry dramatically shift to a marketing and sales industry——

The CHAIRMAN. Senator Santorum?

Senator STABENOW.—as opposed to research.

Senator SANTORUM. And I'd be happy to enter into the record for the Committee the numbers with respect to how much the industry spends on, quote, "marketing and advertising" versus research. Senator Stabenow and I have had a battle of charts on the floor many times on this, and——

The CHAIRMAN. Without objection.

Senator SANTORUM.—I would be happy to submit it to the record.

[The information referred to follows:]

November 25, 2003

Hon. JOHN MCCAIN,
Chairman,
Committee on Commerce, Science, and Transportation,
United States Senate,
Washington, DC.

Dear Senator McCain:

Thank you again for the opportunity to offer testimony at your Committee's hearing on prescription drug importation on November 20, 2003.

During the question and answer segment of the hearing, one issue that was raised by Senator Debbie Stabenow with respect to the advertising of the pharmaceutical industry requires clarification.

Senator Stabenow asserted that the annual promotional spending of pharmaceutical manufacturers in the United States exceeded that which it spends on research and development.

In fact, pharmaceutical manufacturers spend significantly more on research and development than on all promotional activities combined.

According to a 2002 General Accounting Office report, pharmaceutical manufacturers spent an estimated $19 billion on all promotional activities in 2001, including $2.7 billion on direct-to-consumer (DTC) advertising. This remains considerably less than the estimated $30 billion it spent on research and development. (U.S. General Accounting Office, *Prescription Drugs, FDA Oversight of Direct-to-Consumer Advertising Has Limitations,* GA0–03–177 [Washington, DC: GAO, October 2002])

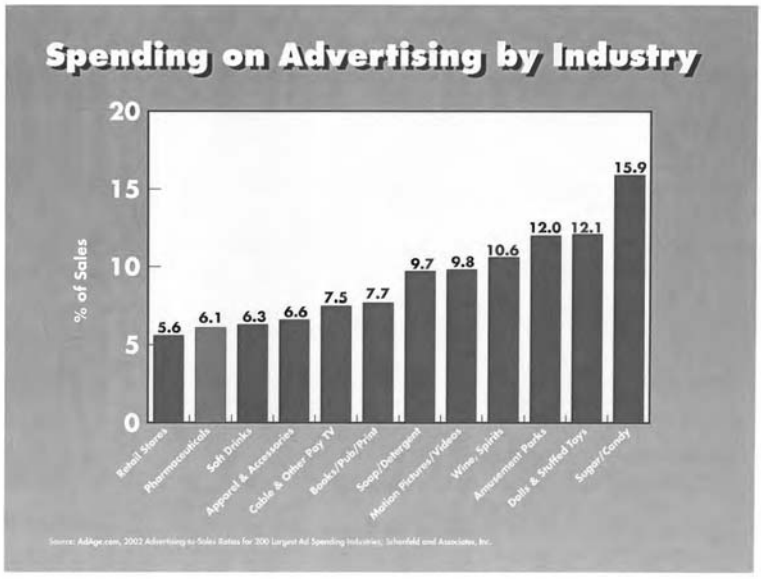
I hope this clarification is helpful to you and the Committee as you continue to examine improvements to our health care delivery system.

Sincerely,

RICK SANTORUM,
United States Senate.

RJS/ps

ATTACHMENT



Senator SANTORUM. And just suffice it to say the vast majority of the advertising and marketing are free drug samples given to doctors that end up in the pockets of poor people who can't afford drugs. So that's number one.

Number two, with respect to what's going to happen, in response to the Senator from Oregon's question, I do agree that I—as I said before, I think they will attempt, as I would think any industry would, to say, "Look, we're only going to send as many drugs up to Canada as the Canadian market needs." If that is against the law, which I don't know how they do that, but if it's against the law, then my guess is, you'll see a lot of pharmaceutical companies pull out of Canada and simply not make those available, particularly if they're not getting very high reimbursements for their drugs and they're not making any money. If, in fact, it's going to be—they're going to sell basically all their drugs through Canada at this point at that low price, they simply won't sell the drug in Canada, and sell it here.

If, as others have suggested, that if we broaden it beyond Canada, so they—to the rest of the world, then the ultimate consequence will be, you'll see a lot less drug research and a lot less new drugs.

The CHAIRMAN. Senator Boxer?

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

Senator BOXER. Thanks. I'm not going to ask a question. I'm going to sum up what I think is happening here, in a minute and a half.

Drug companies get the benefits of research paid for by American taxpayers. Don't forget it. Taxpayers pay a lot of money. And, by the way, I support that research, and I want to spend more on that research.

Second, they get the R&D tax credits for what they do—or R&E, however you define it—and I support that. As a matter of fact, I want to make it permanent.

They get patent protection. And if that isn't abused, I'm all for patent protection.

They get to write off their advertising budget. There are some people that don't want that to be a writeoff. I think that would be a violation of free speech. I support them being able to write off their advertising budget.

What I don't support is their turning their backs on the American people and using their clout to stop any kind of reform here. And this latest one—and the timing of this hearing is exquisite—you've got the conferees sitting over there—I trust they're all there—right now, and they're imposing, basically, a gag rule on Medicare, saying, "You are prevented from bargaining for good prices, but the private sector, you can go out and bargain." What is that? That is outrageous. It's, on its face, beyond outrageous.

We've also got a generic provision, that, although I haven't read the fine print, it looks to be weakened, from what I hear. And you have a importation situation where that will never happen.

So what you've got is the pharmaceuticals, with a lot of help from around here, which I'm embarrassed to say is happening, just

walking away with everything, and it's to the point where I think our people are going to be hurt eventually on this. And I'm just glad you have this hearing.

Thank you.

The CHAIRMAN. I thank the panel, and I thank you for being here, and this has been a very interesting and enlightening discussion, and I appreciate it very much.

Thank you.

The CHAIRMAN. Governor Pawlenty, we are not usually this rude to our visiting Governors. We appreciate your patience, and we thank you for your very significant involvement in this issue. I know it was a major issue when you campaigned for your present office, and I would like to say you are highly respected and regarded on this issue, and we thank you for being here.

We'll begin with you, Governor.

STATEMENT HON. TIM PAWLENTY, GOVERNOR, STATE OF MINNESOTA

Governor PAWLENTY. Mr. Chairman and Senators, thank you for the honor to be here today and present some thoughts about this important issue facing our country. And actually the panel before us was a great pleasure to listen to that testimony. We appreciate that. My formal testimony has been submitted. I know time is short, Mr. Chair, and you want to move things along, so I will cut to the chase.

We have a healthcare crisis in America, as this Committee well knows. The crisis, in part, is a cost crisis. We have healthcare costs in the United States going up between 10 and 25 percent a year. We can't keep up. Families can't keep up. Employers can't keep up. Employees can't keep up. Governments can't keep up. It is going to consume us, Mr. Chair, if we don't get our arms around this crisis. And it's about to get worse, as we experience the demographic shifts that we all know are coming with the graying of America.

One component of that crisis is the prescription drug crisis and the costs associated with that. It's been eloquently discussed in your previous panel. One element of that crisis is that prescription medicines for too many Americans are out of reach because of cost. The Medicare bill that you may well pass in the coming days will help with respect to coverage, but as Senator Snowe so eloquently said earlier, extending coverage to more Americans, while helpful and is good progress, does not address the cost issue. And so we are going to continue to have—as governments, as families, and as individuals—cost pressures that are unacceptable that we're not going to be able to keep up with.

Americans pay 20 to 80 percent more for their prescription medicines. The main justification for that, as you heard this morning, was that we need innovation. We need research and development. I will concede, Mr. Chair, that we should pay a premium for that world-leading innovation, but there's a difference between paying a premium and being a chump, and we're being played.

[Laughter.]

Governor PAWLENTY. The American consumers are being played by this industry, and we're being chumps. And so I don't think

that's a good thing for our country. I don't think it's a good thing for American consumers. And we need to take action.

Franklin Delano Roosevelt said, "We need to try things in the face of crisis. We need to try things." And so as we sit here—and it is ironic that not far from here they're perhaps closing up the Medicare conference report. But, as an aside, if they prohibit Medicare from using group purchasing power, I would be stunned and alarmed. That is an alarming development. I hope that's not the case.

The CHAIRMAN. It would be a commentary on the way the system works here, as well as the specifics of the legislation, wouldn't you think, Governor?

Governor PAWLENTY. It would seem that way, Mr. Chair. It would seem that way.

Importation from Canada and perhaps other developed countries is not the ideal solution. It is probably not the long-term solution, but it is in the spirit of trying something, it's in the spirit of trying to break the logjam and bringing awareness and pressure for change.

I'll tell you briefly what our plan in Minnesota is. We hope that you make a Federal law change that allows importation to go forward. If you don't, we understand the current FDA's position to be that individuals can make purchases for personal use for up to 90-day prescriptions. We would like to facilitate those kinds of purchases by Minnesota, and we're actively developing this as we speak. We hope to have it up and running in a matter of a couple of months, a website that will list and feature those pharmacies in Canada that we've identified as established and credible and reputable and safe and accredited that are willing to provide prescription medicines to Minnesota consumers at a hopefully discounted price savings. That website will also feature generic alternatives and information regarding that. The individual who accesses the website will be able to download instructions, an order form, and a health questionnaire. They, the consumers, then will make the purchase. They will send the information to a Canadian pharmacy, the prescription as well as the health questionnaire. The Canadian pharmacy will then have that prescription reviewed by a doctor, a Canadian doctor, which is a step we don't even require, by the way, in the United States. These pharmacies—we're not talking, Mr. Chair—and the press coverage gets lumped together and confused—we're not talking about rogue Internet sites or pharmacies, virtual pharmacies in the United States or elsewhere. We're talking about established, credible, reputable pharmacies in Canada that the State of Minnesota—ideally, the Federal Government, but at least the State of Minnesota—has reviewed, has deemed appropriate for this purpose, and they have very substantial protocols that they follow.

We were in Canada recently and received that information. We're in the process of verifying it. But there is no reason to believe that those types of pharmacies—established, credible, reputable, accredited pharmacies in Canada—present a safety threat at all to the American consumer. There is no evidence of that. In fact, the FDA was recently in Canada, meeting with Health Canada, and they made certain suggestions or claims previously about the safety of

the distribution or pharmacy system in Canada. The day after the FDA left, the folks from Health Canada issued a clarifying press release saying, "The FDA's concerns have been reviewed, they've been investigated, and they are, quote/unquote, 'not substantiated.'" Not substantiated.

So we're asking, Mr. Chair, that the FDA, if they would be willing—the ideal would be to help us. You know, they're the organization that has the expertise, they're the organization that has the ability to help a system like this go forward. We'd love to have their help. In fact, we'll cut them in on the action. You know, we'll take some of our savings and we'll give it to the FDA. If they want to send up some staff and sit in these pharmacies and help us review and do the due diligence, we will help them.

But we're going to go forward under the guise that current law allows individual purchases for personal use. The protocols, I'll be happy to talk to you about it in more detail. It's in my testimony. But they—we can be confident in the safety of these pharmacies that we will select.

And I also want to just address quickly, if I could, Mr. Chair, this notion that, you know, the retaliation by the pharmaceutical companies, because that's a growing concern in Canada, in terms of the government and their consumers. I think the threat, on national television, by the CEOs and leaders of our pharmaceutical companies, that they are going to cutoff supply to their Canadian pharmacies, is reprehensible. And it may be, it may be, a violation of antitrust and trade laws, and I hope this Committee or other Federal authorities or state authorities will pursue that.

In closing, Mr. Chair, let us try it. Let us try it. Even if you don't change Federal law, we just ask the Federal—the FDA to maintain their current posture, allow these personal purchases to go forward. Let us try it, we'll see if it works. If it doesn't work, we'll come back, we'll admit it frankly, and move on. But we need to try something different.

Thank you for the time and chance to present a few thoughts this morning.

[The prepared statement of Governor Pawlenty follows:]

PREPARED STATEMENT OF HON. TIM PAWLENTY, GOVERNOR, STATE OF MINNESOTA

Chairman McCain, Senator Hollings, and members of the Senate Commerce Committee, it is an honor to be with you today.

Not far from here, along the banks of the Potomac, is our national memorial to President Franklin D. Roosevelt. During an earlier time of crisis, President Roosevelt pushed for innovation. He said, "It is common sense to take a method and try it; if it fails, admit it frankly and try another. But above all, try something."

It's time to try something different in America's prescription drug crisis. This isn't about politics or ideology. It isn't about the New Deal. It's about getting a "Better Deal" for our people.

Individuals, families, job providers, and units of government across the Nation are facing a health care crisis. Simply put, the cost of health care is rising faster than our ability to keep up. The current rate of cost increase is unsustainable. If we do not find effective ways to address this crisis, it will seriously undermine our economy, our ability to provide health care, and our ability to enhance our quality of life.

It is one of the fundamental challenges of our time.

Health care costs are escalating rapidly for a variety of reasons—not just because of the costs of prescription medicines. However, prescription medicine prices are an increasingly significant contributor to the cost crisis.

The tentative agreement regarding a Medicare prescription drug benefit is good progress, and I applaud the Congress for it. However, giving more people coverage addresses only part of the challenge. With or without coverage, costs simply cannot keep increasing at the current rate.

We've all heard the arguments about why Americans pay more for prescription drugs than other countries. But the bottom line is Americans pay more than the rest of the world and the price differential puts prescription medicines out of reach for too many Americans. The current situation is unfair and untenable.

That's why we're doing what we are in Minnesota. We're taking a method and trying it.

Minnesota's Plan

The Minnesota Plan for Prescription Drugs has a very simple goal—to get a better deal for Minnesotans. We are establishing a program to facilitate the purchase of prescription drugs from Canada by individuals.

Through a website, all Minnesotans will be able to determine if their prescription is available at a lower cost from a Canadian pharmacy, and if so, how to order it. The site will focus on only maintenance drugs that can be shipped and are known to be cheaper in Canada. Only reputable Canadian pharmacies licensed by a Canadian province, willing to negotiate a discounted price and have their safety protocols reviewed by the Minnesota Department of Human Services will be used. The site will also let consumers know if there is a lower cost generic alternative about which they should see their doctor.

Those individuals wishing to take advantage of the program will need to obtain a prescription from their own physician and send a copy of the prescription, an order form and a medical history questionnaire to the Canadian pharmacy. To comply with Canadian law, the prescription will be reviewed and countersigned by a Canadian physician. Assuming that all is in order, the pharmacy will ship the medication to the patient by mail and in the manufacturer's original, sealed container.

The next step is to provide incentives, such as waiving co-payments or sharing savings, to our state employees so they also take advantage of this lower cost alternative.

We recognize that these measures are not the ideal or long-term solution. They are, however, designed to provide short-term relief and to build pressure for long-term reform.

Ensuring Safety

I'm pleased to be here today with Deputy Commissioner Taylor from the Food and Drug Administration, which is charged with ensuring the safety of the prescription drugs Americans use.

Those who oppose reimportation often talk of great problems with safety. On this point, it is important to keep straight what we are proposing and what we are not proposing.

We are proposing to reference services available from established, reputable, credible, accredited Canadian pharmacies. There is no evidence to suggest such pharmacies are unsafe. Canadians are not dying or at risk because of their system. Assertions that a plan like Minnesota's is unsafe suggests either the pharmacies we would choose are unsafe or they are too inept to properly mail or deliver medicines safely. Neither is true. Moreover many reputable, established pharmacies in the U.S. already use a mail order, Internet or phone order system. The FDA apparently thinks it works well for them. For example, the Veterans Hospital in Minneapolis mails out a large number of prescriptions to patients each week.

Our proposal should not be confused with the questionable Internet pharmacy or "storefront" marketing entities that are currently offering their services to U.S. citizens with little or no oversight. We agree that such operations present an unreasonable safety risk to consumers.

Our Department of Human Services conducted a review of Canadian practices, similar but independent of that done by the State of Illinois. We came to the same conclusion that they did: the Canadian system is comparable to ours in safety standards.

There is a misperception that reimportation from Canada is some risky endeavor in which we give up safety to use a Third World apothecary just to save a dime. Canada's pharmaceutical regulatory system is strong and effective. At the state level, we're prepared to monitor and ensure that those pharmacies serving our citizens are held to the highest standards of safety.

Let me briefly explain to you some of the safety and security protocols we will be using as part of our reimportation plan:

1. Any pharmacy associated with our website must be accredited by an organization such as the Internet Mail order Pharmacy Accreditation Commission, which uses 92 standards in their process;
2. The pharmacy must agree to allow inspection of their facilities and wholesalers that supply these pharmacies will also be inspected;
3. Medications will only be dispensed in the manufacturer's unopened, safety-sealed containers in dose-appropriate amounts;
4. Those medications shipped must be produced in an FDA-approved manufacturing facility;
5. Medicines will be for maintenance drugs only and the patient will likely be required to have been taking the medicine for at least thirty days before the prescription is filled.

The Industry's Threats

In recent weeks, as the prospects of reimportation facilitated by units of government gets closer to a reality, executives of the pharmaceutical industry have publicly threatened to withhold supplies of prescription drugs to those Canadian pharmacies who supply Americans.

Their threats are reprehensible. I also believe these threats may be a violation of Federal and state antitrust laws and urge this committee to review the comments and actions of the companies involved.

Minnesota is Ready to Lead the Way

The states are often called the "laboratories of democracy." The State of Minnesota is proving that again by moving ahead in implementing this reimportation plan.

As President Roosevelt advised, we have to try something.

Let us be the experiment. Let us try it. Let us put the arguments to the test. If it doesn't work, we'll admit it. The current system is not "safe" because too many people can't afford their medicine.

Thank you very much.

The CHAIRMAN. Thank you, Governor.

Mr. Taylor, welcome back.

STATEMENT OF JOHN M. TAYLOR III,
ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS,
U.S. FOOD AND DRUG ADMINISTRATION

Mr. TAYLOR. Thank you very much.

Before I start my oral testimony, I'd—we would be——

The CHAIRMAN. You might want to move the microphone a little closer.

Mr. TAYLOR. I'm sorry, sir.

We'd be more than happy to meet with the Governor, either before or after the introduction of your plan, and we can discuss that.

The CHAIRMAN. Thank you.

Mr. TAYLOR. Mr. Chairman, I appreciate the opportunity to discuss the Food and Drug Administration's concerns related to the importation of drugs into the United States. FDA shares with Congress its great concern for senior citizens and other patients who have difficulty paying for prescription drugs. That is why the Administration has been working so closely with Congress to enact landmark legislation to provide millions of American seniors with coverage for prescription drugs under Medicare. As part of that legislation, the Administration supports provisions that build on FDA action earlier this year to expand access to more affordable generic drugs.

FDA has also taken a number of other significant steps to provide greater access to affordable prescription medications without compromising safety, including unprecedented steps to lower drug

costs by helping to speed the development and approval of low-cost generic drugs after legitimate patents have expired on branded products. This includes the biggest expansion in history of our generic drug program in a series of regulatory changes to make it easier for generic manufacturers to compete.

However, FDA continues to have serious public-health concerns regarding legislation that will allow the importation of drugs from outside the current safety system established by Congress under the Federal Food, Drug, and Cosmetic Act. When it comes to buying drugs outside our existing regulatory protections, FDA has consistently concluded that the agency is unable to endorse a buyer-beware approach.

Currently, new drugs marketed in the United States, regardless of whether they are manufactured in the United States or a foreign country, must be approved by FDA based on demonstrated safety and efficacy. They must be produced in FDA-inspected manufacturing plants that meet FDA's good manufacturing practice regulations. Also, the shipment and storage of these drugs must be properly documented and, where necessary, inspected. Under the Food, Drug, and Cosmetic Act, unapproved, misbranded, and adulterated drugs cannot be imported into the United States. This includes foreign versions of U.S. approved medications, as well as drugs that are made in the United States, exported to other countries, and the subsequently reimported to the United States.

Our safety concerns are heightened by the proliferation of websites, both domestic and foreign, that sell prescription drugs to consumers. The Internet has opened up vast new opportunities for commerce and exchange of information. However, as beneficial as this technology can be, it also creates a new marketplace place for activity that is already illegal. FDA is doing its best to stop the increasing flow of violative drugs in this country, but the task is daunting. While Regulatory Affairs has inspectors who work in the field, who perform investigational work pertaining to imported prescription drugs, a job that's not limited to inspections at ports of entry, but while the volume of imported drugs has increased enormously, FDA has not received additional resources or authorities to address these thousands of shipments, in contrast to the case for food security, where Congress, 2 years ago, approved substantial new funds and authorities for border protections.

FDA has long taken the position that consumers are exposed to a number of risks when they purchase foreign drugs from Internet sites or from pharmacies that are not licensed and operated under state pharmacy law. These outlets may dispense expired, subpotent, contaminated, or counterfeit products, or medications unaccompanied by adequate directions for use. In addition, FDA cannot provide consumers with any assurance that these products or their active ingredients were manufactured under current good manufacturing practice standards or stored properly.

Taking such unsafe or inappropriate medications put consumers at risk for dangerous drug interactions and other serious health consequences. Moreover, patients are at a greater potential risk, because there's far less certainty about what they are getting when they purchase drugs over the Internet.

Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated that have been diverted to unscrupulous resalers, or dangerous subpotent or superpotent products that are improperly manufactured. Also, in the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse, either because the physical location of the manufacturer is unknown or because the operator of the pharmacy often is not known or that seller is beyond the consumer's reach. FDA has only limited ability to take action against these foreign operators.

To help assess the extent of the problems posed by imported drugs, FDA and the United States Customs and Border Protection conducted import blitzes at four mail facilities this summer. The purpose of these blitzes was to obtain a representative picture of the type of drugs that were entering the United States through the mail, and to identify and stop counterfeit and potential unsafe products from entering the United States. Although many drugs obtained from foreign sources purport and/or may appear to be the same as FDA-approved medications, in fact they are of unknown quality or origin, have not been approved in the U.S., and may pose potential serious safety concerns.

Eighty percent of the drug products that were examined during the blitz were violative because they were unapproved drugs. The potentially hazardous products encountered during the blitz included drugs that FDA has never approved, drugs that require careful dosing, drugs with inadequate labeling, drugs inappropriately packaged, drugs withdrawn from the market, drugs with clinically significant drug interactions, drugs requiring initial screenings and/or periodic monitoring, and controlled substances. Clearly, many of these imported drug products may pose safety problems.

Sixty-five years ago, Congress responded to widespread fears of unsafe, ineffective domestic drugs by directing FDA to create a system for assuring that Americans have a drug supply that they can trust. Fifteen years ago, Congress responded to serious safety problems created by imported drugs that were not tightly regulated by passing the Prescription Drug Marketing Act. Congress limited access to these foreign drugs because of safety concerns it identified with the importation of significant volumes of adulterated and counterfeit drugs.

History has shown that this closed regulatory system has worked well. FDA, however, cannot offer the same assurance to the public about the safety and quality of drugs purchased from foreign sources that are outside our U.S. regulatory system.

Unfortunately, the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. FDA has seen its number of counterfeit drug investigations increase fourfold since the late 1990s. Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well-funded and elaborately organized networks. At the same time, inadequately regulated foreign Internet sites have also become portals

for unsafe and illegal drugs. Evidence strongly suggests that the volume of these drug—of these foreign drug importations is increasing steadily and presents a substantial challenge for the agency to adequately assess and process these parcels, resulting in a increased workload for agency field personnel, ports of entry, mail facilities, and international courier hubs. With the available resources and competing priority space in the agency, experience shows that we are unable to visually examine the large volume of parcels containing prescription drugs that arrive each day. The agency responded to this challenge by employing a risk-based enforcement strategy to target our existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety, and other important tasks. However, this system is already overwhelmed by the number of incoming mail packages that must be evaluated, and this state of affairs presents a significant on-going challenge for the agency.

At a time when FDA faces more challenges than ever in keeping America's supply of prescription drugs safe and secure, legislation to liberalize drug importation could cause additional drug safety concerns. The volume of importation that could result from enactment of these bills could easily overwhelm our already heavily burdened regulatory system.

In general, these bills fail to provide FDA with the adequate authority or resources to establish and regulate the distribution system for incoming foreign drugs. Some of these proposals would take away our existing authorities, creating unprecedented prohibitions on FDA's ability to inspect and test drugs, and FDA's authority to block the distribution of drugs that we think are unsafe. Perhaps most importantly, in addition to allowing in some drugs that might be safe, these bills create wide and poorly regulated channels through which counterfeit drugs, criminally diverted controlled substances, and other unsafe drugs could enter our drug supply.

In closing, Mr. Chairman, FDA remains concerned about any possibility that unsafe drugs may find their way into the American drug supply. We appreciate the Committee's interest in assuring that the American public has access to safe and affordable medicines. We believe that this is an important goal to attain, but affordability must not come at the expense of safety.

Thank you, again, for this opportunity to participate in today's hearing. I'll be happy to answer any questions.

[The prepared statement of Mr. Taylor follows:]

PREPARED STATEMENT OF JOHN M. TAYLOR III, ASSOCIATE COMMISSIONER, REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION

Introduction

Mr. Chairman and Members of the Committee, I am John M. Taylor, Associate Commissioner for Regulatory Affairs at the U.S. Food and Drug Administration (FDA or the Agency).

I appreciate the opportunity to testify regarding the importation of prescription drugs into the United States. Let me begin by saying that the overall quality of drug products that consumers purchase from U.S. pharmacies remains high. The American public can be confident that these medications are safe and effective. FDA cannot, however, offer the same assurance to the public about the safety and quality of drugs purchased from foreign sources that are outside the regulatory system.

My testimony will focus on FDA's efforts to assess and respond to the public health threats posed by the importation of unapproved, adulterated and misbranded

drugs, as well as counterfeit drugs from foreign and domestic sources that pose a threat to the health and safety of U.S. consumers. I will also discuss the law governing drug imports, and the enforcement strategies used to prevent potentially unsafe drugs from reaching the American consumer.

Summary

The Food and Drug Administration (FDA) shares with Congress its great concern for senior citizens and other patients who have difficulty paying for prescription drugs. That is why the Administration has been working so closely with Congress to enact landmark legislation to provide millions of America's seniors with coverage for prescription drugs under Medicare. As part of that legislation, the Administration supports provisions that build on FDA action earlier this year to expand access to more affordable generic drugs. FDA has also taken a number of other significant steps to provide greater access to affordable prescription medications without compromising safety, including unprecedented steps to lower drug costs by helping to speed the development and approval of low-cost generic drugs after legitimate patents have expired on branded drugs. This includes the biggest expansion in history of our generic drug program, and a series of regulatory changes to make it easier for generic manufacturers to compete.

The Agency has also taken steps to help improve the development process to help lower the high cost of developing new drugs. And the Agency has taken steps to improve the process by which drugs are manufactured. FDA is also working to prevent adverse events through new rules that would require bar coding for drugs and better ways to track adverse events automatically—with the goal of preventing billions of dollars in unnecessary health care costs each year. In addition, FDA is striving to promote electronic prescribing, to improve quality and reduce prescription costs as well. And the Agency is taking additional steps to provide better information to health care professionals and patients alike, including new and better electronic product labels and Internet-based information, about the risks and benefits of medication choices available to treat a particular health problem.

However, FDA continues to have serious public health concerns regarding legislation that would allow the importation of drugs from outside the current safety system established by Congress under the Federal Food Drug and Cosmetic Act. When it comes to buying drugs internationally, outside our existing regulatory protections, FDA has consistently concluded that the Agency is unable to endorse a "buyer beware" approach.

All imported drugs are required to meet the same standards as domestic drugs, and thus must not be unapproved, misbranded, or adulterated. Drugs imported by individuals that are unapproved, misbranded, or adulterated, are prohibited by law. This includes drugs that are foreign versions of FDA-approved medications, and drugs that are dispensed without a prescription, because there is no assurance of their safety and effectiveness. FDA is doing its best to stop the increasing flow of violative drugs into this country but the task is daunting. Each day thousands of packages containing prescription drugs are imported illegally into the United States. Our Office of Regulatory Affairs has inspectors who work in the field who perform investigational work pertaining to imported prescription drugs, a job that is not limited to inspections at ports of entry. But while the volume of imported drugs has increased enormously, FDA has not received additional resources or authorities to address these shipments, in contrast to the case for food security at the border.

Under the FD&C Act, a drug is subject to refusal of admission into the United States if it appears that it: (1) has been manufactured, processed or packed under unsanitary conditions, (2) is forbidden or restricted for sale in the country in which it was produced or from which it was exported, or (3) is adulterated, misbranded or in violation of section 505 of the FD&C Act, which relates to new drugs. To determine whether a product is in compliance, FDA may collect an analytical or documentary sample from the shipment for evaluation, and the shipment is held until the results of the examination are known. In some instances, a product may be detained as soon as it is offered for entry into the U.S. This procedure—detaining a product without physical examination—is based on past history and/or other information indicating the product may violate the FD&C Act. At mail facilities, Bureau of Customs and Border Patrol (BCBP) officials identify parcels that should be brought to FDA's attention. BCBP places these packages in a secure location that they maintain for FDA and other agencies. As with all imports, if it appears that the product may be subject to refusal, FDA will issue a notice to detain the product and provide the owner or consignee an opportunity to respond.

Due to the huge volume of drug parcels entering the U.S. through the international mail and courier services, the requirements for notice and hearing, and our limited resources, it is difficult for FDA to detain and refuse mail imports for per-

sonal use. In addition, considerable storage space is needed to hold the large number of detained parcels while a notice, opportunity to respond, and Agency decision are pending.

The recent rise Internet purchasing of drugs has significantly compounded this problem. During a recent drug importation survey at several mail facilities in the United States, FDA found that the vast majority of parcels (88 percent) contained unapproved drugs that could pose significant safety problems. These packages included drugs that have been withdrawn from the U.S. market for safety reasons; animal drugs sold illegally for human use; drugs improperly packaged in sandwich bags or tissue paper; drugs without English labeling or proper instructions for use; and drugs requiring precise dosing and monitoring by a physician.

The Agency has responded to the challenge of importation by employing a risk-based enforcement strategy to target our existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. As an example, the Agency utilizes Import Alerts to identify particular shipments that may pose significant potential risk to public health, *e.g.,* drugs that require careful risk management and products from shippers known to present significant safety problems. However, this system is already overwhelmed by the number of incoming mail packages that must be evaluated and this state of affairs presents a significant ongoing challenge for the Agency.

Sixty-five years ago, Congress responded to widespread fears of unsafe and ineffective domestic drugs by directing FDA to create a system for assuring that Americans have a drug supply they can trust. Fifteen years ago, Congress responded to serious safety problems created by imported drugs that were not tightly regulated by passing the Prescription Drug Marketing Act. Congress limited access to these foreign drugs because of safety concerns it identified with the importation of significant volumes of adulterated and counterfeit drugs.

Unfortunately, the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. This is evident in the recent significant increase in efforts to introduce counterfeit drugs into the U.S. market. FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990s. Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well-funded and elaborately organized networks. At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs. Evidence strongly suggests that the volume of these foreign drug importations is increasing steadily and presents a substantial challenge for the Agency to adequately assess and process these parcels, resulting in an increased workload for Agency field personnel at ports-of-entry, mail facilities, and international courier hubs.

FDA remains concerned about the public health implications of personally imported prescription drugs and the introduction of counterfeit drugs into the stream of commerce. In our experience, 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. FDA cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA. The Agency has long taken the position that consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent against degradation, and there is no assurance that these products were manufactured under current good manufacturing practice standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening.

Patients potentially are at greater risk because there is no certainty about what they are getting when they purchase some of these drugs. Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Furthermore, in the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse either because the physical location of the manufacturer or because the operator of

the pharmacy often is not known or the seller is beyond the consumer's reach. FDA has only limited ability to take action against these foreign operators.

In recent weeks, several governors and mayors around the country have proposed to create systems whereby their employees and/or constituents could be directed to Canadian pharmacies for purchasing Canadian drugs. FDA has spoken with a number of such officials about our legal and safety concerns, and many have declined to proceed and, at this time, no state has put in place such an approach. In general, it is premature for FDA to predict any potential enforcement actions against cities and states. However, it is foreseeable that some jurisdictions may decide to implement such a program, despite the Agency's concerns. FDA has not threatened legal action against specific jurisdictions, but has signaled its safety concern about these proposals and about their potential illegality. FDA laid out these views in a letter to the Attorney General of the State of California in the summer. Under current law, it is fairly clear that states or cities would be encouraging the importation of unapproved (and thus illegal) prescription drugs if they created such programs.

At a time when FDA faces more challenges than ever in keeping America's supply of prescription drugs safe and secure, legislation to liberalize drug importation could cause additional drug safety concerns. The volume of importation that could result from enactment of these bills could easily overwhelm our already heavily burdened regulatory system. In general, these bills fail to provide FDA with adequate authority or resources to establish and regulate the distribution system for incoming foreign drugs—manufactured, distributed, labeled, and handled outside of our regulatory system—or even to ensure their safety. Some of these proposals would take away our existing authorities, which are already being stretched. They would create unprecedented prohibitions on FDA's ability to inspect and test drugs, and FDA's authority to block the distribution of drugs we think are unsafe. The proposals offer no added resources to handle the flow of imported drugs into the United States; a flow that would likely become far larger than it is today. Perhaps most importantly, in addition to allowing in some drugs that might be safe, these bills create wide and poorly regulated channels through which counterfeit drugs, criminally diverted controlled narcotics, and otherwise unsafe drugs could enter our drug supply. By choosing affordability over safety rather than taking new steps to address both, such legislation is a dangerous solution to the twin challenges of safety and affordability.

Today, FDA drug approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Under section 801 of the FD&C Act, only manufacturers may import drugs into the U.S. The drugs must be produced in FDA inspected facilities. These facilities and the drugs produced in them are currently covered by the U.S. regulatory system, and it is legal to import these drugs. But legislation allowing pharmacies or consumers to import drugs directly from foreign sources would bypass the protections provided by FDA's drug approval process and by state regulation of firms that dispense drugs within their jurisdictions.

Some drug importation legislation would limit imports to only those drugs that are FDA-approved and made in FDA-inspected facilities, simply because the legislation states that it is limited to drugs that comply with sections 501 (adulteration), 502 (misbranding) and 505 (marketing approval) of the FD&C Act. However, this approach fails to provide resources, authorities, or the procedural framework necessary for FDA to assure such compliance. As a practical consequence, the Agency would be forced in many instances to rely on visual examinations of incoming drug packages to determine whether a drug is FDA-approved and in compliance with the FD&C Act. A visual inspection, however, is not nearly sufficient to verify whether these drugs are FDA-approved, manufactured in FDA-inspected facilities or in compliance with the adulteration and misbranding provisions of the FD&C Act. This is no substitute for the existing FDA regulatory process, which tracks prescription from the acquisition of active and inactive ingredients to on-site inspection of manufacturing and distribution facilities, with documentation of appropriate product testing and handling.

Even if a manufacturer has FDA approval for a drug, a version produced for foreign markets usually does not meet all of the requirements of the FDA approval, and is thus considered to be unapproved. Even if a drug bound for a foreign market is produced in the same plant as a similar drug approved for the U.S. market, FDA is not ability to track that drug in foreign commerce before it enters the U.S. Consequently, it is difficult for the Agency to determine that a drug appearing at a U.S. border is in fact the one produced in the FDA-inspected plant, pursuant to FDA approval. Taken together, these practical problems create an unworkable system that may appear to provide consumers with safety protections, but in fact is hollowed by

the inadequacy of resources and authorities needed for effective implementation to protect the U.S. drug supply.

FDA firmly believes that we can and should do a much better job of making safe and innovative drugs more affordable in the United States, but to succeed we need to find safe and affordable solutions that, when implemented, do not put consumers at risk. We appreciate and support the commitment to making drugs more affordable for seniors and other consumers and are working hard to achieve this goal. However, the Agency continues to believe that we must focus on solutions that do not put at risk safety in an effort to achieve increased affordability.

Reducing Drug Costs

The Administration believes that Americans should have access to safe, effective and affordable prescription drugs. The Administration is currently engaged in a number of actions to reduce the costs of prescription medications. These initiatives will result in more affordable prescription drugs and will reduce the incentive to look to foreign sources for cheaper medications.

On June 18, 2003, FDA published its final rule to lower prescription drug costs for millions of Americans by improving access to generic drugs. These changes are expected to save Americans over $35 billion in drug costs over the next 10 years. FDA's final rule provides the generic industry with enhanced predictability and certainty, while avoiding unnecessary and lengthy litigation, preserving intellectual property protections and protecting the process of developing new breakthrough drugs.

Specifically, the proposed rule would allow only one 30-month stay for each generic drug application, clarify that certain patents cannot be listed, and improve the declaration that innovators must make about patents they submit to FDA for listing in the Agency's Orange Book publication that lists all drug products approved under section 505 of the FD&C Act.

The President's 2004 budget proposes an unprecedented increase of $13 million in spending for FDA's generic drug program. This will be the largest infusion of resources into the generic drug program in history, increasing the program's size by about one-third. The proposed increase in FDA's generic drug budget will allow FDA to hire 40 experts to review generic drug applications more quickly and initiate targeted research to expand the range of generic drugs available to consumers. The improvements in the efficiency of review procedures are expected to save consumers billions more by generally reducing the time for approving new generic drugs.

The Agency has also taken steps to help improve the development process to help lower the high cost of developing new drugs. And the Agency has taken steps to improve the process by which drugs are manufactured. FDA is also working to prevent adverse events through new rules that would require bar coding for drugs and better ways to track adverse events automatically—with the goal of preventing billions of dollars in unnecessary health care costs each year. In addition, FDA is striving to promote electronic prescribing, to improve quality and reduce prescription costs as well. And the Agency is taking additional steps to provide better information to health care professionals and patients alike, including new and better electronic product labels and Internet-based information, about the risks and benefits of medication choices available to treat a particular health problem.

FDA is also taking steps to reduce the cost and regulatory uncertainties of developing and manufacturing drugs, especially generic drug alternatives. FDA initiatives in the Commissioner'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—those 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. Such reductions will help speed patient access to new drugs and reduce the cost of drug development. FDA has begun major initiatives to reduce some of those sources of uncertainty.

FDA is continuing to improve the methods by which advice is provided to sponsors regarding what we believe are the best approaches to develop new therapies. These ongoing efforts are designed to provide sponsors with the best possible information, and thus increase the efficiency of the development process. 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.

Another important step the Federal Government can take to respond to the need for affordable drugs is beyond FDA's reach. It requires legislation that the President and Congress on a bipartisan basis are close to achieving. The Administration believes that it is time for Congress to pass Medicare legislation that will make safe and effective drugs more affordable for seniors. The legislation would provide immediate discounts through Medicare-endorsed prescription drug cards. Beginning in 2006, Medicare beneficiaries would have access to a drug benefit, through which they would be able to take advantage of lower prices negotiated by private health plans.

The Medicare legislation also contains two other provisions designed to lower prescription drug costs: generic drug reform and legislation approved by the House or Representatives that would open our borders to non-FDA approved drugs. One holds great promise, the other raises serious safety concerns.

Gregg-Schumer Generic Drug Provisions

The Medicare legislation contains a bipartisan proposal sponsored by Senators Gregg and Schumer that would complement FDA rulemaking by providing greater access to more affordable generic drugs. The Senate bill would codify elements of FDA's June 18, 2003, final rule and add a provision limiting 180-day exclusivity to accelerate generic competition in the marketplace. These changes will enable consumers to save billions of dollars each year by making it easier for generic drug manufacturers to get safe and effective products on the market. The increased availability of lower-cost generic drugs will benefit all Americans, especially seniors.

Foreign Drug Imports

Efforts in Congress to enact legislation to restructure the current drug import standard are inconsistent with the realities of drug safety. As any of our dedicated field investigators will attest, and as pharmacy regulators and major health professional organizations have warned, just because legislation declares drugs safe doesn't make them so.

At a time when FDA faces more challenges than ever in keeping America's supply of prescription drugs safe and secure, legislation to liberalize drug importation could cause additional drug safety concerns. The volume of importation that could result from enactment of these bills could easily overwhelm our already heavily burdened regulatory system. In general, these bills fail to provide FDA with adequate authority or resources to establish and regulate the distribution system for incoming foreign drugs—manufactured, distributed, labeled, and handled outside of our regulatory system—or even to ensure their safety. Some of these proposals would take away our existing authorities, which are already being stretched. They would create unprecedented prohibitions on FDA's ability to inspect and test drugs, and FDA's authority to block the distribution of drugs we think are unsafe. The proposals offer no added resources to handle the flow of imported drugs into the United States; a flow that would likely become far larger than it is today. Perhaps most importantly, in addition to allowing in some drugs that might be safe, these bills create wide and poorly regulated channels through which counterfeit drugs, criminally diverted controlled narcotics, and otherwise unsafe drugs could enter our drug supply. By choosing affordability over safety rather than taking new steps to address both, such legislation is a dangerous solution to the twin challenges of safety and affordability.

Today, FDA drug approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Under section 801 of the FD&C Act, only manufacturers may import drugs into the U.S. The drugs must be produced in FDA inspected facilities. These facilities and the drugs produced in them are currently covered by the U.S. regulatory system, and it is legal to import these drugs. But legislation allowing pharmacies or consumers to import drugs directly from foreign sources would bypass the protections provided by FDA's drug approval process and by state regulation of firms that dispense drugs within their jurisdictions.

Some drug importation legislation would limit imports to only those drugs that are FDA-approved and made in FDA-inspected facilities, simply because the legislation states that it is limited to drugs that comply with sections 501 (adulteration), 502 (misbranding) and 505 (marketing approval) of the FD&C Act. However, this approach fails to provide resources, authorities, or the procedural framework necessary for FDA to assure such compliance. As a practical consequence, the Agency would be forced in many instances to rely on visual examinations of incoming drug packages to determine whether a drug is FDA-approved and in compliance with the FD&C Act. A visual inspection, however, is not nearly sufficient to verify whether

these drugs are FDA-approved, manufactured in FDA-inspected facilities or in compliance with the adulteration and misbranding provisions of the FD&C Act. This is no substitute for the existing FDA regulatory process, which tracks prescription from the acquisition of active and inactive ingredients to on-site inspection of manufacturing and distribution facilities, with documentation of appropriate product testing and handling.

It is difficult for the Agency to reconcile the movement to allow consumers to purchase drugs from foreign sources with widespread understanding that the world has changed, that we now face more security concerns than ever, and that our vigilance over imports entering this country must reflect this reality. Just last year, Congress enacted legislation giving FDA an additional new authority to help protect imported food from deliberate or accidental contamination. As a result of this legislation, FDA has substantially boosted its food safety and security activities at the border, adding hundreds of new inspectors and support staff. For example, for the first time, FDA must be notified of essentially all commercial food shipments before they arrive. This will allow FDA to target our efforts to the riskiest products, before they enter the country. So thanks to Congress, we have new abilities to help us prevent the entry of foods that may be unsafe.

Yet in the area of drugs, some in Congress want to move in the opposite direction. The evidence in my testimony today strongly suggests that it simply is not safe to throw open our borders and declare broad new classes of drugs to be "legal." Despite well-intentioned efforts to design safeguards for this proposed drug import regime, many unsafe drugs will enter if Congress establishes a new, wide "legal" avenue for imports.

This approach would encourage the individuals who are currently trying hard to exploit weaknesses in our drug security system to make the most of any new paths that are opened into America's drug supply. The problems we are witnessing now will only multiply if current safeguards are weakened. The evidence that this will occur becomes stronger each day.

For example, an 81-year-old U.S. consumer recently purchased Neurontin, an FDA-approved anti-seizure medication after watching a TV commercial that claimed consumers could save up to 70 percent on prescriptions by calling a 1–800 number. A brochure that was subsequently sent to the consumer after he called the toll free number led him to believe that any drugs he ordered would be FDA-approved, brand name drugs from Canada. The consumer subsequently purchased the Neurontin, along with two other pharmaceuticals. However, the Neurontin the consumer actually received was made in India and unapproved for any use in the United States. This is just one of many examples where consumers thought that they were getting FDA-approved products from Canada, only to find out that their products were coming from countries in Asia and Africa.

International pharmaceutical peddlers are taking advantage of regulatory gaps to move millions of prescription drugs, including controlled substances, into the United States from Mexico, Canada, and elsewhere. Rogue medical merchants who have dubious or no medical background are selling potentially dangerous drugs to people who never see the prescribing doctor in person or undergo necessary tests. At best, these drugs are of unclear origins and safety. At worst, they are poorly manufactured, improperly repackaged, stored, and labeled, or out-and-out fakes. Weakening import restrictions will only compound these problems.

The resources and authorities to assure drug safety that are available to FDA and our state partners must be commensurate with the scope and volume of the drug products that may legally be imported. It is important to remember why Congress made many drug imports illegal in the first place: FDA did not have the resources or authorities to assure their safety. Moreover, in recent years we have seen many more drugs that require "risk management" programs and regular monitoring to be sure they are used safely and effectively. We have also approved biologic and injectable drugs that have especially complex manufacturing and storage requirements. In both cases, the public health safeguards that FDA has imposed are being undermined by the illegal importation of these products. In addition, regulating controlled substances at our borders is an enduring challenge. These factors strongly argue for maintaining, not loosening, the current standards.

Promising Anti-Counterfeiting Technology

Over time, it may be possible to assure drug safety through a multilayered strategy of modern anti-counterfeiting technologies. Promising developments such as "track and trace" technologies that cannot be faked like a paper drug pedigree, and verification technologies built not only into tamper-resistant drug packaging but also into the drugs themselves will make our job of verifying the legitimacy of drug

products much easier. FDA is working to speed the availability of these anti-counterfeiting technologies, but they are months or years away.

In the meantime, FDA needs all of the authorities it has now to assure the safety and effectiveness of legal prescription drugs. This includes the ability to require or conduct tests of product authenticity and potency, the ability to identify and, when necessary, inspect firms involved in the distribution of pharmaceuticals, and the authority to issue regulations and take decisive action to block the distribution of potentially unsafe drugs. Now is not the time to weaken these authorities, or to allow products into this country that circumvent these important public health protections.

Drug Imports: Health and Safety Concerns

Sixty-five years ago, Congress responded to widespread fears of unsafe and ineffective drugs by directing FDA to create a system for assuring that Americans have a drug supply they can trust. FDA responded to this challenge by establishing a system that has become the gold standard that others strive to emulate. The FD&C Act prohibits the importation of unapproved, misbranded, or adulterated drugs into the U.S. Drugs imported by individuals generally fall into one of these prohibited categories. This includes foreign versions of U.S.-approved medications.

More recently, in 1988, Congress enacted the Prescription Drug Marketing Act (PDMA) to establish additional safeguards to prevent substandard, ineffective, or counterfeit drugs from entering the U.S. Under PDMA, it is illegal for anyone other than the drug's original manufacturer to re-import a prescription drug into the U.S. that was manufactured in the U.S.

At least two high-profile cases prompted the passage of PDMA. In one instance, over 2 million unapproved and potentially unsafe and ineffective Ovulen-21 "birth control" tablets from Panama were distributed throughout the U.S. They were falsely imported as "American goods returned." In another case, a counterfeit version of Ceclor, a widely used antibiotic at the time, found its way into the U.S. drug distribution from a foreign source. Over the years, our professional staff has employed PDMA and other pre-existing authorities to build a drug safety infrastructure to ensure that Americans enjoy the highest-quality drug supply in the world.

Unfortunately, the drug supply that we work so hard to safeguard is under unprecedented attack from a variety of increasingly sophisticated threats. Today everything from product packaging to labeling and product containers can be readily purchased created or counterfeited and counterfeiters and diverters take advantage of this opportunity. Moreover, the skill and ingenuity demonstrated by counterfeiters and diverters have improved significantly. As a result, more than ever before, well-organized criminals have the ability to exploit our regulatory system and profit at the expense of public health.

A large and growing volume of parcels containing foreign prescription drugs ordered by individuals from foreign sources is entering American commerce through U.S. Postal Service international mail facilities. Evidence strongly suggests that the volume of foreign drug imports is increasing steadily. The volume presents a substantial challenge for the Agency to adequately assess and process these parcels, resulting in an increased workload for Agency field personnel at ports-of-entry, mail facilities, and international courier hubs.

FDA remains concerned about the public health implications of foreign prescription drugs imported by consumers and counterfeit drugs introduced into the stream of commerce. In our experience, 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. FDA cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA.

FDA has long taken the position that consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent degradation, and there is no assurance that these products were manufactured under current good manufacturing practice (cGMP) standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening. These risks could include potential side effects from inappropriately prescribed medications or side effects due to drug contamination.

Patients also potentially are at greater risk because there is no certainty about what they are getting when they purchase some of these drugs. Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are expired and have been diverted to unscrupulous resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Moreover, consumers who are desperately seeking a cure for a serious medical problem may be more willing to accept a product of unknown origin.

Furthermore, in the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse either because the physical location of the manufacturer or the operator of the pharmacy is unknown the seller is beyond the consumer's reach. In addition, as a condition of doing business, many of these foreign operators require the U.S. consumer to sign a document releasing the operator from all potential liability. FDA has only limited ability to take action against these foreign operators since they operate outside if the United States.

Due to the huge volume of drug parcels entering the U.S. through the international mail and courier services and the requirements under current law for notice and hearing if we detain an import, it is difficult for FDA to detain and refuse mail imports for personal use. The advent of the Internet and the proliferation of "storefront pharmacies" has significantly compounded this problem. As a consequence, tens of thousands of parcels that FDA is unable to review given the Agency's multiple competing enforcement priorities are released by the BCBP even though the products contained in these parcels may violate the FD&C Act and may pose a health risk to consumers. We acknowledge that this is not an optimal public health outcome and are working on strategies to better utilize our available resources to minimize potential public health risks.

The Agency has responded to this challenge by employing a risk-based enforcement strategy to deploy our existing enforcement resources in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. As an example, the Agency utilizes Import Alerts to identify particular shipments that may pose significant potential risk to public health. In the case of the increased volume of certain unapproved drugs arriving at mail facilities throughout the country, the Agency has issued Import Alerts to instruct field personnel to work with BCBP to detain all such shipments from specific manufacturers, distributors and countries of origin.

FDA Response To Illegal Imports

FDA is working on a number of fronts to address the influx of unapproved and counterfeit prescription drugs coming into the U.S. from foreign sources. These efforts include: (1) educating the public about the potential safety issues presented by the purchase of drugs from foreign countries, (2) working with professional groups to disseminate FDA's message on the potential dangers of Internet drug sales, (3) partnering with state governments and other Federal agencies to develop more effective enforcement strategies, and (4) enforcement activity directed at the most significant concerns. Recent high-profile regulatory actions send a strong message that FDA is actively working to take strong steps to protect the public from conduct that threatens the U.S. drug supply.

Public Outreach and Education

Public outreach is an important tool that the Agency uses to inform consumers about potentially dangerous or ineffective drugs. FDA is expanding its public outreach to further educate consumers about potentially dangerous practices associated with some Internet drug sales. We also are conducting outreach to explain the nature of 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 has also 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. Cross-border travelers at certain land border stations are provided with information regarding the potential risks of imported drugs and another brochure entitled, "Looks Can be Deceiving," which describes the dangers of purchasing drugs directly at cross-border pharmacies. This information is also available on FDA's website.

In October 2000, FDA's Center for Drug Evaluation and Research (CDER) launched an education campaign on the subject of buying prescription medicines on-

line 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* that has information for consumers, including tips and warnings, how to spot health fraud, frequently asked questions and how to report suspect pharmacy sites. The website is one of the most frequently visited web pages on FDA's website.

Another central piece of our campaign is a brochure entitled, "Buying Prescription Medicines Online: A Consumer Safety Guide," a brochure 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 also is posted on FDA's website. The number of consumer inquiries FDA receives has grown steadily with the circulation of the brochure. 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.

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.

Recall of Asthma Drug Sold in Canada

On November 14, 2003, FDA issued a precautionary press release to alert the public to the recent recall of GlaxoSmithKline "Diskus" medicines sold in Canada to treat asthma and chronic obstructive pulmonary disease (COPD). In cases such as these, our ability to warn U.S. consumers about defective products may be compromised when patients purchase drugs from outlets in foreign countries.

Asthma, COPD and related diseases can be serious and life threatening. The three asthma products—Ventolin Diskus, Flovent Diskus, and Serevent Diskus—were recalled in Canada on November 12, 2003, because the products' drug delivery system may not function properly and may deliver too little of the drug, or none at all.

FDA emphasized that FDA-approved Diskus products (Advair and Serevent) sold in the U.S. through legitimate marketing channels are not subject to this recall. But because some Americans are buying prescription drugs from Canada and elsewhere through on-line or storefront operations, U.S. patients may be using these potentially substandard and ineffective products.

FDA urges any patients who bought these Diskus products from a foreign source to review the recall information on the manufacturer's website and check the lot numbers of Diskus products they have purchased. FDA advised U.S. patients with questions or concerns about these products to call their physician, pharmacist, or other knowledgeable care provider.

Partnering With Professional Organizations

FDA continues to meet with organizations representing state regulatory and law enforcement bodies, consumers, health care practitioners and industry to address our concerns. The purpose of these meetings is to discuss and coordinate efforts to respond to issues relating to online drug sales, including who should regulate and how they should regulate, whether and what policy changes should be considered, and when to develop partnering arrangements. The organizations we regularly meet 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 Pharmacists Association
- The National Consumers League
- AARP (formerly the American Association of Retired Persons)
- 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
- Healthcare Distribution Management Association

In addition, we have Memoranda of Understanding (MOUs) with the National Association of Boards of Pharmacy (NABP) and the Federation of State Medical Boards (FSMB) that enhance our collaborative working relationship. State pharmacy boards have primary responsibility for the licensing of pharmacies and regulating the dispensing of drugs.

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 and the growth of storefront pharmacies. While some state laws are stronger than others, FDA has actively engaged with a number of states in jointly pursuing Internet sites that are engaged in illegal prescription drug sales. In some cases, the states have acted unilaterally. FDA is continuing to expand its cooperative activities with states in order to address effectively the many challenges in this area of electronic commerce. FDA also is continuing to work closely with our partners in the states in support of their efforts to curtail illegal and potentially dangerous operations, especially when they involve misleading claims about drug safety.

State-Federal Enforcement: Rx Depot

On March 21, 2003, FDA issued a "warning letter" to a storefront operation known as Rx Depot. We commenced this action in conjunction with the Arkansas State Board of Pharmacy. Rx Depot generally obtained drugs from Canada for U.S. consumers, exposing the public to the significant potential risks associated with imported prescription medications. Rx Depot and similar companies have often incorrectly stated to consumers that FDA condones their activities and even that their prescription medications are "FDA approved." This could lead consumers to the mistaken conclusion that the prescription drugs sold by the companies have the same assurance of safety as drugs actually regulated by FDA.

While Rx Depot responded to FDA's "warning letter," the response was inadequate. Therefore the U.S. Department of Justice and FDA filed an injunction on September 11, 2003, to stop Rx Depot Inc. from importing prescription drugs from Canada in violation of U.S. law. The Agency brought the suit because the storefront chain posed a risk to public health by importing unapproved prescription drugs and drugs that may only be imported by the U.S. manufacturer. These drugs posed a public health risk because they do not have the same assurance of safety and efficacy as drugs regulated by FDA

On November 6, 2003, U.S. District Judge Claire Eagen granted the government's motion for a preliminary injunction and ordered Rx Depot to stop importing drugs and stop advertising and promoting any service that causes or facilitates drug imports. Judge Eagen also ruled that the firm had ten days to send a letter to its customers informing them that the company's business violated the law and that the safety and efficacy of drug products obtained through the firm could not be assured.

FDA, and the District Court Judge, concluded that operations such as Rx Depot expose the public to significant potential risks associated with unregulated imported prescription medicines. FDA's decision to bring this action and the court's subsequent ruling sends a clear signal that FDA is committed to protecting the public health and challenging those who put profit before safety. This case also demonstrates FDA's commitment to protect the American public from illegal drugs that may be unsafe, ineffective, or substandard.

As of November 10, 2003, twenty-two states have taken, or are prepared to take, regulatory actions against storefront pharmacies that facilitate illegal imports of prescription drugs from Canada. .

Federal Enforcement Actions

Although the Rx Depot case is a recent prominent action, we have also taken action in other similar cases, discussed in more detail below.

CanaRx

On September 16, 2003, FDA issued a "warning letter" to CanaRx notifying the firm of our concerns about supplying prescription drugs from unregulated sources and making unwarranted claims about these products. Specifically, FDA's "warning letter" stated that CanaRx runs an Internet website and mail operation that illegally causes the shipment of prescription drugs from a Canadian pharmacy into the U.S., thereby subjecting Americans to risky imported drug products. This potential risk is compounded by the fact that CanaRx makes misleading assurances to consumers about the safety of its drugs.

An FDA investigation of this firm showed that CanaRx operates a drug purchasing arrangement that channels drugs through companies that are not licensed pharmacies and does not consistently use shipping practices necessary to ensure its drugs are safe and effective. For example, FDA has evidence demonstrating that CanaRx shipped insulin, a product that should be stored under refrigerated conditions, in a manner that did not satisfy the storage conditions specified in FDA approved labeling. This failure could genuinely compromise the safety and effectiveness of the insulin. CanaRx's response to the Agency's "warning letter" was inadequate. Therefore, on November 6, 2003, FDA sent a second letter reiterating our concerns about the potential safety of the product, and the firm's business practices, which could expose the firm's customers to unnecessary risk.

Alliance Wholesale Distributors

On September 15, 2003, FDA announced the seizure of all drug products labeled in a foreign language and/or labeled as repacked by Phil and Kathy's, Inc., dba Alliance Wholesale Distributor and/or Local Repack, Inc. ("Local Repack") of Richton Park, Ill.

FDA acted to prevent these drug products from entering the U.S. drug distribution system because there is no assurance that they are safe or effective. Many of the products received and repackaged at Local Repack are of unknown origin, and their storage and handling is unverifiable. Local Repack has repeatedly failed to comply with cGMP requirements. In addition, many drugs at Local Repack's facility are misbranded. These drugs may also pose a serious or even life-threatening risk to patients who use them.

FDA inspections conducted after an August 1999 "warning letter" to Local Repack revealed significant and continuing violations. A series of inspections and other recent evidence revealed numerous deficiencies including the failure to properly handle customer complaints, discrepancies surrounding the signatures of quality control employees, records indicating the review and approval of repackaging operations before the operations were completed, incomplete or missing repackaging records, duplicate and inconsistent repackaging records for the same batch, and unreliable receiving and distribution records for drugs.

This September seizure follows the July 9, 2003, seizure of more than 4,500 bottles of prescription drugs that were being repackaged by Local Repack stemming from an investigation of counterfeit Lipitor. Many of the products seized in July were marked with expiration dates to permit them to be sold after similar U.S.-approved drugs would have expired. For example, Portuguese-labeled product that Local Repack labeled as Lipitor had expiration dates well beyond the two-year limit that is based on stability studies performed under the new drug application (NDA) approved in the U.S. for Lipitor. Furthermore, none of these products were shipped to Local Repack in authentic, original manufacturer's packaging with appropriate labeling. This case demonstrates the Agency's continued commitments to protect consumers from potentially dangerous drugs and the litigation is ongoing.

FDA/Customs' Import Blitz Exams

This past summer, FDA and BCBP conducted a series of blitz examinations on mail shipments of foreign drugs destined for U.S. consumers. This joint operation was carried out to help FDA and BCBP target, identify, and stop counterfeit and potentially unsafe drugs from entering the U.S. from foreign countries via mail and common carriers. It was also designed to help FDA and BCBP assess the extent of this problem posed by imported drugs.

These "blitz" exams were conducted in the Miami and New York (JFK) mail facilities from July 29–31, 2003, and the San Francisco, and Carson, California, mail facilities from August 5–7, 2003, and one of the goals was to obtain a representative picture of drug products entering the United States. In each location, the agencies examined packages shipped by international mail through U.S. Postal Service facilities over a 3-day time span.

Approximately 100 parcels per day, per facility, were selected based upon their country of origin and historical experience. In some cases, packages contained multiple drug products.

Although many drugs obtained from these foreign sources purport, and may even appear to be, the same as FDA-approved medications, these examinations showed that many foreign drug products are of unknown quality or origin; have not been approved in the U.S., and may pose potentially serious safety concerns. For example, potentially hazardous products encountered during the blitz exams included:

- Unapproved drugs such as Roaccutane, an unapproved version of Accutane.

- The unapproved drug Taro-warfarin, an unapproved version of Warfarin used to prevent blood clotting. This drug requires careful blood monitoring during administration.
- Drugs such as Dilantin, Synthroid and Glucophage that require individual titration and very careful dosing in order to avoid serious and potentially life-threatening side effects.
- Drugs with missing dosage information and whose labeling was not in English.
- Inappropriately packaged drugs that were shipped loose in baggies, tissue paper or envelopes.
- Drugs that had been withdrawn from the U.S. market for safety reasons such as Buscapina, which appears to be the drug Dipyrone. This drug was removed from the market in 1977 because of several reports of cases of agranulocytosis, some of which were fatal.
- Animal drugs not approved for human use such as Clenbuterol, a drug approved for the treatment of airway disease in horses but which is also known as a substance of abuse in the "body building" community and is banned by the International Olympic Committee.
- Drugs that have the potential for clinically significant interactions with other drugs a consumer may be taking.
- Drugs such as Lipitor and Pravachol that require initial screening and/or periodic monitoring to assure safety.
- Controlled substances that are sedating, associated with respiratory depression, or have abuse potential for abuse.

These drugs arrived from many countries. For example, 15.8 percent (161) entered the U.S. from Canada; 14.3 percent (146) from India; 13.8 percent (141) from Thailand, and 8.0 percent (82) from the Philippines. The remaining entries came from other countries. Overall, of the 1,153 imported drug products examined, the overwhelming majority, 1,019 (88 percent), contained unapproved drugs.

The blitz results will assist the Agency in its efforts to:

- Employ its resources more strategically to focus on the foreign sources of illegal, unsafe imported drugs.
- Identify shipping patterns so that it can target future shipments and sources of such drugs.
- Seek out partnerships with other Federal and state agencies to combat this problem. To continue to refine its efforts at identifying and stopping potentially unsafe, imported drugs, FDA will continue to conduct additional blitzes.

Import Entry Studies

In addition to the import blitz exams described above, FDA conducted an informal study to screen and examine mail-entry drug samples from foreign countries, including Canada, during a six-week period in early summer, 2003. FDA's Buffalo and Detroit FDA import offices conducted the import entry studies. The study confirmed FDA's belief that an increasing number of U.S. citizens are choosing to fill their prescriptions through mail-order purchases from pharmacies located in Canada. During the course of this study, FDA reviewed 154 entries from Canada representing 350 drug items. In terms of safety concerns, this study affirmed what FDA has learned to expect from imported pharmaceuticals. For example, it was not possible to verify where, or under what conditions, the drugs were manufactured for any of the pharmaceutical products that were offered for import. For those drugs that were apparently ordered from websites, the need for a valid prescription was not always specified, and if the sites identified a prescription requirement, it did not disqualify prescriptions coming from other countries. Moreover, some websites specifically solicited U.S. business by stating that their drug products' quality and manufacturing requirements were "equivalent" to those in the U.S.

The following examples of imported drugs, although not specifically restricted to Canada, further illustrate the types of products and situations FDA has encountered since it started examining this issue. For example:

- Apo-Metformin, a drug used as a daily treatment for diabetic patients to prevent high glucose levels, arrived with no pharmacy label, no warnings of potential serious and life threatening side effects, no specific directions for use or instructions for proper storage, and no contact information (such as phone number) in the event that the patient needed a pharmacy or physician in the case of an emergency.

- Apo-Gabapentin, a drug used as a daily treatment for seizures. 1,200 tablets were mailed to the patient, a dangerously large volume. While the quantity could last for years for a typical patient, the product began expiring within one month of receipt.
- Lipitor, a drug used to treat elevated cholesterol, was shipped to a U.S. consumer. The product was manufactured in Germany for export to Ireland, but had been exported to Thailand and forwarded to the consumer.

The results of the July–August blitz and our import entry study concern FDA because the products we encountered move through many channels of commerce in many countries, and fall well outside established safety controls. Consequently, these products are especially vulnerable to abuses such as counterfeiting, diversion and degradation. These conditions represent safety threats to the American consumers who purchase them.

Summary Of Federal Enforcement Activity

FDA's Office of Regulatory Affairs (ORA), including the Office of Criminal Investigations (OCI), works with state and Federal investigative agencies and prosecutors to uncover violations of the FD&C Act and other laws with respect to unapproved, misbranded, illegally imported, or otherwise unsafe or substandard drug products. This includes violations associated with drugs sold over the Internet.

Recent criminal and civil cases involving drugs sold over the Internet provide insight into the seriousness of the risks these products pose to the public health. With respect to Internet drug sales, FDA to date has initiated the following actions:

- 372 Internet-related drug criminal investigations;
- 142 Internet-related drug prosecutions resulting to date, in 106 convictions;
- 90 open Internet-related drug investigations;
- Nearly 200 cyber "warning letters" sent to domestic and foreign online sellers;
- 9 preliminary injunctions;
- 19 product seizures;
- 16 product recalls and the voluntary destruction of 19 illegal products; and
- 1 Contempt Action.

Controlled Substances Cases

As a part of its larger efforts to address the illegal sale of pharmaceuticals, the Agency has committed substantial resources to controlled substances cases, including controlled substances sold over the Internet. The Drug Enforcement Administration (DEA) is the lead Federal Agency responsible for regulating controlled substances and enforcing the Controlled Substances Act (CSA). FDA has also worked with the FBI on criminal investigations involving the illegal sale, use, and diversion of controlled substances, including illegal sales over the Internet. FDA's Office of Criminal Investigations (OCI), however, is responsible for managing and conducting the Agency's criminal investigations. OCI conducts these investigations with support from other Agency components. In some cases, illegal activity may involve both imported and domestic controlled and non-controlled prescription drugs, and thereby violate the FD&C Act and the CSA. Even though FDA does not initiate investigations where the sole violation is thought to be a CSA offense, OCI works closely with DEA on criminal investigations involving the illegal sale, use, and diversion of controlled substances, including illegal sales over the Internet. This close working relationship with DEA, as well as with local law enforcement agencies, has led to the successful prosecution of many criminal cases involving controlled substances. These cases show the extent to which criminal investigations involving controlled substances can quickly encumber the resources and finances of local and Federal law enforcement agencies in their attempts to combat the growing problem these drugs present.

FDA has investigated drug diversion schemes and hundreds of illicit Internet sites by reassigning its criminal investigative staff from other priority efforts. Our goal is to reduce the illegal promotion, sale, and distribution of unlawful prescription drugs via the Internet and other channels and this can include controlled substances. These efforts have protected consumers from unsafe, ineffective, and fraudulent products that present a danger to the public health. Here are some of our most recent cases involving controlled substances:

- In August 2003, a doctor pled guilty and was sentenced to 30 months' imprisonment for conspiring to dispense Schedule III and IV controlled substances. The conspiracy transpired via a web-based pharmacy with an Internet address of *www.thepillbox.com* and a physician referral service with the Internet address

of *www.physicianreferral2000.com.* From 1999 through early June 2001, customers in the U.S. and abroad who accessed Pill Box's website would be referred to the physician referral website to obtain prescriptions prior to placing their orders. The doctor would prescribe drugs such as hydrocodone and diazepam (Valium) to customers without establishing a patient history or performing a mental/physical exam, and despite the fact that he had no means to monitor the medications' response. Moreover, whenever a prescription was issued, the doctor and Pill Box would subsequently split a "fee" for the service. Over the course of the conspiracy, the doctor illegally prescribed, and Pill Box dispensed, over 4,214,945 dosage units of hydrocodone and 537,080 dosage units of diazepam. This enterprise grossed more than $7.7 million from Internet sales of these two drugs alone. This case was the product of an 18-month investigation by the DEA, FDA, IRS and the U.S. Attorney's Office.

- In August, 2003, an individual pled guilty to charges relating to various counts of conspiracy, distribution, and importation of controlled substances as a result of a case initiated by OCI in July 2000 after the individual was identified as the principal for Vinci-online and CFF Pharma Consult. The website domain used by the defendant, Vinci-online.com, was found to be registered to CFF Pharma Consult at an address in Germany. Vinci-online.com offered golf training services and investments, along with pharmaceutical drug products including controlled prescription drugs, antibiotics, anti-allergenics, weight loss medications, steroids, and hormones for sale via its website. Agents made several undercover purchases of prescription drugs from the website without providing prescriptions. Following the e-mail purchase request, an invoice was generated instructing the purchaser to send a money order or cashier's check to Vinci American Ltd. in Las Vegas, NV. The products received as a result of these online purchases were sent from Germany and contained German labeling.

Drug Counterfeiting Cases

FDA takes very seriously any allegations or information regarding the counterfeiting or adulteration of drug products. As the drug manufacturing and distribution system has become more global in nature, the challenge of protecting against counterfeit, adulterated or substandard drugs has become more difficult. The Agency is concerned about a spate of drug counterfeiting and tampering cases that have occurred in recent months, and is aggressively pursuing these types of enforcement cases.

FDA's OCI has opened 85 counterfeit drug cases since October 1996. Investigations have so far netted 44 arrests and 29 convictions. Fines and/or restitution have been imposed in excess of $250,000.

Over this timeframe, however, FDA has witnessed a gradual, but troubling, increase in the incidence of finished dosage form counterfeit activity. Much of this activity has targeted high volume, high cost drugs where counterfeiters attempt to obtain the highest return possible in a short time period. Many of these drugs are used for treating cancer and AIDS patients. However, Viagra and Lipitor have also been counterfeited. The public perception of a more dramatic increase in counterfeit drug activity stems from the fact that the latest several counterfeits have appeared in the wholesale market and received wider distribution than has been the case historically.

FDA Counterfeit Drug Initiative

In July 2003, Commissioner McClellan announced a major new initiative to more protect American consumers from drugs that have been counterfeited. The initiative includes creating an internal task force to explore modern technologies and other measures to make it more difficult for counterfeit drugs to be distributed with—or deliberately substituted for—safe and effective drugs.

The task force submitted its initial findings in an interim report presented to the Commissioner in October 2003, and will issue a final report in early 2004, after opportunities to hear from the public. In addition, FDA plans to coordinate more closely with other Federal agencies and state and local governments that share the responsibilities with FDA for ensuring the safety of the U.S. drug supply and distribution system as well as with members of Congress who have worked closely with FDA in the past on these important public health issues.

Counterfeit prescription drugs are not only illegal but also are also inherently unsafe. Many counterfeit drugs are visually indistinguishable from the authentic versions, and thus pose a potentially serious health threat to Americans.

Although FDA believes domestic counterfeiting is not widespread, the Agency has recently seen an increase in counterfeiting activities as well as a more sophisticated ability to introduce finished dosage counterfeits into the otherwise legitimate drug

distribution channels. FDA has likewise seen its counterfeit drug investigations increase to over 20 per year since 2000, after averaging only about 5 per year through the late 1990s.

At the same time, worldwide counterfeiting of drugs is believed to be more commonplace. The World Health Organization has estimated that perhaps seven or eight percent of drugs worldwide are counterfeit, and reports from some countries suggest that as much as one-half of those countries' drugs are counterfeit.

FDA's initiative is designed to better identify the risks and threats from counterfeit drugs, to coordinate public and private efforts to fight drug counterfeiting and distribution, and to develop new tools to aid in identifying, deterring and combating counterfeiting. Specifically, the FDA task force will:

- Develop a strategic action plan to decrease the risk of counterfeit drugs entering the U.S. marketplace and to protect consumers from potentially harmful effects of using these products.
- Continue to strengthen FDA's collaborative relationships with other Federal agencies, including the Bureau of Immigration and Customs Enforcement (BICE), BCBP, and the U.S. Secret Service in the Department of Homeland Security and entities within the Department of Justice, as well as with health professionals, industry, consumer, and other stakeholders to gather information regarding the best practices for dealing with drug counterfeiting.
- Identify mechanisms for strengthening the Nation's protections against counterfeiting, including such possibilities as developing state model practice acts, best practices for those who sell and distribute prescription drugs, and better education for patients, pharmacies, and others about how to identify counterfeit drugs and alert others to their existence.
- Assess the extent to which new technologies, *e.g.,* counterfeit-resistant packaging, product identifiers such as chemical taggants, and implanted radio-frequency chips in packaging can help assure the authenticity of drugs. Although some of this technology is not currently mature enough to adequately protect the drug supply, it may have great promise as an added counter-measure against counterfeit pharmaceutical products.

FDA believes the increase and shift in this illicit activity has occurred for a number of reasons. These include:

- Better counterfeiting technology, including improved technology to make labeling, packaging and products that appear real.
- Better organized, more effective criminal groups attracted by financial opportunities.
- The use of the Internet as a sales tool by unlicensed pharmacies and/or foreign websites.
- Opportunities for introducing foreign-made counterfeit and unapproved drugs into large and rapidly growing import flows.
- Weak spots in the domestic wholesale drug distribution chain, including some wholesalers who acquire most of their inventory from secondary sources, do not maintain effective due diligence efforts on these sources and ignore warning signs indicative of illegal or unethical behavior.

The details of what we have cataloged so far in this initiative were released in an interim report dated October 2, 2003.

Reporting of Information on Counterfeit Drugs by Manufacturers

In another move to respond to the increase in counterfeit drug cases and to strengthen the Agency's and industry's collaboration in those situations where counterfeit drugs are suspected, on April 22, 2003, the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the country's major research-based pharmaceutical and biotechnology companies, announced the adoption of a voluntary program to report suspected instances of drug counterfeiting to FDA. The information provided by PhRMA members under this program will assist FDA in carrying out its responsibilities to protect the safety and integrity of the Nation's drug supply. It will enhance the Agency's ability to detect quickly and remove counterfeit drugs from the marketplace.

Under this program, PhRMA member companies have agreed to notify FDA's OCI within five working days of determining that there is a reasonable basis to believe that a product has been counterfeited. The program also applies to counterfeits discovered in foreign countries if there is clear evidence that the counterfeits are intended for distribution in the U.S. Drug manufacturers already conduct their own

investigations of suspected distribution of counterfeit drugs. This formal collaborative agreement will strengthen FDA's ability to assure the safety and effectiveness of drugs used by U.S. The reporting program went into effect on May 1, 2003 and has already led to some useful tips. The two most recent cases of counterfeit prescription drugs in which FDA has played a significant role are those involving the drugs Procrit and Lipitor.

Procrit

On May 21, 2003, the U.S. Attorney's Office for the Southern District of Florida filed charges against Eddy Gorrin, William Chavez and Duviel Gonzalez for unlawful sale and wholesale distribution of counterfeit versions of Amgen, Inc.'s, prescription drug Procrit, a medication indicated mainly to help cancer, anemia and HIV patients increase their red blood cell count.

Between January and February 2003, Gorrin intentionally engaged in the sale of counterfeit versions of Procrit. During that same time period, Chavez and Gonzalez also were engaged in unlawful wholesale distribution of counterfeit Procrit without a state license. The undercover operation and tests conducted by FDA's Forensic Chemistry Center revealed that the vials being distributed by all three men labelled as "Procrit" did not contain any active ingredient for Procrit, but instead, contained only bacteria-tainted water. In early June 2003 all three defendants plead guilty to criminal charges in the Southern District of Florida. Gorrin was sentenced to a 3-year, 1-month Federal prison term; Chavez was sentenced to 3 months in prison, and Gonzalez was sentenced to 6 months house arrest for their respective roles in this counterfeit operation.

Lipitor Investigation

On May 23, 2003, FDA issued an alert on a counterfeit version of Pfizer, Inc.'s, prescription drug, Lipitor. The alert warned health care providers and others that three lots of counterfeit Lipitor represent a potentially significant risk to consumers. One in five people have high cholesterol that may lead to cardiovascular disease, such as heart disease and stroke. According to the American Heart Association (AHA), every 33 seconds, someone in the U.S. dies from cardiovascular disease. (Source: AHA 2002 Heart and Stroke Statistical Update) Lipitor is the number one prescribed cholesterol-lowering medication, and is currently used by more than 18 million people. Lipitor is proven to lower total cholesterol and decrease the risk of developing cardiovascular disease. FDA investigators have aggressively pursued a variety of leads all along the supply and distribution chain in an effort to identify the source of this counterfeit activity and to facilitate the recall of any counterfeit products.

In conjunction with the manufacturer of this product, FDA also issued several press releases warning consumers and pharmacists about the counterfeit Lipitor and providing guidance to identify of any suspect product. For example, FDA published a list of lot numbers to identify the counterfeit product. We also urged health care providers and patients alike to check the packaging very carefully before using this product. Patients who had the product (labeled as "Repackaged by MED–PRO, Inc.") with the specified lot numbers were told not to consume it, and to return the product to their pharmacies. Because of the breadth of the distribution of counterfeit products, FDA issued several warnings.

FDA's advice to health care providers and consumers remained the same as when the Agency issued its original alert on counterfeit Lipitor. They should check the packaging very carefully before using Lipitor. Patients who have any of the product with any of the lot numbers we identified should not take it, and they should return the product to their pharmacies.

As part of the FDA's ongoing efforts to investigate and respond to unscrupulous counterfeiting activities, FDA's OCI is investigating this case of counterfeit Lipitor in carrying out its public health mission. The investigation is ongoing but it appears that some of the counterfeit product originated from overseas.

Other Counterfeit Cases

Other counterfeit prescription drug cases in which FDA has had a central role include:

- *Serostim (somatropin (rDNA origin)) for injection*—In late 2000 and early 2001, FDA became aware of consumer complaints about adverse effects, and a recall was initiated at the distributor level for Serostim, a growth hormone often used to treat AIDS wasting. After further investigation by the manufacturer, Serono, Inc., and FDA, Serono issued press releases regarding the apparent counterfeiting of two lots of the product. In May 2002, Serono became aware that counterfeit Serostim displaying a fake lot number again had been distributed. Lab-

oratory analysis by FDA showed that the product contained no active ingredient, and that the product did not originate from Serono.

- *Neupogen (filgrastim) for injection*—In the spring of 2001, based on observations by a distributor about the appearance of Neupogen, a colony stimulating factor used mostly in cancer patients, the manufacturer, Amgen Inc., analyzed a suspect lot and determined that the vials contained only saline solution. Amgen issued Dear Health Care Professional letters nationwide informing patients, physicians, pharmacies and wholesalers about the counterfeiting of Neupogen. The counterfeit product was labeled with fake lot numbers and/or wrong expiration dates.
- *Epogen (epoetin alfa) for injection*—In May 2002, FDA, state regulators and the manufacturer, Amgen Inc., became aware that a potential counterfeit of Epogen was in commerce. Epogen is used to stimulate red blood cell production in cancer and AIDS patients. Amgen analysis indicated that certain vials of a counterfeit product labeled as Epogen contained active ingredient approximately 20 times lower than expected. Further investigation revealed that a major wholesale distributor was holding approximately 1,600 cartons of counterfeit product. Later that month, Amgen warned health care professionals that two additional counterfeit lots of Epogen had been discovered.
- *Combivir (lamivudine plus zidovudine) tablets*—In the spring of 2002, the manufacturer, GlaxoSmithKline (GSK) received four complaints that bottles containing 60 tablets of Combivir had been replaced with Ziagen tablets. In addition, the firm determined that counterfeit Combivir labels had been placed on authentic bottles of Ziagen tablets, a different GSK product with a label containing a black box warning about the dangers of possible fatal hypersensitive reactions to Ziagen. A black box warning placed at the beginning of an FDA-approved label is the strongest warning to prescribing physicians, health care professionals and consumers, that severe adverse reactions have been experienced from use of the product. Both Combivir and Ziagen can be used as part of a combination regimen to treat HIV infection. The concern in this case was that if an individual were to take the wrong tablet and is sensitive to Ziagen, a potentially life-threatening hypersensitivity reaction could occur. In May 2002 distributors were advised to initiate a recall to their customers.
- *Zyprexa (olanzapine) tablets*—In the winter and spring of 2002, bottles of Zyprexa, an Eli Lilly and Company product, indicated for the treatment of schizophrenia and acute bipolar mania, had been emptied and replaced with white tablets labeled as aspirin. The tampering situations occurred in two strengths and in three different lots. In May 2002 Lilly issued a press release and Dear Health Care Professional letter concerning the tampering situation.

FDA Import Enforcement Efforts

FDA has conducted numerous investigations and enforcement activities of imported products. The Agency has taken action when it believes imported products, including prescription drugs, pose a significant public health risk. FDA takes regulatory action in the import arena, which covers a wide range of products including foods, drugs, medical devices, human and animal drugs and biological products. If a situation appears to involve criminal activity, FDA's ORA has the option of referring the information to the Agency's OCI.

FDA has a number of enforcement tools that can be used to regulate imported products. These include: (1) "warning letters," (2) recalls, (3) seizures, (4) injunctions, or (5) prosecution. FDA may issue a "warning letter" in a number of scenarios including when: (1) a party fails to hold its entry intact before FDA releases it, (2) a party consistently imports in violation of the FD&C Act, or (3) an importer presents misleading information, or (4) FDA informs an importer that the Agency has requested that BCBP deny immediate delivery privileges.

FDA also may ask a firm to voluntarily recall an imported product if FDA deems it a potential health hazard or if there is some evidence of distribution of detained or refused merchandise. FDA may opt to seize a product if it: (1) represents a health hazard and has been or is likely to be distributed following detention or refusal, (2) has been previously refused, or (3) has been identified fraudulently in documents submitted to FDA.

Injunction may become the action of choice when FDA sees a pattern of violations with some recognizable danger of reoccurrence. This is a judicial action that may result in quicker corrective action than a prosecution, and, if successful, it legally enjoins the defendants from continuing to violate the law. Prosecution may be used when conventional import enforcement approaches are determined inadequate to correct violations or the violation is sufficiently egregious to warrant punishment.

Prosecution may be warranted when there is: (1) continued illegal distribution after receipt of a notification of detention, (2) submission of false or misleading entry documents, (3) repeated entry of previously refused products, or (4) evidence of fraud.

None of the potential actions described above are mutually exclusive. In some cases, FDA may take complementary steps that involve a combination of these actions in order to protect the public health from drugs that violate the FD&C Act. Evidence of this type of mix of regulatory actions can be seen in FDA's ongoing work on counterfeit Lipitor.

Many imported prescription drugs that are arriving at mail facilities are ordered over the Internet. 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. In some cases the Agency will conduct exercises to better understand the products that are coming in through specific ports-of-entry. As discussed above, the Agency is conducting import exercises to 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. However, due to the ever increasing volume of imported drugs and multiple competing enforcement priorities, the Agency is working on focusing its resources more efficiently.

Improvements to FDA's Import Compliance Program

FDA is re-evaluating, refining, and improving the programs and procedures that it is using to ensure the availability of safe and effective drugs to U.S. consumers. As part of our efforts to improve the programs and procedures that are used to ensure the availability of safe and effective drugs to U.S. consumers, FDA is considering several concepts that will improve the Agency's ability to target resources applied to regulation of imported drug products. As with all of FDA's activities, priorities are established based on benefit/risk to public health. In terms of prioritizing the Agency's domestic and import compliance workload, products that present a direct health hazard to the user are FDA's highest priority. Such products include those that have a reasonable potential for causing direct serious adverse effects, or where there is documentation of injury or death. Examples of such products include counterfeit Procrit and counterfeit Serostim. Products that are not themselves hazardous can still present an indirect health hazard in that the consumer may delay or forgo proven medical treatment and the use of approved therapies. These are also a top priority for the Agency. Examples include unapproved products that are promoted for the treatment of cancer, Alzheimer's disease, arthritis, heart disease, high cholesterol and high blood pressure.

ORA Enforcement Successes

AstraZeneca

On June 20, 2003, officials from FDA's OCI joined with representatives of the U.S. Attorney's Office for the District of Delaware, the Department of Health and Human Services (DHHS), and the Defense Criminal Investigative Service (DCIS) to announce that AstraZeneca Pharmaceuticals LP had pleaded guilty to a large-scale health care crime. The firm agreed to pay $355 million to resolve the associated criminal charges and civil liabilities. The massive conspiracy involved illegitimate pricing and marketing of Zoladex, an AstraZeneca drug for the treatment of prostate cancer. The various schemes used by the firm caused multimillion-dollar losses to Federally and state-funded insurance programs and individual patients.

FDA's OCI began investigating AstraZeneca's pricing and marketing practices after a private individual filed a civil False Claims Act suit. The broadly-based investigation, which also involved the Office of the Inspector General for the DHHS, the DCIS and the Federal Bureau of Investigation, discovered that AstraZeneca employees were using several illegal methods to stimulate the demand for Zoladex by enabling prescribers to reap illicit profits.

The agreement included the following provisions:

AstraZeneca pleaded guilty to criminal conspiracy to violate the Prescription Drug Marketing Act by causing Medicare, Medicaid and other Federal providers to be overcharged for Zoladex that had been provided as free samples to urologists. As part of the plea agreement, the company agreed to pay a $63,872,156 criminal fine.

- AstraZeneca also agreed to settle its civil liabilities and to resolve allegations that its fraudulent drug pricing schemes, and sales and marketing misconduct had caused false and fraudulent claims to be filed with Federal and state health care programs.
- AstraZeneca agreed to payments of $266,127,844 to the U.S. Government for claims filed with the Medicare, TriCare, Department of Defense and Railroad

Retirement Board Medicare programs, and $24,900,000 to the U.S. and state governments for claims involving state Medicaid programs.

The investigation, which is continuing, also resulted in charges against three physicians for conspiring with AstraZeneca to bill patients and third party payers for free Zoladex samples. Two of the prescribers have pleaded guilty.

Procrit

As previously stated, on May 21, 2003, the U.S. Attorney's Office for the Southern District of Florida filed charges against Eddy Gorrin, William Chavez and Duviel Gonzalez for unlawful sale and wholesale distribution of counterfeit versions of the prescription drug Procrit. In early June 2003, all three defendants plead guilty to criminal charges in the Southern District of Florida. Subsequently, the defendants received sentences of 3 years, 1 month in prison; 3 months in prison; and 6 months' house arrest, respectively.

Lipitor

As described in detail above, FDA's ORA is conducting a significant investigation to respond to unscrupulous counterfeiting activities involving Lipitor. FDA is conducting this activity in close cooperation with health professionals, particularly pharmacists and pharmacy associations and has issued statements to alert the public about this counterfeit product.

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 that in the overwhelming majority of applications, no medical reviews, consultations, or physical examinations by a physician took place before drugs were shipped to customers. Defendants repackaged drugs obtained from a drug wholesaler, even though defendants were not a registered manufacturer or a licensed pharmacy and there was never a licensed pharmacist involved. 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. In October 2003, one of the physicians entered a guilty plea. Legal proceedings against the other defendants are ongoing.

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 an 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, plead guilty to five misdemeanor counts

of dispensing drugs without a valid prescription (21 USC 331[k]). 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 been manufactured in New Zealand for distribution in Australia.

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 2 years in prison. The case was initiated on information received from BCBP concerning an Internet website called Medications Express. Bevins sold Mexican prescription pharmaceuticals from this website and claimed that a doctor's prescription was not 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.

Dagoberto Paz-Tamez diet drug case

This case involved the sale of unlabeled/adulterated diet drugs in Pasadena, Texas by an alleged medical doctor from Mexico. The alleged doctor, Dagoberto Paz-Tamez, is not licensed to practice medicine in the state of Texas or anywhere else within the U.S. This case was assembled in conjunction with the Harris County Precinct 6 Constable's Office, the Texas Department of Public Safety (DPS), and the U.S. Postal Inspection Service.

Investigation revealed that Paz-Tamez had been selling unlabeled diet pills to patients for several years in the Pasadena, Texas area. A sample of the diet pills was submitted to the Harris County Precinct 6 Constable's Office by a confidential informant. These samples were later submitted to FDA's Forensic Chemistry Center and were found to contain amphetamines and other dangerous substances.

On August 22, 2002, Paz-Tamez was arrested in Pasadena, Texas. Law enforcement officials seized diet drugs and U.S. currency consisting of the following: $10,236 in U.S. currency, 4,350 tablets, 30,488 gelatin capsules, and 44.5 pounds total weight of unlabeled diet drugs. The diet pills and tablets seized were found to contain mazindol (an amphetamine discontinued in the U.S.), diethylpropion (an amphetamine), diazepam (generic for Valium), and hydrochlorothiazide (a diuretic).

On March 16, 2002, Paz-Tamez was convicted of Possession of a Controlled Substance and Delivery of a Dangerous Drug. He was later sentenced to ten years of deferred probation.

Conclusion

The standards for drug review and approval in the U.S. are the best in the world, and the safety of our drug supply mirrors these high standards. The employees of FDA constantly strive to maintain these high standards. However, a growing number of Americans are obtaining prescription medications from foreign sources. U.S. consumers often seek out Canadian suppliers, sources that purport to be Canadian, or other foreign sources that they believe to be reliable. While some foreign drug manufacturers submit their products to FDA for approval, the imported drugs arriving through the mail, through private express couriers, or by passengers arriving at ports of entry are often unapproved new drugs that may not be subject to any reliable regulatory oversight. FDA cannot assure the safety of drugs purchased from such sources.

The vigilance of FDA and BCBP inspectors is an important tool in detecting imported products that violate the FD&C Act. Given the available resources and competing priorities facing these agencies, however, experience shows that inspectors are unable to visually examine many of the parcels containing prescription drug products that arrive through the mail and private courier services each day. Many of the packages that the Agency is able to examine appear to contain foreign versions of U.S.-approved products. The growing volume of unapproved imported drugs, which often are generated from sales via the Internet, presents a formidable enforcement challenge.

The Agency has responded to the challenge of importation by employing a risk-based enforcement strategy to target our existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety and coun-

terfeit drugs. As an example, the Agency utilizes Import Alerts to identify particular shipments that may pose significant potential risk to public health, *e.g.,* drugs that require careful risk management and products from shippers known to present significant safety problems. However, this system is already overwhelmed by the number of incoming mail packages that must be evaluated and this state of affairs presents a significant ongoing challenge for the Agency. In sum, at this time the Agency cannot assure the American public that drugs purchased from foreign sources are the same as products approved by FDA, or that they are safe and effective.

FDA firmly believes that we can and should do a much better job of making safe and innovative drugs more affordable in the United States, but to succeed we need to find safe and affordable solutions that, when implemented, do not put consumers at risk. We appreciate and support the commitment to making drugs more affordable for seniors and other consumers and are working hard to achieve this goal. However, the Agency continues to believe that we must focus on solutions that do not put at risk safety in an effort to achieve increased affordability.

The CHAIRMAN. Thank you, sir.

I think it might be important to enter in the record a Congressional resource memorandum that was given to Congressman Gutknecht, which is very interesting. It says, "This memorandum is in response to your request regarding statutory language that expressly limits the reimportation of products to the manufacturer of the product, as is the case with respect to pharmaceutical importation." They go on to say, "We've been unable to locate any statutory provisions similar in language and structure to the one in the Food, Drug, and Cosmetic Act." In other words, anything else can be reimported—chemicals, pollutants, munitions—anything else, except for drugs. And it's remarkable testimony to the power of the pharmaceutical industry in the legislative body.

Governor, your Minnesota plan, now, has it been adopted by the legislature?

Governor PAWLENTY. Mr. Chairman, we don't believe we need legislative authority for it. We're pursuing it administratively, and we believe we can implement it without legislative approval.

The CHAIRMAN. If you went to the legislature, could you get it?

Governor PAWLENTY. I believe so, yes.

The CHAIRMAN. Let me suggest that you do, just so that you get that stamp of approval. What do you see as an impediment to the implementation? What do you foresee roadblocks are going to be in your way here?

Governor PAWLENTY. Mr. Chairman, it's mostly the allegations from the pharmaceutical industry, and, candidly, from the FDA, that this could raise safety concerns. And my first response to that is, show me the dead Canadians. You know, where are the dead Canadians? And we're not talking about rogue Internet sites in Malaysia or, you know, some third-world country. We're talking about established, credible, reputable, accredited pharmacies that we have identified.

The CHAIRMAN. Do you think legal action will be taken to try to prevent you from implementing this plan?

Governor PAWLENTY. We hope not. Candidly, we've gotten some mixed signals. In a Boston newspaper, an FDA official was reported as saying they would unlikely go after a state or a government entity that tried an approach like ours. But, more recently, their comments have been more ambiguous, and they have said they are reserving their options. Now, if they sue me, I'm willing

to be sued. If they want to throw me in prison, that's something I at least have to give some pause to.

[Laughter.]

Governor PAWLENTY. And I'm hopeful that—it might not deter us, but I at least need to think about that. So I'd like to get some signals from them before they prosecute me.

The CHAIRMAN. Well, Governor, given the threat that this really poses to the pharmaceutical industry, if I were you I'd be prepared for most anything, and that's why I suggest that you go to the legislature. These people will stop at nothing. Because if this works in Minnesota, it's going to work in every northern state, and sooner or later it's going to work in every other state. So stand by, sir, because I wouldn't be surprised at whatever they would do, including what's already been rolled out, and that is, of course, the needless deaths of so many citizens.

Governor PAWLENTY. I appreciate it. Mr. Chair, could I add one other quick thing?

The CHAIRMAN. Sure.

Governor PAWLENTY. You've visited our Veterans Hospital in Minneapolis—and thank you for your leadership on that issue, as well—but at the Veterans Hospital in Minneapolis, it's federally regulated, federally funded, federally administered. They have a pharmacy there. Guess what? They mail out lots of prescriptions every day. And if you assume the pharmacies that we would contract with and identify in Canada are credible, we know—we already have in place the distribution mechanisms, because our Vets Hospital does it. So do lots of other approved, established pharmacies in Minnesota and elsewhere. It can be done, Mr. Chair. We're just asking for a chance to try.

The CHAIRMAN. I have visited that facility. And another point about the pharmacy there, the drugs that they acquire are much less expensive than drugs that are acquired outside of the VA or DOD because they bargain the prices.

Governor PAWLENTY. Thank you, Mr. Chair.

The CHAIRMAN. Thank you.

Senator Dorgan?

Senator DORGAN. Mr. Chairman, thank you very much.

First of all, Governor Pawlenty, thank you for a refreshing approach to this issue. I have written you a letter, about 2 weeks ago, actually a joint letter to you and the Governor of North Dakota, suggesting that we create an alliance and that both states move together on this. I think what you're doing is innovative and interesting, and I encourage you and am pleased that you're here to present testimony today.

Mr. Taylor, I know that you are here on behalf of Commissioner McClellan, and I deeply regret that he is not here. I don't know the reason for that. But I must tell you that your testimony is extraordinarily disappointing to me. The behavior and the actions of the FDA have been very disappointing to me. They are not in the character, in my judgment, of an agency that is really interested in the safety and well-being of the American people. They seem almost too anxious to find a way not to help the American people on this issue of pricing.

And I want to ask you a question. Do you know anything about meat inspection, Mr. Taylor?

Mr. TAYLOR. A little bit, sir.

Senator DORGAN. Do you know how we handle meat inspection with Canada?

Mr. TAYLOR. My understand is that USDA actually has people stationed overseas and help——

Senator DORGAN. I'm talking about Canada.

Mr. TAYLOR. I mean, or Canada or——

Senator DORGAN. There's no body of water in North Dakota.

Mr. TAYLOR. In other countries. And they help ensure that before the product is imported, that the product meets standards here in the United States.

Senator DORGAN. You know what we do? Let me tell you what we do, because if you were at Pemina, North Dakota, today at the border, you'd discover that there's a truckload of meat that comes from Canada into our marketplace. That meat has been inspected by the Canadians in a Canadian meat plant, and we say that we will allow reciprocal treatment with respect to inspections. We accept their inspections, and they accept our inspections as having represented the issue of safety for both people. And so we have decided that reciprocal treatment across the border with respect, for example, to inspecting meat—and so that meat comes across in a truck, we say, "Inspected in a Canadian plant? Good enough for us," because we've taken a look at that.

OK. So if that's the question with respect to meat, you're saying that drugs are different. And so let me ask this question. A pharmacist from Grand Forks, North Dakota, licensed by our state, studied in pharmacy, running a drugstore and practicing pharmacy in Grand Forks, goes to Winnipeg, Manitoba, and goes to a pharmacist in Winnipeg, Manitoba, licensed by that country, which I think you will admit has a nearly identical chain of supply and custody for their drugs. Would you tell me that in that circumstance there is any danger at all to the consumers in this country, when that Grand Forks, North Dakota, pharmacist acquires that Tamoxifen at the Winnipeg pharmacist and brings it back and passes the savings along to the consumers? Describe to me the danger to the consumer in that transaction.

Mr. TAYLOR. Sure. And let me take a step back. We think that the—we think that the Canadian regulatory system is a good one, and we are by no means suggesting that Canadian drugs are not bad. The problem, though, is that the Canadian system, like the U.S. system, is essentially designed to afford protection to its citizens. And so the potential harm here—and the Canadian authorities have said this—is that their authorities are not really set up to ensure that products that are exported from Canada to the United States are safe and effective. And so there's a little bit of a regulatory gap between the Canadian regulatory system and the U.S. regulatory system. So when we are talking about our concern regarding products that are imported to the United States, it's because those products are being imported outside the U.S. regulatory system, and they also are being exported outside the Canadian regulatory system, which allows this gap and the potential for

abuse and the introduction of products of unknown origin or quality.

Senator DORGAN. Mr. Taylor——

Mr. TAYLOR. So that's the concern.

Senator DORGAN. Mr. Taylor, that is just not true. It's just—I mean, you can say it, but it is just not true that—if, in the circumstance that a U.S. pharmacist, who is licensed, or a U.S. distributor, licensed, accesses a supply of prescription drugs from a licensed pharmacist or distributor from Canada, it is not true that somehow that is outside of the established regulatory framework. You can say it, but it is not true.

Mr. TAYLOR. With all due respect, Senator, it is true. Because at the end of the day, that—that example does not necessarily get to the quality or origin of the product that is being discussed and being passed between the two pharmacists. That is one of the potential risks. And we have tangible examples of that.

Senator DORGAN. Mr. Taylor——

Mr. TAYLOR. Yes.

Senator DORGAN.—Vioxx. If you are a licensed pharmacist in this country and you drive to Canada today to buy Vioxx from a licensed pharmacist in Canada, and you pay not the $2.20 a tablet that you would pay as a U.S. consumer, but $.78 a tablet, because the same drug in the same bottle made by the same FDA-approved company is marketed in Canada for less than a third, there is no circumstance under which that is leaving the regulatory framework of the U.S. and Canada. The person that sold it to you in Canada is licensed and part of the chain of custody. And you, as a licensed pharmacist in this country, are part of the chain of custody. You're simply wrong when you say that somehow this is outside of the regulatory framework.

Mr. TAYLOR. Sir, as I noted in my written testimony, there are certainly circumstances where an overseas manufacturing facility will manufacture a product for the American market, but they will also manufacture a product for other markets. For example, they might manufacture a product for Asian, Canadian, European market. In some cases, those products are very identical, but they do not have to undergo the same requirements as a product that is introduced here in the United States. So there still is a difference in those two products, albeit in some cases smaller than if the product was completely unapproved and had not undergone any type of testing for safety or efficacy.

Senator DORGAN. Mr. Taylor, you know, look, I'm not trying to browbeat you here, but it is just too labored for you to get to that point and then find out you're wrong. I mean, you say "very identical." It's either identical or it isn't. And the fact is, Lipitor, which is sent to this country and to Canada from Ireland, and I assume produced in Ireland as a result of materials that are gathered from Asia and other parts of the world, producing a pill in Ireland, put in this bottle, and sent in identical form to a pharmacist in Canada and the U.S., the only thing that is not identical is the price. The U.S. consumer pays triple. And the Governor says that there is a way to access that supply without at all injuring his constituents, because it would still be within the chain of custody, especially with respect to pharmacists and licensed distributors.

But let me make one other point, if I might. Mr. Taylor, you've heard testimony today that we have one-million-plus people who go across to Canada to buy those prescription drugs. Lewis Lubka is going to testify. Lewis is right over there. Lewis, would you wave? Lewis actually went to Canada with me to the one-room pharmacy in Emerson, Canada, and bought some prescription drugs. He knows what he bought. He bought the identical drug in the identical container made by the same company with exactly the same safety standards.

Now, can you cite one instance—not a bunch—one instance in which a U.S. consumer has been harmed by accessing a prescription drug from Canada?

Mr. TAYLOR. I do not have—I do not have any reports of death. However, based on the information, the blitzes that we've done, and the information that we've seen from products coming from Canada—for example, as part of our blitzes this summer, we noticed controlled substances coming from Canada, which are, per se, potentially harmful, we noticed products that did not have the requisite labeling, which is potentially harmful, we certainly know that there is a potential for harm that could befall some citizens who are——

Senator DORGAN. Well——

Mr. TAYLOR. And, if I may, Senator, going back to your Lipitor example—and you might not find this compelling, but it's illustrative of our concerns—in the context of Lipitor, this summer we had one of the biggest drug recalls ever in regards to a counterfeit product, and it involved Lipitor. One of the challenges for the FDA, and one of the challenges in terms of educating consumers, is that many of the bottles contained FDA-approved Lipitor for—Lipitor that was manufactured and approved for foreign countries, as well as purely counterfeit Lipitor. One of the difficulties that we had in protecting the public health was getting out a public-health message that explained to consumers why they need to be careful. And the reason that was so difficult was, when we did the testing there was very little difference, at times, between the foreign version, the FDA- approved version, and the counterfeit version. But that difference was enough so that it could negatively impact the benefits that patients were deriving.

And so I'm just saying that that's a situation where ostensibly it looks somewhat innocuous, but, in this case, the counterfeiters used and introduced FDA-approved product, foreign-version product, and counterfeit product in the same bottles, which had a confounding effect. And so those are some of the situations that are of concern to us.

Senator DORGAN. Mr. Taylor, I might just conclude by saying that that's not exclusive to prescription drugs. That could be Similac, baby food, couldn't it?

Mr. TAYLOR. You're absolutely correct.

Senator DORGAN. I've seen two cans of baby food—one counterfeit, one not.

Mr. TAYLOR. You're absolutely correct.

Senator DORGAN. So why don't we have a law banning the reimportation of baby food? I can think of a thousand items that we might want to do this to we start down that road.

Our point is this. A piece of legislation that is protective of the interests, with respect to safety, and against counterfeiting, that allows a chain of custody in Canada to represent a connection to the chain of custody in this country, and, therefore, afford American consumers lower prices for prescription drugs, is something that I would hope the FDA would find a way to help us implement, instead of going out of his way—Mr. McClellan goes out of his way to see if he can't find a way to stop this stuff. It's almost as if he represents the prescription drug industry rather than has some interest in American consumers. I regret he's not here today, because I think he is creating a terrible record on behalf of the FDA.

I don't mean to—you're here, I know, at his request, and your job is to represent what the FDA's current views are, according to Mr. McClellan.

One final point. You know that the FDA even communicated with an insurance company in North Dakota to say, "We demand that you not cover prescription drugs, even if you have a prescription drug piece in your insurance policy. We demand that you not cover it if they get it from Canada." I mean, that's the sort of nonsense that's going on with the FDA, and I regret it.

Mr. TAYLOR. Sir, can I—and in regards to the insurance company, I remember your exchange with Dr. McClellan on that at the appropriations——

Senator DORGAN. I was no happier that day, was I?

[Laughter.]

Mr. TAYLOR. No, sir, you were not. We, indeed, are going to address that concern, and then we are going to send you a letter by the end of the day. And what the letter is going to state is that for insurance companies that are merely reimbursing, it's not a concern for us.

Senator DORGAN. But that exchange took place, I think, probably 8 months ago.

Mr. TAYLOR. Fair point.

The CHAIRMAN. Senator Snowe?

Senator SNOWE. I think I want to yield to Senator Wyden.

The CHAIRMAN. Senator Wyden?

Senator WYDEN. I want to thank you my colleague, and I'll be real brief.

I just have one question, Mr. Taylor. Dr. McClellan has been quoted in the financial press several times in the last couple of months, the last 60 days, talking about how the agency is going to put a new focus on trying to make medicine more affordable. And the interviews essentially say, "Look, our obligation is safety and efficacy, but we also have a new focus on affordability." I cannot, however, find any initiatives that actually translate into something specific that the agency is doing to make medicine more affordable, and I wanted to give you a chance, on the record, to tell us what the agency specifically is doing to make medicine more affordable.

Mr. TAYLOR. Sure. I will take a shot at it. As I stated in my oral testimony, one of our main focuses is to ensure that there is greater access to generic drugs, both in terms of the work with the Hill and the work on our own. We want to make sure that there is less legislation in regards to the introduction of generics so that more generics get on the market faster, and so people have greater ac-

cess to it. We want to do more outreach and education of the American public regarding the benefits of generics.

One of the things that's been discussed today was Tamoxifen. Well, the generic version of Tamoxifen was introduced in February of this year, and actually only cost $47, which is even cheaper—which is cheaper than any branded version either in Canada or the United States.

We're also taking steps as part of—we have what is called a—it's called the Good Manufacturing Practice Initiative. What it really is, is an initiative to look at innovations in manufacturing to try and find a way to help industry reduce manufacturing costs without easing up on the oversight, the regulatory oversight, that we currently maintain over industry.

We're also trying to improve our education outreach, in terms of making sure that—whether it be generic sponsors or sponsors of innovator products—that they have a better understanding of the agency's expectations in regards to the approval process—once again, to ensure that there are fewer delays that, again, will lead to more products being available to Americans.

So I think those are some of the initiatives that form the basis of his statement.

Senator WYDEN. I'd like to hold the record open on this point, because, again, you know, it seems to me what the agency has always said is that they're going to try to delay red tape and bureaucracy, in terms of getting drugs out. I think that's good, but that hasn't translated into making medicine more affordable. And I can't see anything, other than these sort of outreach programs, and I was going—when I was director of the Gray Panthers, I was going to FDA outreach programs to tell people about medicine.

And I don't want to take Senator Snowe's time, but I'd like to hold the record open and have you tell us exactly what these new initiatives are to make medicine more affordable that is being pursued at the agency.

Senator WYDEN. Because I will tell you, I cannot find anything specific that really is different.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Snowe?

Senator SNOWE. Thank you, Mr. Chairman.

Governor Pawlenty, I want to commend you for your assertive and bold leadership. The people in Minnesota are being well served. And it's just regrettable that we haven't reached a point here in the Congress and with FDA to remove those hurdles and obstacles to give you a clear path toward doing what you need to do on behalf of the citizens of Minnesota.

And, Mr. Taylor, I would like to ask you a particular question about what is preventing the FDA from seeking to "do no harm" when it comes to helping consumers? Because the point here is the safety certification under current law, and that is what's preventing us from implementing, because the Secretary of Health and Human Services has not implemented, hasn't made the safety certification a requirement under law. So it is that you need a new law without those safety certification requirements? Are there things that you could do now to assist in this process, like listing, you know, licensed websites of pharmacies, establishing a pedigree,

because it would get to the point that you raised earlier about some of the problems in tracking medications coming across the border? That obviously would help. We obviously have FDA-approved labs in Canada. We have not discerned any problems with those medications, because they've been certified through the FDA-approved standards. They have the comparable safety requirements.

So what is the issue here? Is it because we don't have the right law in place at this point to remove the safety certification, which we had hoped that Senator Dorgan's legislation would accomplish—what is it that will help you to do your job now?

Mr. TAYLOR. Well, Senator, I—for the agency, I mean, our overarching concern is that the legislative proposals that have been brought to us so far, we feel, create loops in the FDA safety net and the states' safety net, and we have not—in light of the increasing number of products coming overseas, we just think that that is problematic, from a public-health standpoint.

As I noted earlier, it's also in stark contrast to the situation that we're involved with in food, which is where we are actually taking steps to strengthen our ability to protect the food supply.

So our overarching concern is that, so far, the proposals that have been forth are proposals that actually undermine a system. And, you know, I, right now, have people—I will acknowledge that my investigators are overwhelmed. I mean, you'll hear that there are various estimates as to the number of packages that are coming overseas. In some cases, it's as little as two million; in some cases, five, ten, or 20. But it doesn't really matter, the number, because we are completely overwhelmed. And even if, in the legislation, you set up a system that, you know, purports to introduce a product that is introduced in accordance with certain provisions of the Act, at the end of the day, we're the ones—my people are the ones who are going to have to make sure that those products do no harm to the American consumer. So our——

Senator SNOWE. What we've heard so far, according to William Hubbard, Senior Associate Commissioner of the FDA, in his testimony last June before a House Subcommittee is that there is no evidence that any Americans died from taking a legal drug from another country. While, at the same time, according to data tracked by the National Institutes of Health, it is reported that 5,000 Americans die year of foodborne illnesses, food imported from other countries that are monitored and inspected by the FDA. So I'm confused. I think we've got a problem. We want a solution.

Mr. TAYLOR. Sure.

Senator SNOWE. Now, I'm not hearing any solutions from the FDA. You've had plenty of opportunities to develop solutions. OK? For example, in the pedigrees. That was mandated for prescriptions back in 1992 by Congress.

Mr. TAYLOR. That's correct.

Senator SNOWE. I mean, that would take care of that problem, because you could easily monitor and track any medications coming across the border. Now, the FDA Commissioner acknowledged there's little risk in walking into a licensed Canadian pharmacy and filling a prescription.

So what is the issue here that we need to solve immediately? We're not talking about something down the road 10 years. It's al-

ready been 10 years since the pedigree tracking. What can we do right now, rather than threatening consumers? Why aren't we trying to solve the problem?

Mr. TAYLOR. The problem, Senator—you just read the Commissioner's statement—it's as I described earlier. We think that the Canadian system obviously is a strong system that ensures that its citizens get safe and effective products. However, the Canadian government does not assure that the products that are coming to the United States are safe and effective. And so there's a gap between——

Senator SNOWE. But couldn't you not do it? I mean, seriously.

Mr. TAYLOR. We currently——

Senator SNOWE. OK——

Mr. TAYLOR. We currently——

Senator SNOWE.—let's go through a list of suggestions. Publish lists of licensed pharmacies and associated websites. Could you not do that now?

Mr. TAYLOR. No, we can—I mean, no, we cannot—I mean, right now——

Senator SNOWE. Could you do that right now to help Governor Pawlenty in his job? I mean, could you do that?

Mr. TAYLOR. List——

Senator SNOWE. What is difficult about doing that?

Mr. TAYLOR. List pharmacies that—no.

Senator SNOWE. List pharmacies. You couldn't do that?

Mr. TAYLOR. Well, to the extent that we have taken action against pharmacies or against manufacturers, we do post that on our website so that the American consumers can know what products to stay away from and what websites to stay away from.

Senator SNOWE. How about enforcing the requirement for all drug pedigree sales?

Mr. TAYLOR. Right now, the pedigree——

Senator SNOWE. Could you do that?

Mr. TAYLOR.—the pedigree requirement has been stayed, Senator. And what we did is, we sent a report to our house Appropriations Committee explaining the reason why it's been stayed and asking for their advice on that issue.

Senator SNOWE. What about require counterfeit-resistant packaging? How difficult is that? We do that with foreign currency and numerous other instances, so what is the difficulty there?

Mr. TAYLOR. We currently, as part of our counterfeit initiative, we are looking at the different types of counterfeit technologies that are available. I think, however, we need to be cautious about relying on any one technology. One of the things that we've discovered as part of this initiative, one of the things we're exploring, is that there are going to need to be the use of multiple strategies to prevent counterfeiters from overriding the technology, but that's something that we are currently——

Senator SNOWE. You don't believe——

Mr. TAYLOR.—looking at.

Senator SNOWE.—that 21st century America could develop that technology?

Mr. TAYLOR. Well, Senator, just like the challenges of the Secret Service with the currency, over time there's enough of an incentive

for people to try and override the technology, Senator, no matter how good they are. So there needs to be constant steps to develop new and stronger technologies. I mean——

Senator SNOWE. Many of the drugs sold, as I understand, in Canadian pharmacies were manufactured in the very same plants as those sold in the U.S. pharmacies. In fact, Dr. McClellan was quoted as saying, "With regard to the safety of prescription drugs in Canada, they keep drugs safe within Canada, and I think they do a very good job of that."

So, again, it's getting back to the issue of, what can we do that's proactive? I mean, what I'm hearing from you, if we passed a different law without any safety certification requirements, you still wouldn't do the job.

Mr. TAYLOR. Well——

Senator SNOWE. That's what I'm concerned about. That's what I'm hearing.

Mr. TAYLOR. Well, let me try and answer the question to the best of my ability. Obviously, once again, our overarching concern is that we realize that affordability is important, but we want citizens to have products that are safe, effective, and affordable. And we understand that—that produce drugs that, as part of our steps—we've looked at generics and other ways to try and ensure that affordability. And as the head of my—as the Office of Regulatory Affairs, it's my job to ensure that to the extent that these products are coming across, that they're safe and effective.

The decision really rests at the feet of Congress, in terms of how best to change the Act. Because it was Congress that decided that these safeguards needed to be in place. We recognize that whatever that change will be, if there's a change in place that's going to be used to facilitate the importation of drugs, we realize that change will be a fundamental change from the way that we've done things before. And what we need are steps that will help us, despite that fundamental change, still provide the American citizens with the same requisite level of safety and effectiveness, and that includes the need for the American citizens and my agency to go out and work together to inspect facilities to make sure that there's the requisite level of controls that are in place now that allow the system that we have in place to ensure that people are not being injured——

Senator SNOWE. And we know——

Mr. TAYLOR.—and not being harmed.

Senator SNOWE.—they do, because they have FDA-approved facilities in Canada. We know that to the be case. And the reason why—and so the Secretary of Health and Human Services under the existing law is not meeting that safety certification. So is your agency charged with developing safety stance? Could you not do that?

Mr. TAYLOR. Well, we——

Senator SNOWE. Would that not be possible?

Mr. TAYLOR. Well, Senator, certainly every day we try and take steps to try and build on that safety. But, right now, we still have—we still are unable to say, based on that certification—this is a certification that was made by Secretary Shalala and Secretary Thompson—that that plan will ensure that American citizens are

getting products that are safe and effective. We just cannot make that determination.

Senator SNOWE. That was several years ago. Now we're in 2003, going into 2004.

Mr. TAYLOR. That's correct.

Senator SNOWE. That's the point. I mean, this wouldn't be difficult, Mr. Taylor. And I realize, you know, you're not the Commissioner, but—you know, this would not be difficult. I mean, we're just, you know, complicating what could be a very simple situation. I mean, the counterfeiting that was referred to earlier was basically a domestic problem.

Mr. TAYLOR. That's not exactly true. Some of the counterfeit cases that we've handled this year, including the Procrit case, which involved cancer and AIDS medications, indeed was domestic in nature, originated from the state of Florida. However, the Lipitor counterfeiting case, those products were introduced from overseas.

Senator SNOWE. But if you had the pedigree in place, that—you would have been able to identify it, would you not?

Mr. TAYLOR. I——

The CHAIRMAN. Senator?

Senator SNOWE. OK.

Mr. TAYLOR. Senator Snowe, I can't say—in light of the scheme, in light of that particular counterfeit scheme, it's not clear that the pedigree would have definitively stopped the spread of the product.

The CHAIRMAN. Senator Boxer?

Senator BOXER. Thank you.

I want to thank you my colleagues for their questioning. This has been very enlightening.

I want to say to Mr. Taylor, I've been in Congress for 21 years, and I know a phoney trade barrier when I see it, and that's what's going on here. I mean, you could tell, from Senator Snowe's questioning—not you, personally—this Administration—and I might say, the one before—didn't want to do this, period. And it seems to me that you're saying you're overworked and understaffed, and I understand—then tell us what you need in order to identify a couple of places where the good Governor can go that you think would be safe. What would it take? I don't think much.

I think, you know, you're reading a line that I've heard over the years, and the only people, I believe, who are hurting are the senior citizens who can't afford the medicine. It is a moral issue.

Governor, I want to tell you something. I think you're terrific. I want to tell you that everything in this bill that I know of—this Medicare bill—and I withhold judgment, because it hasn't come out. I haven't read every line of it, but everything I've read so far, unless they change it——

The CHAIRMAN. Not before we vote on it.

Senator BOXER. We have to read it before we vote on it. But everything I know about it says to me, "They're doing everything they can to stop our people from getting cheaper drugs," period, end of quote. They took a generic provision that was written by Schumer and some others, and weakened it. They took the importation measures that have been worked on for so long by folks in the House and Senate, including Senator Dorgan, who really brought

this to my attention, and what they have done to that is essentially emasculated it, because you've got people like Mr. Taylor, sitting over there, who don't want to do anything, even if it didn't have a certification in it. So, you know, it's kind of a hopeless deal. They put a gag rule on Medicare, in terms of their ability to negotiate cheaper drug prices. The only thing they haven't done is stop you. They haven't stopped you yet.

So my hope is that you'll listen to what Senator McCain is offering you as a suggestion. Get the broadest support you can back home, hold these open hearings, get your senators and your assembly people, or whatever they're called there, to go with you on this thing, and let's have you be a model for the rest of us. I mean, I know they're doing it in some other states, but I think you, it seems to me, are going to go forward. And in these days of the Internet, you'll be able to ID for the rest of the country Internet sites for our senior citizens so they can get a 90-day supply of drugs, so they won't have to make these horrible choices they are making, awful choices they are making, between living and eating and helping your kids and the rest of it.

This is really a life-and-death type of deal, and to have a trade barrier, artificial one, put in place that is going to—that's leading to people becoming impoverished—every penny they get in Social Security increase is gone before they even turn around. It's just awful.

And so I guess that's all I wanted to say, Mr. Chairman. I'd like to hear from the Governor one more time, because I hope you'll make news all—I hope my Governor is listening, because I think that he, you know, should make a move on this situation. We have folks going to Mexico, day in and day out, to get cheaper drugs.

The CHAIRMAN. So do we.

Senator BOXER. You do, too, from Arizona. Day in and day out.

I just don't believe it, that you can't, in the FDA, pick out four places in Canada, pick out two places in Mexico, pick out one place in Canada, pick out one place in Mexico, and say, "We have done due diligence on this," and help our Governors. Because, right now, our people are hurting, and it's our job to make life easier for people, not harder for people. The health and safety of our people, that's our number-one responsibility, whether it's military protection or whether—but this is our number-one. And, you know, we need to do it.

So, Governor, tell us one more time, have you given a little thought to what Senator McCain said about making this, sort of, a whole united—Republicans, Democrats, Independents, farm labor, whatever you've got out there—kind of a move?

Governor PAWLENTY. Senator, thank you. And thank you for the chance to add a few closing thoughts.

First of all, I think this is the prescription drug equivalent of the Boston Tea Party. People are fed up, they've had it, and whether it's this year in Congress, or next year in another state, or this year in Minnesota, the rebellion is underway, and we hope you join us, because the current structure cannot be sustained.

The generalized concerns that you hear from the FDA and others always gets fogged up—you now, we've got our fingers in the dike from all over the world, we've got all these problems. That's not

what I'm talking about. We're talking about establishing a relationship with experienced, credentialed, accredited, established, reputable pharmacies in Canada and maybe a few other countries as a second step.

And as applied to those institutions and as applied to the mail mechanisms we know already exist, the system does not have the problems that are being suggested by the FDA. So please don't let the voices confuse the debate. Please narrow it to what we're actually talking about.

And I would hope that the FDA, instead of finding a hundred reasons to say no and a hundred reasons why this can't work, would pull up alongside and say, "We'll help you." I'll even pay them for it. You don't even have to do it. I'll find the money to get some people to come out and help us, if they'll do that. If they won't, the concerns about health, safety, and welfare are precisely what government is supposed to do. We can, in our own little Minnesota way, bring a Good Housekeeping seal of approval to these entities on our website and give people more assurance than they're getting now on these rogue sites that these are credible places.

And then, last, it probably is fair to say that if everybody in the whole country moved to this all at once, we would overwhelm the FDA, we would overwhelm the Canadian pharmaceutical industry and infrastructure and their regulatory authorities. And so I have a suggestion for you. I hope we've demonstrated that this debate has crossed a threshold of credibility and it's at least worth a try. So, as a compromise, could the Senate say, "We're going to authorize a certain number of pilot projects. We'll road test these theories, for or against, and in a year and a half, we'll evaluate it, or 2 years we'll evaluate it." We're not afraid of the results. I hope the industry and the FDA isn't either. And then we can see.

And then, last, to Senator McCain's point and your point, I would be delighted to lead the charge in Minnesota to not only have us do this administratively and unilaterally, but to get the legislature, on a bipartisan/tripartisan basis, to endorse it and come along with us. Please know, as you do know, that, you know, once you put it into the broader political arena of the legislature, all the forces, namely the industry, you know, comes down hard. And so we'll have a fight on our hands, and it's a fight I'm willing to fight. I mean, I'm happy to do it. I'll add some extra security, Senator, and away we'll go.

[Laughter.]

The CHAIRMAN. Well, there are some of us who would love to come up and help you, and I mean that. I mean that very sincerely. As you mentioned, this has passed a certain threshold, which is—the Secretary of Health and Human Services doesn't testify on this issue, the pharmaceutical industry doesn't show up. Mr. Taylor, you do, and I want to thank you for that. And your reward, I'm sure, will be in heaven, but I do appreciate it.

[Laughter.]

Mr. TAYLOR. I hope so.

The CHAIRMAN. I do appreciate the fact that you have had the willingness to appear before this Committee.

Your suggestion, Governor, we'll try it. We'll try it. But I've got to tell you, when they have the kind of power that's on this prescription drug bill, which is supposed to be saving not only individuals, but the government money, and they put in a provision that you can't—the government is not allowed to negotiate in a fashion to keep those cost of drugs the lowest, and they're able to get that as a provision in the bill, I'm sorry to tell you, I'm not optimistic. I will not deter us from fighting for it, but there's ever ample evidence of the incredible power of the pharmaceutical. And you know what you're going to see when they pass this bill, even though it'll have huge costs associated with it and it'll put a $600 billion cost on a collapsing Medicare system, which it cannot stand more than six or seven more years? Thank your Senator or Congressman for voting for this bill and prescription drugs paid for by—guess who?—the pharmaceutical association, who have been able to prevent—been able to prevent the cost of drugs from being lowered, by allowing the government to do what the Department of Defense and the VA——

I'm sorry to make you cynical about the way we try to do the Lord's work in the City of Satan, Governor, but I did want to respond to——

[Laughter.]

Governor PAWLENTY. Mr. Chair, I tell people in Minnesota that big change comes in one of three circumstances—war, crisis, and particularly gifted leadership. And we—in Minnesota—and we have a war, of course, internationally, but we have a war, we have a crisis, and—I don't know about the leadership, but we—the circumstances are such that change will come, and now it's just a matter of when and where and how.

The CHAIRMAN. Well, it is an issue of—if I go to any town-hall meeting with seniors in my state, and I'll tell you, it's a huge issue.

Governor PAWLENTY. Most of the seniors in your state are from my state.

The CHAIRMAN. Yes, sir.

[Laughter.]

The CHAIRMAN. Yes, indeed. Many of them that I attend the town-hall meetings in Arizona are from your state, yes, indeed.

Mr. TAYLOR. Mr. Chairman, for fear of continuing this, I just want to make a point, that we obviously—we, you know, respect the government's goals and wishes, and we do look forward to sitting down and talking to you and not putting you in jail and hoping that we can at least express and articulate our concerns. I mean, we obviously want to make sure that you know the source of your products, because we know that there—at least in the press, there was some question about whether the pharmacies were getting—and just provide you other—you know, we can even provide you information on what we've seen today, and that, we think, will help you inform your decision and engage—allow us to engage in good give and take.

So, as I said before, I just want to extend the offer to meet with you, before you introduce your plan, or afterwards, but, I mean, we're happy to do so.

The CHAIRMAN. Thank you very much. Thank you.

Our last panel is Mr. Carmen Catizone, who's the Executive Director of the National Association of Boards of Pharmacy; Mr. David Funderburk, who's the Legislative Counsel of TREA Senior Citizens League; Mr. Lewis Lubka, who's a Senior Citizen from Fargo, North Dakota, and Mr. Donald MacArthur, Secretary General, European Association of Euro-Pharmaceutical Companies.

Welcome.

Mr. Catizone—is that the proper pronunciation?

Mr. CATIZONE. Yes, sir.

The CHAIRMAN. Welcome. Please proceed.

STATEMENT OF CARMEN A. CATIZONE, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

Mr. CATIZONE. Thank you. It's an honor to appear before the Committee today and share our thoughts on this very important issue.

I am the Executive Director of the National Association of Boards of Pharmacy, which was founded in 1904 and consists of all the pharmacy regulatory and licensing jurisdictions in the United States, Guam, Puerto Rico, the Virgin Islands, eight provinces of Canada, the Australian states, New Zealand, and South Africa. Our association also maintains a list of pharmacies that operate on the Internet that are legal and safe, in response to questions from Senator Dorgan and also the Governor of Minnesota.

The purchase and import of drugs from other countries places access to affordable medications squarely in opposition to preserving the safeguards of our drug approval process and state regulation. If allowed to proceed along the present course, it will remove the Food and Drug Administration's approval process in the dispensing of medications for chronic diseases from the U.S. to the country, territory, or back room with the lowest prescription drug prices, regardless of the standards or safeguards in place in those other countries or territories.

NABP also understands that the pricing of pharmaceuticals in the U.S. differs from Canada and other parts of the world. We believe that the U.S. pharmaceutical industry must address this situation and propose meaningful changes to the pricing policies in place in the U.S. and the world. NABP has no affiliation with the pharmaceutical industry, nor do we receive any appreciable funding from the pharmaceutical industry.

NABP acknowledges that appropriate safeguards exist within Canada's Federal and provincial regulatory systems to ensure that the dispensing of medications in Canada to Canadian patients is safe. Important to note, from information obtained directly from Canadian regulatory authorities, is that Health Canada prohibits the import of drugs for dispensing to Canadian patients, but it does not prohibit or regulate the distribution of drugs for import—imported for export to U.S. patients. This regulatory void and breach of the safety net for U.S. patients is significant and unknown to the overwhelming majority of patients ordering drugs from Canadian pharmacies.

Shockingly, Internet operations in Canada are already providing U.S. patients with drugs unapproved in Canada or the U.S. Several newspapers have documented interviews with Canadian Internet

pharmacists, who admit to freely purchasing and exporting to the U.S. medications from Pakistan, Bulgaria, and Latin America, that were not approved or regulated by Health Canada. The example given by Senator Dorgan of two licensed pharmacies and pharmacists interacting and exchanging medications would provide a safety net between the two countries. However, that system is not in place in all instances. And, in fact, the later situation is predominantly in place for those Internet operations.

NABP and its counterpart in Canada, the National Association of Pharmacy Regulatory Authorities, will be launching a VIPPS program in Canada, which is a Verified Internet Pharmacy Practice Site program, to accredit, identify, and alert to Canadian patients which pharmacies are legal and safe to practice pharmacy and conduct business on the Internet.

We are also working with NAPRA to discuss a regulatory framework for the inter-border regulation of the practice of pharmacy and dispensing of medications to patients in the U.S. and Canada. The framework will coordinate the regulatory efforts and resources of the Canadian provinces and the U.S. state boards of pharmacy, and look to the FDA for guidance and assistance.

However, even if NABP and NAPRA successfully formulate the appropriate regulatory framework, neither NABP nor NAPRA can make any representations for safety when drugs are shipped to U.S. patients and originate outside of the U.S. and Canadian approval processes.

In closing, NABP respectfully requests your support for a careful and thoughtful approach to resolving this complex issue, and a rejection of reactionary proposals fueled by populist rhetoric that irresponsibly casts aside valid concerns about patient safety.

NABP requests further the Committee's assistance in preserving the sanctity of current laws and regulations so as to prevent any patient from being seriously injured by the illegal importation of medications from another country. NABP believes that no patient should suffer or be harmed as a consequence of disregarding Federal and state laws that assure the dispensing of safe and effective medications to U.S. patients.

Thank you.

[The prepared statement of Mr. Catizone follows:]

PREPARED STATEMENT OF CARMEN A. CATIZONE, MS, RPH, DPH, EXECUTIVE DIRECTOR/SECRETARY, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

Mr. Chairman and Members of the Committee:

I am honored to be here today and discuss with you how the purchase and import of drugs from other countries affects the health and safety of U.S. patients. The purchase and import of drugs from other countries places access to affordable medications squarely in opposition to preserving the safeguards of our medication approval and state regulatory processes. NABP respectfully requests your support for a careful and thoughtful approach to resolving this complex issue and a rebuff of reactionary proposals fueled by populist rhetoric that irresponsibly cast aside valid concerns about patient safety.

The National Association of Boards of Pharmacy (NABP), which I represent, was founded in 1904. Our members are the pharmacy regulatory and licensing jurisdictions in the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, three Australian States, New Zealand, and South Africa. Our purpose is to serve as the independent, international, and impartial Association that assists states and provinces in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. We

have no affiliation with the pharmaceutical industry nor do we receive any appreciable funding from the pharmaceutical industry.

As a charitable and educational organization, we do accept unrestricted, educational grants of no larger than $4,000 for educational programs at our Annual Meeting and Fall Conference. Among the sponsors for our educational sessions are some pharmaceutical manufacturers. NABP's primary revenue sources are examination fees from the development and administration of the national licensure examination (NAPLEX) and application fees for the licensure transfer and clearinghouse system (NABP Licensure Transfer and Clearinghouse Program), NABP maintains for the states. These fees are paid by the applicants for licensure and licensure transfer and not the states. The only fees paid to NABP by the states and provincial jurisdictions are annual membership fees of $250.

Collapse of the U.S. Drug Approval and Patient Dispensing Systems

NABP's involvement with the distribution and dispensing of medications from pharmacies utilizing the Internet began in 1997. At that time NABP introduced our Verified Internet Pharmacy Practice Sites (VIPPS) program, to inform consumers of legal and safe Internet pharmacies. From the first awarding of a VIPPS certificate in 1999 to the present time, NABP has monitored the activities of Internet sites distributing medications. We have observed firsthand the birth, evolution, and revolution of an industry that holds promise for select populations of patients but, if allowed to proceed along the present course, will remove the Food and Drug Administration's (FDA) drug approval system and dispensing of maintenance medications for chronic diseases from the U.S. to the country, territory, or back room with the lowest prescription drug prices, regardless of the standards or safeguards in place in those other countries or territories.

The facts of the situation are indisputably clear; the importation of prescription medications is illegal. This fact has been explicitly stated by the FDA and state boards of pharmacy. On November 6, the United States District Court for the Northern District of Oklahoma affirmed this fact by noting in its decision in the United States of America versus RX Depot, Inc. and RX of Canada that prescription medications imported into the U.S. violate Federal law. The Court noted further that individuals involved in this activity violated the law openly and notoriously.

It is also a fact that the pricing of pharmaceuticals in the U.S. differs from Canada and other parts of the world. The difference in price is a primary incentive for individuals abandoning the safe and legal U.S. system to purchase and import drugs from other countries. NABP believes that the U.S. pharmaceutical industry must address this situation and propose meaningful changes to the pricing policies in place in the U.S. and the world.

Patient Harm and Compromise of the U.S. Regulatory System

Critics of the regulatory actions of the state boards of pharmacy against entities distributing or assisting in the distribution of medications from other countries contend that there have been only a few reports of patient harm and injury. Although the number of reports may be low, the actual harm to patients is immeasurable and could be significant. NABP maintains that the number of reported patient injuries is low and immeasurable because patients may not be able to discern whether the drugs received from other countries are authentic or appropriate, injuries resulting from patients receiving wrong or counterfeit drugs may not manifest in the health care system until sometime later when the patient's condition worsens and requires emergency treatment or hospitalization, and consumers purchasing drugs from other countries are reluctant to report any adverse consequences because of the fear of prosecution for violating Federal and state laws. In recent correspondence to the State of Illinois,[1] the FDA documented instances where patients suffered harm from the purchase and import of drugs from other countries. The letter also identified drugs purportedly shipped from Canada that were actually distributed from India and drugs being shipped that were unapproved generic versions or sub or super potent. NABP and its member boards are collecting data on incidences of patient harm caused by the purchase and import of drugs from other countries and will submit any information accumulated through this process to the Committee.

NABP is alarmed by the data collected by the FDA and recent reports of additional incidents of patient harm:

- A patient in Illinois ordered an inhaler to treat her child's asthmatic condition from a Canadian pharmacy. After using the inhaler, the child told her mother that the medicine "seemed different." Shortly after using the inhaler, the child

[1] November 6 letter to the State of Illinois' Special Advocates for Prescription Drugs.

suffered an asthmatic episode, the first in a considerable time. The mother only learned that the drug sent to her by the Canadian pharmacy was wrong when she asked the pharmacist at her local pharmacy to identify the medication.

- An Oregon patient being treated for breast cancer received the wrong medication from a Canadian pharmacy. She continued to take the wrong drug for three months as her condition worsened.

NABP has also learned that the purchase and import of drugs from other countries is gravely compromising state laws and regulations by granting the authority to practice medicine and prescribe medications to unqualified, unlicensed individuals. Public officials who openly endorse violating Federal and state laws in order to obtain lower priced pharmaceuticals are supporting these transgressions and further damaging the regulatory system in the U.S.

- A U.S. entity affiliated with a Canadian pharmacy operation is paying paramedics in the U.S. to conduct the physical examination and diagnosis of patients. The paramedics' examinations and diagnosis are then forwarded to a Canadian pharmacy where prescriptions are issued by a Canadian doctor and drugs shipped to U.S. patients. This activity contravenes U.S. laws by allowing paramedics to practice medicine without appropriate education, training, and licensure.
- A certification/purchasing program is providing the means for psychologists to illegally order psychotropic drugs (*e.g.,* barbiturates, clozapine, haloperidol, etc.) for their patients through a Canadian pharmacy. Again, the opportunity to obtain prescription medications through foreign sources is directly abrogating the U.S. regulatory system and allowing individuals to practice medicine without the appropriate education, training, and licensure.
- Within the last four months, a staggering number of websites brazenly offering controlled substances without a valid prescription (as required by Federal and state laws) and a never before witnessed preponderance of spam e-mails offering unrestricted and illegal access to controlled substances have flooded the computers of U.S. citizens. Prior to the advocacy for the purchase and import of drugs from other countries by public officials in certain cities and states, such sites and offerings did not exist.

Importation from Other Countries Places Patients Outside of Regulatory Safeguards

NABP acknowledges that appropriate safeguards exist within Canada's Federal and provincial regulatory systems to ensure that the dispensing of medications in Canada to Canadian patients is safe. Similarly, NABP attests that the dispensing of medications to U.S. patients within the U.S. regulated system is safe. In fact, the safety and regulatory standards in place in the U.S. are often regarded as the best in the world.

Unfortunately, the same safeguards do not exist for patients purchasing and importing drugs from other countries. Although Health Canada prohibits the import of drugs for dispensing to Canadian patients, it does not prohibit or regulate the import of drugs for export to U.S. patients. The regulatory void and breach of the safety net for U.S. patients is significant and unknown to the overwhelming majority of patients ordering drugs from Canadian pharmacies. NABP learned first-hand from the president of an Internet pharmacy corporation based in Canada that drugs shipped to U.S. patients may not be approved by the Canadian drug approval process and may originate in New Zealand, Vietnam, or any country in the world where prescription drug prices are lower than those in the U.S. or Canada. In fact, there are no limitations as to where drugs will originate from for delivery to U.S. patients. Shockingly, Internet operations in Canada are already providing U.S. patients with drugs from other countries unapproved in Canada or the U.S.! A recent advertisement brought to NABP's attention offers to match the price of any medication from Canada by shipping drugs from Israel. Several newspapers have interviewed Canadian Internet pharmacies who admit to freely purchasing and exporting to the U.S. medications from Pakistan, Bulgaria, and Latin America.

Allowing for the purchase and import of drugs from other countries essentially abolishes the FDA's drug approval process and circumvents state regulation. Advocating that it is acceptable to violate Federal and state laws because the price of pharmaceuticals is high, creates the opportunity for unscrupulous and dangerous individuals to operate Websites or distribution enterprises that will ship drugs to U.S. patients that may be nothing more than placebos, wrong, inappropriate, or even counterfeit. If the safeguards in place for drug approval and the regulation of pharmacies and wholesale distributors are deliberately compromised, U.S. patients will

be placed in a "buyers beware" environment and left unprotected to gamble with their health and safety when purchasing and importing drugs from other countries.

Inter-border Regulatory Proposal

NABP requests the Committee's support for the enforcement of current Federal and state laws concerning the illegal importation of medication from other countries and prosecution of individuals involved in these activities, whether they are private citizens or mayors or governors. In the interim, NABP and its counterpart in Canada, the National Association of Pharmacy Regulatory Authorities (NAPRA), recognize that a solution resolving the conflict of access versus safety must be developed to address the needs of U.S. patients and prevent irreparable damage to, if not the elimination of, the regulatory systems in the U.S. and Canada. To this end, NABP and NAPRA are in discussions to develop a regulatory framework that regulates the inter-border practice of pharmacy and dispensing of medications to patients in the U.S. and Canada and provides similar protections as those afforded U.S. patients who utilize pharmacies engaged in the interstate practice of pharmacy and dispensing of medications. The framework will coordinate the regulatory efforts and resources of Canadian provinces and U.S. state boards of pharmacy.

NABP and NAPRA will also be launching the VIPPS program in Canada to identify for Canadian patients legal and safe Internet pharmacies. The combination of the VIPPS Canada program and inter-border regulatory framework between the U.S. and Canada will ensure for U.S. patients that the purchase and importation of medications from licensed Canadian pharmacies will be safe and legal.

However, even if NABP and NAPRA successfully formulate the appropriate regulatory framework for the inter-border dispensing of prescription medications, neither NABP nor NAPRA can make any representations for safety when drugs are shipped to U.S. patients and originate outside of the U.S. and Canadian approval processes. NABP's concern with patients purchasing and importing medications from countries other than Canada will not be resolved unless this problem is addressed. In fact, NABP and NAPRA cannot move forward with the implementation of an inter-border regulatory framework until Health Canada takes decisive action to prohibit the importing of medications from other countries, outside of Canada's drug approval process, by Canadian pharmacies for dispensing or distribution to U.S. patients. NABP also believes it essential before the implementation of an inter-border regulatory framework for the FDA and Health Canada to establish a means for mutual recognition of drug products.

In closing, NABP respectfully requests that the Committee recognize that allowing and encouraging the purchase and importation of medications from other countries is a serious threat to our regulatory foundation and patient safety and may thrust the U.S. back in time to the days when snake oil salesmen and quack tonics threatened the well-being of unknowing and unsuspecting patients. NABP requests further the Committee's assistance in preserving the sanctity of current regulations so as to prevent any patient from being seriously injured by the illegal importation of medications from other countries. NABP believes that no patient should suffer or be harmed as a consequence of disregarding Federal and state laws that ensure the dispensing of safe and effective medications to U.S. patients.

Thank you for the opportunity to address this important issue.

PREPARED STATEMENT OF THE AMERICAN PHARMACISTS ASSOCIATION

The American Pharmacists Association (APhA) appreciates this opportunity to provide our perspective to the Committee on the issue of expanding prescription drug importation. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians. APhA, dedicated to improving medication use and advancing patient care, is the first-established and largest national association of pharmacists in the United States.

Access to Prescription Medications

As you know, prescription medications have proven to be a valuable tool in our health care system. That value doesn't materialize, however, if patients do not have access to the medications they need. Clearly, as members of the profession which makes improving medication use and advancing patient care its priority on a daily basis, pharmacists are supportive of efforts to enhance patients' access to prescription medications. As pharmacists, we share the Committee's concerns that many patients—especially seniors—face challenges in accessing valuable, but sometimes unaffordable medications.

Any pharmacist that has ever worked in a community pharmacy can vividly recount the dismay they feel when having to tell one of their patients—especially seniors on a fixed income—the cost of their medication, knowing that cost may be more than the patient can afford. Some pharmacists work with patients to solve that access problem by recommending lower-cost generic alternatives or even over-the-counter medications, providing the medication to the patient at no charge, or establishing a payment plan. Pharmacists also work with patients to assure that patients know how to make the best use of that medication—to maximize their investment in the technology we call medication. While those stories illustrate pharmacists' first-hand experience with access problems and their compassion for their patients, patients need a Medicare drug benefit.

Another so-called solution that has received a lot of attention from Congress and is now the subject of the hearing before this Committee is prescription drug importation. While APhA appreciates the Committee's commitment to exploring methods to increase access to valuable medications, we have significant concerns with expanding importation. Expanding importation would circumvent the United States regulatory structure—a system intended to help patients receive safe and effective medications. 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 it creates the potential for long-term costs in patient harm. While pharmacists are supportive of efforts to enhance patients' access to prescription medications, expanding importation without sufficient oversight and involvement of regulators, pharmacists, and physicians is not the answer.

Patient Safety

Patient safety is the one overriding reason for the many laws and regulations that help assure Americans receive safe and effective medications—medications that are "what the doctor ordered." These controls not only guide what medications are available in the U.S. market and how those medications are manufactured, but also how they are labeled, packaged, shipped, stored, and dispensed. 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 provide patients with medications that do what's expected and nothing that's unexpected. By their very nature, medications are highly susceptible to counterfeiting: the products are expensive, necessary for our health, and difficult, if not impossible, to detect a fake product through visual inspection. Because of these challenges, Congress and state regulators established a closed system for pharmaceutical product approval and distribution. The current closed system protects American consumers from unsafe products.

Our concern extends to the packaging and labeling of products as well. Prescription medications are powerful; that's why they work. But they "work" when patients understand how to use them, and how to use them appropriately. U.S. prescription labeling language and presentation goes through an intensive review process by manufacturers and the Food and Drug Administration (FDA). Different nations have different standards. Simply put, a medication is not just a tablet; it's the tablet, the labeling, and the packaging.

Purchasing prescription medications outside of the U.S. means leaving our closed system. And efforts to facilitate this activity punch holes in our regulatory safety net. Those holes yield risks for patients, risks that they may receive 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, packaged, labeled, distributed, or regulated in the country where they are purchasing the drug, or simply, the wrong product.

Other regulatory systems are different, and that difference can create problems. For example, bisoprolol is a beta blocker used to treat hypertension (high blood pressure)—something we know better by its brand name is Zebeta® in the United States. In Canada, however, bisoprolol goes by the brand name Monocor®. Simply having a different name doesn't immediately create a problem, but in the U.S., the name Monocor® sounds like the medication name Mevacor® (a statin drug used to treat high cholesterol). The potential for error, then, appears when patients or health care providers confuse the U.S. product Mevacor® with the international product Monocor®.

Additionally, when products are recalled in the U.S. because of manufacturing difficulties, or in rare instances when counterfeit products appear in the U.S. system, the FDA, pharmacists and physicians work in conjunction with each other to identify and notify patients who may have received such medications. Patients who go outside of the U.S. regulatory system risk not knowing if a prescription has been

recalled in another country. We have seen this risk materialize. On November 12, 2003, Canada recalled certain medications to treat asthma and chronic obstructive pulmonary disease (COPD) because the drug's delivery system may fail to provide patients with an adequate dose of the medication. Canadian patients were advised to return the product to the pharmacy or physician's office where it was obtained—but what happens to U.S. patients that ordered the medication over the Internet? Will they be informed about the recall? The outreach from Canadian regulators was not directed to patients in the U.S. And although the FDA re-issued the Canadian alert, the alert places U.S. pharmacists and physicians in a quandary—they know they did not prescribe or dispense the faulty product, but cannot be sure that their patients are not using it. Who should U.S. patients see? Because the medications were obtained outside the U.S. system, there is little that U.S. pharmacists and physicians can do to alert patients. And it raises the question: who is responsible for alerting the patients in those circumstances?

Opening the Closed System Means Opening the System beyond Canada

The idea of opening our current closed system is critical to this discussion. It is true that some countries, such as Canada, may have a system to regulate medications that appears comparable to our system. However, "opening the door" to Canada opens the door—period. Our closed system is then open to products from other countries—countries without strong regulatory systems. Even if attempts are made to limit access to one country or just a few, opening the system creates incentives for unscrupulous providers to pretend that they operate in Canada. By adding a Canadian flag to their website, they purport to provide quality products and "hide under the maple leaf."

By opening the door—and substituting a porous system for our closed system—we risk the introduction of counterfeit medications. The World Health Organization estimates that 5 percent to 8 percent of *all* pharmaceuticals are counterfeit. With our current system, few consumers perceive a threat from counterfeit medications, but that changes when the safety structure is damaged. And even *with* the comprehensive U.S. system, counterfeit products have penetrated our system. In February, 2003, 11,000 boxes of counterfeit Epogen® and Procrit® (anemia drugs often given to cancer, AIDS and kidney failure patients) were found on pharmacy shelves and even in patients' homes. And earlier this year, the FDA announced the discovery of three lots of counterfeit Lipitor® (cholesterol lowering medication). The FDA's continuing investigation found two additional lots of the same drug. These situations support the need for review and refinement of our existing safety net, not the expansion of efforts to circumvent or relax that system.

Impact on Patient Care

Not only do imported medications directly impact patient health, but the circumvention of U.S. health care providers creates a situation that is best described as "working in the dark." Because of the questions involved in importing medications, many patients do not tell their pharmacist about medications they're securing over the borders. This is understandable, but dangerous. Unless the patient provides this information, physicians and pharmacists have no way of knowing what a patient is taking. And it is important to recognize that products available in other countries may not be identical to the FDA-approved version available in the U.S. products available in other countries may differ in brand name, strength, form of release, or in a number of other ways. Because of these differences in foreign drugs, even providing the name of a product may not be enough. Pharmacists' ability to identify drug-to-drug interactions is hindered to the point of nonexistence without knowing about a patient's entire medication regimen or the content and strength of a particular drug. Consider the scenario where a patient is in need of a prescription medication in a hurry—such as an antibiotic for an infection or a pain medication to treat an injury. If that patient has been getting his or her medications from a different source, the pharmacist is unable to determine whether the new prescription will conflict with any other medications the patient takes, has ingredients that duplicate a current prescription, or whether its mere presence suggests other medical problems for the patient that should be followed-up with the patient's physicians. This virtual blindness compromises the ability of physicians to care for their patients and the ability of pharmacists to partner with patients to improve medication use and advance patient care.

Many have asked for the evidence of harm caused by circumventing our safety net. One of the reasons we don't have more bodies in the streets is because of the way medications work. Consider a patient working with their local physician to take a medication to lower their blood pressure. This patient imports a faulty medication that has no, or little, active ingredient. It is unlikely that the patient will actually

feel anything different, unlikely they would actually notice any difference in the product. When the patient visits their physician for a check-up, the blood-pressure reading will show that the medication isn't working—that the patients' blood pressure was not decreased by the medication. Because of our trust in the medication supply, it's highly unlikely that the physician would consider that there was a problem with the medication. Rather, the physician will likely assume that the medication just didn't work and consequently will either increase the dose or choose another medication. This sets the stage for using a stronger medication, one that they patient may not have needed if they had actually gotten what their doctor ordered. Modern medication management is already complex enough without plunging the process into darkness.

Concerned Allies

The American Pharmacists Association is not alone in raising concerns about this practice. The export of medications from other countries is far from universally supported. Health care providers and regulators—including regulators in other countries—have similar concerns with prescription drug importation. In May 2003, the U.S. National Association of Boards of Pharmacy (NABP) and the Canadian National Association of Pharmacy Regulatory Authorities (NAPRA) announced an agreement documenting their commitment to "work together to protect the citizens each are mandated to serve, and to promote compliance with the federal, state, and provincial laws and standards of Canada and the United States, to ensure the integrity of the prescription drug supply in their respective jurisdictions" (Attachment A). APhA joined with the Canadian Pharmacists Association and 45 other pharmacist groups to support that agreement, and to pledge our commitment to protecting the integrity of the medication supply (Attachment B). NAPRA voiced its concern with importation last week, calling on the Canadian government to ban exports by Canadian pharmacies until governments can implement systems that will ensure the effective regulation of these practices to protect patient safety. And within the U.S., FDA and state boards of pharmacy have issued statements of concern or have taken action against entities that are facilitating importation and practicing pharmacy without a license.[1]

Other members of the health care team have expressed concern with illegal importation. The Canadian Medical Protective Association (CMPA), a mutual defense organization for Canadian physicians, has cautioned Canadian physicians about cosigning foreign prescriptions and warned of the potential for liability in the foreign jurisdiction resulting from an alleged doctor-patient relationship that could result from such an action. In the event of an American or other foreign lawsuit a physician may not be eligible for help from the CMPA. The Association advises its members not to participate in such activities. The CMPA's actions were recently amplified by the Coalition for Manitoba Pharmacy, a group of practicing pharmacists in Manitoba, who announced their opposition to exporting prescription drugs from Canada to the U.S.

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. Effective patient care is about real relationships—physician-patient, pharmacist-physician, and pharmacist-patient relationships. Patients are not mechanisms into which you input "pills" and achieve uniform results. The practice of healthcare is both an art and a science. Direct observation and conversation with the patient tells healthcare providers much, as do diagnostic tests. But these are not effective alone. To remove such a basic protection of our health care delivery system's safety net seems diametrically opposed to the "pro patient safety" environment we are all working to achieve.

There is an underlying fallacy that often is not raised in this debate. Patients are not mechanisms we adjust for better health—we are human beings. Medications are not inert objects that patients ingest, inhale, or inject. They are powerful compounds that affect the patient's body and being—that's why they work. Medications are subject to degradation due to contamination or even due to temperature fluctuations during shipping. And medications can be counterfeited. If your mother or father or child were consuming questionable food, you'd snatch it away as soon as you detected an unusual odor or color. Faulty medications can be many times more harmful to health than a rancid sandwich—but without the odor, who can identify the

[1] The Boards of Pharmacy in Alabama, Arizona, Arkansas, Montana, North Carolina, Oregon, Oklahoma and Vermont, for example, have been involved in such activity.

legitimate product? We are so careful of what we ingest when we call it food. Should we not be equally careful when we call it medicine?

Conclusion

Importation can create safety hazards by circumventing the current medication 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." It is time for Medicare to meet the standard of other health benefit programs and help beneficiaries get the medications they need.

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 and pharmacist services patients need every day. We applaud Congressional action in this area and hope that a quality Medicare pharmacy benefit becomes law in the very near future. 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 patient 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.

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.

National Association of Pharmacy Regulatory Authorities and National Association of Boards of Pharmacy Agreement

WHEREAS, the members of the National Association of Pharmacy Regulatory Authorities (NAPRA) in Canada and the National Association of Boards of Pharmacy (NABP) in the United States have the common responsibilities of regulating the practice of pharmacists and ensuring public safety; and

WHEREAS, NAPRA and NABP are mutually committed to working together to support the ability and effectiveness of individual member organizations in fulfilling their regulated mandates; and

WHEREAS, the United States Food and Drug Administration has repeatedly stated that importation of prescription drugs is potentially dangerous and unsafe for United States citizens; and

WHEREAS, Canadian provincial pharmacy regulatory authorities recognize that the exportation of prescription drugs from Canada raises legal, ethical, and public policy issues for Canadians, in the context of health care, pharmacy services, and availability of prescription drugs; and

WHEREAS, provincial pharmacy regulatory authorities in Canada and state pharmacy regulatory authorities in the United States agree that the international movement of prescription drugs between Canada and the United States undermines the regulatory systems established in each country to protect consumers; and

WHEREAS, businesses, individuals, and organizations that facilitate prescription drug importation for United States consumers are encouraging the violation of federal and state laws in the United States that are designed to protect the health and safety of its citizens; and

WHEREAS, concerns have been expressed by many Canadian provincial pharmacy regulatory authorities regarding the export of prescription drugs into the United States to the extent that importation violates the federal or state laws of the United States; and

WHEREAS, despite the concerns regarding patient safety and the laws mentioned above, certain business, individuals, and organizations continue to facilitate the importation of prescription drugs into the United States,

THEREFORE, the undersigned representatives of the pharmacy regulatory authorities in Canada and the United States pledge to work together to protect the citizens each are mandated to serve, and to promote compliance with the federal, state, and provincial laws and standards of Canada and the United States, to ensure the safety and integrity of the prescription drug supply in their respective jurisdictions.

Barbara A. Wells, NAPRA	*Carmen A. Catizone, NABP*
Date	*Date*

ATTACHMENT B

45 U.S. Pharmacist Groups Endorse Cross-Border Communiqué On Illegal Importation of Prescription Drugs

(as of May 13, 2003)

An unprecedented 45 U.S. pharmacist groups joined forces with the Canadian Pharmacists Association on May 13, 2003, to strongly endorse a landmark statement opposing illegal importation of Prescription Drugs. More organizations are signing on daily in support. The Cross-Border Communiqué between the U.S.-based National Association of Boards of Pharmacy (NABP) and the Canadian National Association of Pharmacy Regulatory Authorities (NAPRA) addresses the issue of illegal cross-border importation of prescription drugs.

Alabama Pharmacy Association
Alaska Pharmacist's Association
Arizona Pharmacy Association
Arkansas Pharmacists Association
American Pharmacists Association (APhA)
American Society of Health-System Pharmacists (ASHP)
American Society of Consultant Pharmacists (ASCP)
California Pharmacists Association
Colorado Pharmacists Society
The University of Connecticut School of Pharmacy
Duquesne University Mylan School of Pharmacy
Florida Pharmacy Association
Georgia Pharmacy Association
Hawaii Pharmacists Association
Illinois Pharmacists Association
Iowa Pharmacy Association
Kansas Pharmacists Association
Kentucky Pharmacists Association
Maryland Pharmacists Association
Michigan Pharmacists Association
Minnesota Pharmacists Association
University of Missouri-Kansas City School of Pharmacy
Missouri Pharmacy Association
Montana Pharmacy Association
Nebraska Pharmacists Association
New Jersey Pharmacists Association
Pharmacists Society of the State of New York
North Carolina Association of Pharmacists
North Dakota Pharmaceutical Association
Ohio Pharmacists Association
Oklahoma Pharmacists Association
Oregon State Pharmacists Association
Pennsylvania Pharmacists Association
Rhode Island Pharmacists Association
University of Rhode Island College of Pharmacy
College of Pharmacy, Medical University of South Carolina
Tennessee Pharmacists Association
Texas Pharmacy Association
Utah Pharmaceutical Association
Vermont Pharmacists Association
Virginia Pharmacists Association
Washington DC Pharmaceutical Association
West Virginia Pharmacists Association
Pharmacy Society of Wisconsin
University of Wisconsin School of Pharmacy
Wyoming Pharmacy Association
Total: 45

The CHAIRMAN. Thank you.

Mr. MacArthur, welcome. Thank you for joining us, and would you take the microphone?

Mr. MACARTHUR. Surely.

STATEMENT OF DONALD MACARTHUR, SECRETARY GENERAL, EUROPEAN ASSOCIATION OF EURO-PHARMACEUTICAL COMPANIES

Mr. MACARTHUR. Mr. Chairman, Senators, the European Association of Euro-Pharmaceutical Companies, which represents around 70 parallel traders in medicines across 15 European countries, is very grateful for the opportunity to contribute to this important debate.

I think we can best do this by summarizing the experience gained over the past 25 years and more of parallel trade in medicines in Europe. Ours is an industry that, last year alone, moved 140 million packs of prescription drugs safely and efficiently across national borders within Europe. Given the opportunity, some of our members would undoubtedly also like to bring the benefits of parallel trade to the U.S.

Listening to some of the remarks made today and to those I've read in the U.S. press provokes a feeling of déjà vu. Fears of unsafe, substandard, or counterfeit products flooding the market, and that any savings from parallel trade would only pass to the middlemen, were made by drug manufacturers in Europe in the early 1980s. Both allegations are still made today. But the mere fact that they're repeated so often doesn't make them true. They are not.

Our biggest battle has been with misinformation. The facts clearly show that parallel trade is safe. There have been no adverse consequences for public health. Parallel trade is thoroughly regulated. All of our importing members hold manufacturing authorizations. All of our importing members hold wholesale dealing authorizations. All of our members trade only in drugs which have European marketing approval in Europe to common standards.

Every country, except one, in the EU has abbreviated procedures for double-checking parallel imports. The one country that doesn't have procedures for allowing incoming parallel trade is France. So it's interesting that, at least in one case, France and the U.S. have one thing in common, they don't allow parallel imports.

[Laughter.]

Mr. MACARTHUR. But parallel trade can be strictly regulated with relatively light touch legislation, and it allows only genuine products that have been approved for marketing elsewhere to common standards and produced by the same original brand manufacturers, often in the very same plants.

Parallel trade is totally free of counterfeits, pirated, and substandard products. During the 25 years plus, 30 years, there has been not one confirmed case of a counterfeit drug ever reaching a patient in Europe as a parallel import. Furthermore, on no occasion has the substantial product liability insurance that parallel importers are required to maintain ever been needed.

Parallel trade is the only form of price competition with patented drugs, the part of the market that generics can't reach. Its presence, or even just the threat of this, is sufficient to moderate

launch prices by manufacturers and to curtail subsequent price increases.

Parallel trade brings significant savings to payers and patients. A recent independent study from one of the world's leading academic centers for health economics, the University of York, shows that parallel trade in medicines directly saved payers and patients the equivalent of almost $750 million in 2002—that's at current exchange rates—in just five EU countries—U.K., Germany, Netherlands, Denmark, and Sweden.

Parallel trade fits in with the free-market principle. It's only when I come to the U.S. do I hear about drug prices being fixed. In Europe, they're not. We have controls through the reimbursement system, which I gather is the main method here. The minority of countries allow—have price fixing. The majority don't.

Two of the countries that have total free markets for prescription drugs, U.K. and Germany, are able to allow free pricing because they allow and indeed incentivize parallel imports.

Parallel trade has absolutely no impact on the ability of the pharmaceutical industry to invest in R&D. We're fully aware that the discussion in the U.S. is focused on personal importation by the Internet and other means, and that Canada is seen as the main source opportunity. However, parallel trade, unlike the Internet, can be effectively regulated. It's capable of handling high volumes of all types of products, benefiting all patients, rather than the favored few, and supports, rather than destroys, the local pharmacy and wholesaler infrastructure.

While the quality of Canadian products is not in doubt, the same is true of products from the EU, with the EU having the advantage of much larger scale. At ex-factory prices, the U.S. drug market in 2002 was worth $196 billion, while Canada was only $8 billion, one-twenty-fifth of this amount. To achieve just 10 percent penetration of the U.S. retail drug market would require an impossible 262 percent of Canadian domestic sales. In contrast, next year the EU will expand to 25 member states, the population of almost 500 million, and a drug market of in excess of $100 billion. But, even more important than adequate volume and attractive prices, Europe is where proven expertise in all aspects of parallel trade lies, in sourcing, quality assurance, regulatory, legal, labeling, transport, and distribution.

We believe that dialogue with the FDA should be started. We are already in regular dialogue with the European Medicines Evaluation Agency. In fact, we have a regular meeting with them next week. The EMEA, of course, is in dialogue with the FDA. Let's pool our expertise. We would welcome both members of the U.S. Congress and the FDA to visit our plants, to look them over and check our procedures.

In closing, though, I believe that I should say that Europe has a lot to learn from the U.S., and not least from your democratic processes and openness. Never once in its existence has EAPC's views ever been sought out by a European policymaker in a forum like today. So I thank you for that.

Thank you.

[The prepared statement of Mr. MacArthur follows:]

PREPARED STATEMENT OF DONALD MACARTHUR, SECRETARY GENERAL, EUROPEAN ASSOCIATION OF EURO-PHARMACEUTICAL COMPANIES

Concern over rising prescription drug prices in the U.S. and in particular the heavy out-of-pocket financial demands placed on seniors to maintain regular drug treatment has led to a surge in cross-border purchases by patients via the Internet and other means. This in turn has triggered a debate as to whether parallel importation of prescription drugs from foreign countries should be legalised. The European Association of Euro-Pharmaceutical Companies (EAEPC) is delighted to be given this opportunity to contribute to this important debate. It can best do this by summarising the European experience of parallel trade with prescription drugs. This experience—gained over 20+ years—clearly shows that parallel trade is

- safe,
- uses only genuine, regulatory-approved products from original brand manufacturers,
- totally free of counterfeit, pirated and substandard products,
- able to stimulate price competition among otherwise monopolistic manufacturers,
- brings significant savings to payers and patients, and
- has no impact on the ability of the pharmaceutical industry to invest in R&D

It should be emphasised that parallel trade is very different from personal importation by individual patients, the main cross-border activity in the U.S. so far. Parallel trade is a large-scale industry, a highly-regulated and thoroughly professional business-to-business activity that requires considerable investment in qualified staff, state-of-the-art facilities and equipment, and rigorous quality assurance procedures. In 2002 alone, an estimated 140 million packs of medicines were traded across Europe's internal national borders.

EAEPC member companies have more experience of parallel trade in prescription drugs than any in the world. They enjoy excellent relationships with national and EU regulatory authorities in Europe, and would welcome dialogue with the FDA, other U.S. authorities, as well as U.S. politicians, payer and consumer groups. Visits to EAEPC member company facilities across Europe can also be arranged.

EAEPC

Established in 1998 with its registered office in Brussels, Belgium, EAEPC (*www.eaepc.org*) is the representative voice of pharmaceutical parallel trade in Europe. Through national association or individual company membership it encompasses over 70 firms from 15 of the 18 countries in the European Economic Area (EEA*). Together these firms account for well over 90 percent of medicines parallel-traded in the region.

All products handled by EAEPC members have either national or pan-European regulatory approval, and are exclusively sourced from and sold to EEA countries using authorised trade channels. Some EAEPC member companies have been in business for 20 years and are amongst the top-10 pharmaceutical suppliers to their national markets.

EAEPC's primary aims are to safeguard the free movement of medicines within the EEA's Internal Market—a principle first laid down in Article 28 (formerly Article 30) of the European Community's founding Treaty of Rome and reaffirmed in subsequent Treaties—and to counteract any attempts to restrict the freedom of choice for the consumer through trading patterns in breach of EU competition rules (Articles 81 EC & 82 EC).

The Association believes that free trade will lead to improvements in health standards through the provision of innovative medicines at lower cost, benefiting statutory healthcare systems, other third-party payers, and the public as both patients and taxpayers, as well as assisting the EU to achieve its objective of a single market.

Parallel Trade: The Basics

What is Parallel Trade?

Parallel trade occurs when products are purchased in a country where they are cheaper and transported for resale to other countries where they are more expensive, in competition with the same product sold by the manufacturer or its local li-

* The EEA consists of the current 15 EU member states (*i.e.,* Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom) plus Iceland, Liechtenstein and Norway.

censee. Parallel trade increases the effectiveness of the market and consumers enjoy lower prices as a result. It helps to restrain costs in markets that are not very price sensitive.

Parallel trade will exist wherever there are price differentials. It has been ongoing worldwide since goods were first traded and is found across Europe today with a wide range of branded products, including such diverse items as motor cars/motor cycles, computers, cameras, pianos, compact disks, clothing, food and ski equipment (table 1).

Table 1.—Extent of parallel trade within the EU

footwear and leather goods	<5%
musical recordings	overall 5–10%, some releases up to 20%
motor cars	estimates up to 5%
consumer electronics	around 5%
domestic appliances	<5%
cosmetics and perfumes	around 13% for upper end of market
Clothing	5–10%
soft drinks	0–15%
Confectionery	<10%
alcoholic drinks	<5%

Source: NERA & SJ Berwin, 1999[1]

For parallel trade to be possible, four preconditions must be met:

- there must be unrestricted free trade between the countries involved;
- there must be substantial differences between the prices of identical goods in these countries;
- the costs of transport in relation to the cost of goods must be low;
- the distribution of goods must be entirely separate from their manufacture.

All these conditions are found in the case of prescription medicines in the EEA. Yet, in the context of the penetration by parallel trade with other goods, the overall level with medicines is unremarkable. Various estimates by independent economic consultants[2,3] on the share of the prescription pharmaceutical market in the EU taken by parallel-traded products from 1990 through to 2000 have consistently arrived at a figure of 2 percent. EFPIA estimates put the 2002 penetration at 4 percent.

Why Do Price Differences with Medicines Occur?

Pricing of prescription medicines and controlling access to reimbursement via social health insurance schemes are purely national responsibilities throughout Europe. Today and for the foreseeable future, these tasks remain in the hands of individual member states, subject only to the condition that the methods they employ are transparent and to do not discriminate by country of origin.

Willingness and ability to pay, medical and prescribing practices, the balance of supply-side versus demand-side cost containment interventions, and even value judgements in healthcare differ between countries, and therefore so do prices. Further important factors are inflation differences and currency fluctuations outside the euro-zone.

An exacerbating issue is a proactive policy of price differentiation undertaken by many international pharmaceutical manufacturers. As commercial enterprises, companies naturally aim to obtain the highest price each national market will bear, and so discriminate between countries to reflect differences in the ability to pay. Price differentiation is known to yield higher profits than uniform pricing. Companies also control the sequence of launches across Europe so as to limit the opportunities for the authorities to depress these prices in major markets through application of international price referencing.

A number of surveys, some repeated year-on-year, have shown considerable interstate price differences for the same or very similar product. Such differences are found regardless whether comparisons are made at the price the manufacturer sells the medicine to wholesalers, or at the cost that social health insurance has to meet,

which includes margins for the wholesaler and the pharmacy, plus, in most countries, value-added tax.

Is it Legal?

Yes, parallel trade is completely legal. A core objective of the Treaty of Rome is the creation of a single, Internal Market through which goods, services, people and capital—the "four freedoms"—can freely pass. Article 28 of the EC Treaty provides that:

> *'Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between member states.'*

A direct consequence of free movement is the classic Cassis de Dijon doctrine of the European Court of Justice (ECJ),[4] that a product lawfully placed on the market of one member state must be allowed to circulate freely throughout the EU. This principle was later extended to the three European Free Trade Area countries—Iceland, Liechtenstein and Norway—that together with the present 15 EU member states makes up the EEA.

Pharmaceutical parallel trade in Europe is strictly limited—in terms both of where the products are sourced and where they are finally sold—to within the EEA. Therefore the term "parallel import", in a European context anyway, is now redundant. Trade between EEA member states is no longer classified as imports or exports, rather it merely represents the free movement of goods within a single European marketplace having no internal borders.

The products that are traded may be patented, or marked with the originator's trade mark or brand name. Such intellectual property rights attached to goods are regarded as having been exhausted. The principle of exhaustion of rights (sometimes referred to as 'the first sale doctrine') is that once a product is legally placed on the market in a country within the EEA by the owner of the rights, or with the owner's consent, the owner cannot use these rights to hinder the further sale of the product elsewhere within the EEA, except in very exceptional circumstances.

Pharmaceutical parallel trade has been supported by the European Commission since its outset and by an unbroken series of almost 30 ECJ judgements.[5]

How Does it Work?

Parallel traders buy medicines from well-established, authorised pharmaceutical wholesalers in countries where the products are cheaper. If the parallel trader has obtained a specific authorisation from the government in the country of destination for the product concerned, it can be resold there to wholesalers or direct to pharmacies, in parallel with the same medicine sold by the manufacturer's subsidiary or its licensee.

Parallel traders do not manufacture any medicines themselves, but merely adapt the labelling—and perhaps the packaging—to meet local requirements under government supervision according to national law. This adaptation process includes removing the original patient package inserts and replacing them with others giving the same information in the local language.

Parallel traders do not deal directly with the public. All transactions are done through authorised trade channels, and the pharmacist—who effectively is in the position to buy the same product at two different prices—dispenses it to the patient in the normal way.

Parallel traders take pride in being reliable, responsible and professional business partners for wholesalers and for pharmacists in community and hospital practice. Great importance is attached to consistently making available a broad range of products, in all package sizes and strengths, and to ensure that only the most up-to-date product information is supplied. In some cases, additional features beneficial to patients, such as Braille labelling, is added by parallel traders.

The products that enter into parallel trade are surplus to local needs. Wholesalers in the supplying states are naturally obliged to meet domestic demand first; if they didn't, given the level of competition between wholesalers for pharmacy customers, they would not remain in business long. Most countries also impose, through national law or a voluntary code of conduct, a so-called 'public service obligation'. This requires wholesalers to guarantee to keep an adequate range of medicines in stock and to deliver over the whole of their normal area of operation all supplies requested within a very short time period.

What are the Economics?

It is impossible to generalise as to the level of price differential between member states sufficient to trigger parallel trade. To a trader, a small margin on a best-selling product may be equally acceptable to a larger margin on a low volume product. There are also other important considerations, especially availability and mainte-

nance of supply. Parallel trade is constrained much more by supply than by demand.

The gross margin for the parallel trader does not, of course, represent profit. He has first to meet costs associated with regulatory compliance, purchasing, transport, warehousing, insurance, repackaging, quality assurance, distribution and promotion.

As with any other supplier, the parallel trader also has to cover the costs of the distribution chain and provide it with an appropriate level of profit. The margin structure of pharmacists in many member states is based on a linear scale. This provides a perverse financial disincentive to dispensing lower-cost products, and the impact of this has to be taken into account by parallel traders when negotiating terms with the trade.

Patients throughout Europe expect to take a doctor's prescription for any one (or more) of literally thousands of products into their local community pharmacy and receive it (or them) with minimal delay. Modern medicines can be very costly and no pharmacy could either afford the funds or find the space to keep in stock the entire range. The wholesale network or the parallel trader's own distribution system acts as the vital intermediary, but maintaining multiple daily deliveries all year round to tens of thousands of pharmacies is itself associated with high costs.

Finally, a large part of the price advantage that the parallel trader has achieved through prudent purchasing must be passed on to whosoever pays the bill—normally, the social health insurance system or national health service. The price charged for a parallel-traded product is always less than that for the domestic version. If this were not the case, the entire *raison d'etre* of parallel trade would cease to exist, as would the trade itself.

Just What the Physician Ordered

It is accepted that a part of the medicines market in every member state—a part that makes a disproportionately large and growing contribution to overall costs—consists of branded preparations under patent, where there is either no therapeutic alternative at all or only limited interchangeability in respect of particular patients. Different active ingredients within the same therapeutic category often affect individuals in different ways. Moreover, doctors, if persuaded by the merits of a branded product, are reluctant to switch on cost grounds alone to even a closely similar variant because of the risk of lower efficacy, poorer tolerability or allergy. Patients, too, prefer the familiarity of their usual brand.

A patent confers a monopoly and, by definition, a monopoly denies the right for the forces of competition to effectively work for the benefit of consumers. Parallel trade is the only form of competition to any specific medicine during the life of its patent.

Parallel trade offers a real solution to the funding problem that all European healthcare systems increasingly face. It provides, along with guaranteed cost savings, the original products from innovative research-driven manufacturers, not substitutes or copies. It also minimises the implementation of other, more interventionist or market-distorting cost-containment measures.

Which Countries are Involved?

There are many decades of experience with incoming parallel trade in the Netherlands, the United Kingdom and Germany. Since the early 1990s, Denmark followed by most of the other Nordic countries and Ireland have been added to the list, with a small number of parallel-traded products appearing most recently on the markets of Austria, Belgium, Italy, Spain and Greece. As regards supplying states, no one source is dominant, either as a whole or where any individual product is concerned.

No official figures on the trade are gathered and conjectures about its size in different member states vary widely. Estimates of the extent that parallel trade has penetrated national pharmaceutical markets, obtained from mainly manufacturer sources, are shown in table 2.

Table 2.—Approximate parallel trade retail pharmaceutical market penetration by value, 2002

Country	% share	source
Denmark	10.2	LIF[6]
Germany	7.1	IMS
Netherlands	13.3	SFK[7]
Norway	6.3	LMI[8]
Sweden	9.3 (2001 figure)	LIF[9]
United Kingdom	16.5	IMS

Some of the tougher recent cost-containment measures have been imposed in the traditional free markets of Denmark, Germany, the Netherlands and the UK. At the same time, some former low-price countries, like France, Italy and Spain, are now awarding higher prices than previously, due to the authorities referencing against prices in other countries and because of "European price corridor" strategies by multinational companies.

The result is that some prices in a "low-price" country are higher than those for the same product in a "high-price" country. Prices are also relatively fluid, being affected by exchange rate variations and by subsequent price movements.

What is certain is that parallel trade with medicines is no longer a simple south-north process, or even one-way. Almost all EEA countries are involved, as the product source or the product destination; indeed, many countries simultaneously act, with different products, as both source and destination. Attempts by some manufacturers to stifle the trade by applying supply quotas to wholesalers have, paradoxically, lead to its spread across Europe. Whereas five years ago a parallel trader in Germany, for example, might have sourced a particular brand from a single country, today the figure can be eight or more source countries.

Parallel trade consequently boosts intra-Community trade. Indeed, the European Commission views it as decisive vehicle for the completion of the EU Internal Market in medicines:[10]

> *'Parallel trade acts an important driving force for market integration where there are important differences in prices between Member States.'*

Parallel Trade: The Safeguards

As befits their special position with the maintenance of human health, all medicines—including parallel-traded ones—are strictly regulated in Europe by either national authorities or by the European Agency for the Evaluation of Medicinal Products (EMEA).

A number of EU Directives and Regulations have been adopted over the years with the aim of removing barriers to trade in medicines while ensuring that public health was not endangered. None has dealt specifically with parallel trade. It was left instead to the European Court to play a key role in establishing and regulating this sector.

***De Peijper* Judgement**

The most important test case to establish the regulatory position arose in the Netherlands in the early 1970s. A Dutch parallel trader, Adriaan de Peijper of Centrafarm, was prosecuted for importing a medicinal product from a wholesaler in the UK without the approval of the Dutch authorities, and without possessing either the product marketing approval documents or the batch records. De Peijper argued that he was unable to adduce such evidence because the manufacturer would not give him access to the necessary data. The product was authorised in both the Netherlands and the UK, and the Dutch court referred the matter to the ECJ.

The Court found in favour of the plaintiff; asking him to produce the records demanded by the Dutch authorities was held restrictive:[11]

> "National rules or practices which make it possible for a manufacturer of the pharmaceutical product in question and his duly appointed representative, simply by refusing to produce the documents relating to the medicinal preparation in general or to a specific batch of that preparation, to enjoy a monopoly of the importing and marketing of that product, must be regarded as being unnecessarily restrictive."

The Court felt that as the relevant documentation was already held by one set of authorities, they should co-operate in making these available on a reciprocal

basis, and that member states should develop a presumption of conformity. If the parallel-traded and the domestic versions were slightly different it was up to the authorities to investigate whether this was therapeutically significant.

The only measures which a national regulatory authority were justified in taking as regards parallel trade, the Court said, were those intended to verify that such products were identical with the version already marketed in that country by the domestic trade mark owner, or that the difference had no therapeutic effect.

> "Public health authorities should be encouraged 'not' to place parallel imports at a disadvantage, since the effective protection of health and the like of humans also demands that medicinal preparations should be sold at reasonable prices." [11]

This was to guard against unnecessary over-regulation as the products had all been previously approved by the regulatory authorities. Parallel trade makes modern, innovative medicines more affordable, while an unaffordable medicine is neither safe nor efficacious.

Commission Communication

Following the *de Peijper* judgement, the European Commission produced a Communication outlining the basic principles for an abbreviated form of marketing authorisation for parallel-traded medicines.[12]

The Commission recommended that the information supplied to the national authorities by the parallel trader should just be sufficient to ensure that the product concerned is effectively covered by an existing authorisation in the member state of destination.

In relation to the product sold by the domestic holder of the full marketing authorisation, the parallel-traded version must therefore:

- contain the same active ingredient(s);
- be administered to patients through the same route;
- have the same therapeutic effects; and
- have a common origin (*i.e.,* made by, or under licence to, the same company, or a member of the same group of companies)

Detailed information is obtained from the authorising authority in the country of origin to allow full comparison with the domestic version. The parallel trader is required to provide as a minimum:

- the product name and where it is sourced;
- the name and address of the holder of the full marketing authorisation, both in the member state of origin and in the member state of destination;
- the name and address of the parallel trader;
- the product's marketing authorisation number in the source country;
- the product's summary of product characteristics;
- specimens or mock-ups of the product in the form in which it will be sold in the member state of destination; and
- the appropriate fee.

A "reasonable period" (a maximum of 45 days was suggested) after receipt of such information should be adequate to assess it, the Commission said. In practice, the assessment period facing parallel traders in several countries is often very much longer. All EEA countries—with the notable exception of France—that are actual or potential destinations for parallel trade now have national rules based on the Commission Communication in place. Every parallel-traded product is required to have its abbreviated marketing authorisation number issued by the national authority and the name of the owner of that authorisation clearly labelled on the pack. If the manufacturer makes any change to the product or its labelling, parallel traders have to quarantine any stock they hold until they obtain regulatory approval for the necessary variation. Pharmacists who supply unauthorised products are open to disciplinary action.

EMEA Approvals

A compliance check is used by the EMEA on the request of a parallel trader for high-tech or biotech medicines that have already received centralised, pan-European marketing approval by the Agency.[13] Such products are, by definition, identical in every respect across the EU, with the Community marketing authorisation covering all linguistic versions of the label and package insert. As a result no further regulatory approval is necessary before parallel distribution takes place.

What Other Regulations Apply?

As one of the conditions for their abbreviated marketing authorisations, parallel traders are required to keep records of the origin, quantity and batch numbers of all products they sell, as well as to retain a sample from every issued lot. An authentic reference sample is also kept for every presentation against which every incoming batch is checked.

If as is usual they are involved in modifying the outer packaging to enable the product to enter the local supply chain parallel importers need a manufacturing authorisation, with all the usual obligations this entails (*e.g.,* employment of an EU Qualified Person, maintenance of Good Manufacturing Practice standards, periodic government inspection). Under manufacturer liability provisions, parallel traders in several countries are required to maintain substantial insurance cover, yet this has never once been needed.

In most countries, it is also a requirement for parallel traders to hold a wholesale dealing authorisation, as well as a manufacturing authorisation, if pharmacies are supplied direct. Granting of such an authorisation is conditional upon compliance with a number of EU-set requirements and Good Distribution Practice guidelines, including:

- maintaining suitable premises for the storage of medicines;
- employment of an EU Responsible Person;
- restrictions upon the sources and supply of such products;
- maintenance of the cold chain for temperature-sensitive products;
- establishment of approved product recall procedures;
- record keeping requirements, in addition to maintaining measures to ensure an audit trail for product traceability

Parallel Trade: The Savings

Parallel trade can only be realised in case of demand and demand would not exist if the parallel trader did not pass on a large part of the price differential to the payer. Across Europe, payers for prescription drugs are primarily national social health insurance schemes/national health services, though, except with the very young, the elderly, the unemployed and the chronically-ill, there is also usually an element of patient co-payment.

Direct savings accrue in every member state with incoming parallel trade. The European Commission, in its 2003 Communication following the G10 process, described these savings as "significant". This is because national governments and/or their national health providers have introduced measures to incentivise the use of and guarantee savings from parallel trade. How these measures apply and how the savings are split between the statutory healthcare system and patient vary by country.

> *"The UK reimbursement system with fixed reimbursement fees and its clawback system de facto provides an incentive for intermediaries and pharmacies to purchase cheaper parallel-traded drugs. It has also been shown that other Member States give more specific incentives to parallel trade, in order to achieve cost savings for the healthcare budget. Denmark, Germany and Sweden serve as an example."* [14]

An independent study by health economists at the UK's University of York estimated that direct savings accruing to payers and patients from pharmaceutical parallel trade in 2002 in the UK, Germany, Sweden, Netherlands and Denmark totalled the equivalent of $734 million (at current exchange rates).[15] This figure does not include hospitals, the private sector, or other countries with incoming parallel trade like Norway, Finland, Ireland and Austria.

In addition to direct savings in all countries that realise incoming parallel trade, there is also general price erosion, benefiting all buyers. This is because parallel trade brings an important competitive element to bear, especially in the notoriously price uncompetitive patent-protected segment, the part of the market that generics cannot reach.

> *". . . parallel trade. . .that is the nearest to price competition in drugs that Europe gets."* Kenneth Clarke (former UK Health Secretary), UniChem conference, Mauritius, 2002
>
> *"For a manufacturer to enjoy a monopoly of the importing and marketing of the product must be regarded as unnecessarily restrictive."*[12]

"Patented medicines enjoy patent protection for at least 20 years. In cases where only a few alternatives are available, parallel trade will offer the only source of competition."[15]

The availability of parallel-traded products, or even just the threat of this, can result in lower prices for domestic equivalents than would otherwise be the case. Market prices are reduced and/or price rises forgone, and greater discounts or improved terms are offered to distributors in an attempt to buy their loyalty.

"Parallel trade also generates indirect savings by creating competition, whereas otherwise there is none, and thus forcing pharmaceutical manufacturers to reduce the prices of domestically sourced products. These indirect savings are difficult to quantify but they could be larger than direct savings."

Governments which cap reimbursement for multisource products are also able to set lower reimbursement ceilings when parallel-traded versions are available.

What are the Benefits to the Patient?

Patients as taxpayers or as members of health insurance funds have a clear interest in seeing their hard-earned contributions well spent by the statutory healthcare system.

"Ultimately, all patients pay for the national health system. Public health systems are financed by contributions or by general taxes. Any savings made by these schemes via the purchase of cheaper parallel-traded drugs indirectly benefit the schemes' members."[15]

In many European countries (*e.g.,* Belgium, Denmark, Finland, France, Greece, Luxembourg, Norway, Portugal, Spain, Sweden), the majority of patients pay a share of the cost of prescribed medicines they consume, so use of cheaper parallel-traded products will mean lower out-of-pocket demands.

"Patients benefit directly from parallel trade either when they have to pay the full amount of the purchase price themselves or when reimbursement is only partial and is expressed as a percentage of the actual purchase price (in contrast with a flat fee)."[15]

Some member states employ forms of reference pricing (similar to 'maximum allowable cost' in the US), in which interchangeable products are grouped with the amount reimbursed by the statutory healthcare system capped at some predetermined amount per group. If a parallel-traded product is dispensed the patient may avoid paying any excess payment that would otherwise be due.

With the growing use of so-called "lifestyle drugs" (*e.g.,* treatments for erectile dysfunction, smoking cessation aids, hair restoratives, slimming agents) as well as oral contraceptives—products that are not widely if at all reimbursed—the consumer makes a direct saving from the cash purchase of a parallel-traded medicine on private prescription.

Parallel Trade Myths & Reality

Against an obvious background of commercial interests, it is the aim of some international pharmaceutical manufacturers to keep the market share of parallel-traded products as low as possible by obstructing inter-state movement. Initiatives taken include:

- supply quota-fixing measures
- price corridor strategies
- dual pricing strategies
- market segmentation practices
- variable pack size
- variable brand name
- variable form of administration
- different packaging
- selective distribution
- targeting with legal actions

Such attempts are invariably in vain, for, as the Competition Directorate-General of the European Commission has said:[16]

"On several occasions the Court of Justice has ruled that parallel imports should not be blocked, irrespective of the factors that determine price differences. Hence,

in the pharmaceutical sector, the Commission has correctly applied the competition rules to agreement or conduct which restrict parallel trade in drugs."

The EAEPC believes that criticism and resistance from some quarters is based on a misunderstanding of the actual facts. This section aims to dispel some of the erroneous folklore that has developed around the topic.

Myth: "The dogma of free movement within the internal market is incompatible with price-fixing by national governments"

Fact: The ECJ has stated quite clearly that existing inter-state price differences with medicines cannot justify a derogation from the principle of free movement, even if such differences result from price controls imposed by member states.[17]

Despite this ruling, manufacturers continue to argue that a correctly working market entails not just the free movement of products, but also the freedom to set prices. This viewpoint ignores today's reality:

- Only a minority of member states still exert direct price control on new prescription medicines at the level of the factory gate. Instead, the preferred approach, adopted across the entire EEA in various country-specific ways, is to limit access to the public reimbursement system or curtail payments made under it.
- Even where actual price control still exists, the authorities no longer price by inflexible formulae, and allow instead a true negotiation, by which a company's asking price for its key brands is increasingly accepted, sometimes in return for offsets elsewhere.

  ". . . given the fact that companies actually negotiate the prices with the Spanish government and manage to achieve price increases by invoking one or more of the justifications set forth in the relevant Royal Decree, it is too simplistic to regard pharmaceutical companies as price takers because the national competent authorities set maximum prices."[14]

Payers are primarily concerned with keeping the growth in the total cost of the drugs bill under control and give considerable commercial freedom to companies to set individual product prices as long as overall budgetary limits are respected. Various types of 'deals' concluded by multinational firms so as to achieve comparable prices for their new potential blockbusters with those in other countries have resulted. These may include, for example, provision of the results of a cost-effectiveness study, volume sales caps, prescribing or advertising restrictions, delayed price cuts, or immediate price cuts and/or reimbursement delistings with other, unrelated but ageing products in its portfolio.

Other arrangements, agreed by national associations on behalf of their members, make provision for cash paybacks by industry as a whole if the growth in the drugs budget exceeds pre-set limits. These allow prices higher than otherwise on individual products to be agreed in an environment of cost containment. Such schemes are in place in Belgium, France, Portugal and Spain, and formerly applied in Italy.

Myth: "Patients will be frightened and confused by foreign language packs"

Fact: Labelling of parallel-traded medicines is fully in accordance with EU and country-specific legislation. This includes provision of a label and a patient package insert in the local language, whose texts have been approved by the national regulatory authority.

In some cases, one or more self-adhesive over-labels will be applied to the original cartons, though in other circumstances the parallel trader will totally replace the carton by a new one giving the required information only in the local language. This latter situation might occur, for example, when the manufacturer markets the product with different pack sizes in different countries, where the amount of information to be provided on the label is extensive, or to enhance patient compliance.

Any repackaging done by the parallel trader is performed under strict GMP conditions and affects only the outer container; the actual dosage form is entirely untouched. Almost all solid dosage forms in Europe are blister or foil wrapped before inclusion by their manufacturer in patient packs; dispensing from bulk is very rare.

The ECJ has laid down the circumstances under which repackaging can be undertaken:[18]

- the product inside the packaging must not be affected;
- the new packaging must clearly state who repackaged the product and the name of the manufacturer;
- the reputation of the trade mark or its owner must not be damaged; and
- the trade mark owner must be given adequate prior notice before the repackaged product is put on sale and, on demand, be supplied with a specimen of the repackaged product.

Many parallel-traded dosage forms are identical in appearance with the domestic version. In other cases, as also happens quite frequently with generic medicines, the shape and colour may vary. In a very few cases the additives are different. This may require explanation by the pharmacist to the patient and checks for intolerance. Some patients may not be suitable to receive parallel-traded products. As the expert on medicines, the pharmacist is well qualified to conduct screening, and to give the necessary advice and reassurance.

The considerable market shares, of well over 50 percent, achieved and maintained by certain individual parallel-traded products in certain countries, provide clear proof of their high level of acceptance by patients.

Myth: "Doctors would prefer their patients to receive locally-made rather than foreign products"

Fact: Today, in the majority of EU member states, the source of production of most medicines is in other member states. To save costs, companies have consolidated manufacturing into a handful of sites to serve the entire continent. Several are situated outside the EU. Most specialise as "centres of excellence" for particular types of dosage forms. In such cases, "parallel imports" compete with 'direct imports' The motivation for the manufacturer is the same as for the parallel trader—to exploit lower costs.

Myth: "Manufacturers will withhold new introductions from countries that supply parallel trade"

Fact: There is no evidence of this. It seems unlikely, as the main supplying countries are typically high-volume users of medicines and hence attractive markets for industry.

Myth: "Parallel trade will deter the search for new cures"

Fact: There is no link between parallel trade and investment in R&D

European patients are best served not only by having access to the lowest possible prices for today's first-choice treatments but also by assuring that a stream of new innovations continues to emerge from research and development pipelines to tackle unmet medical needs. Diversion of sales from one European country to another with parallel trade has not, however, led to the research-based industry cutting back on R&D. In fact, just the opposite; spend on pharmaceutical R&D in Europe grew more than three-fold from 1985 to 1999.[19]

With the market share of parallel trade in its peak year of 2002 amounting to only 4 percent EU-wide, this cannot influence investment in R&D.

> *'There does not appear to be any causal link between the losses due to parallel trade and GlaxoWellcome's R&D investments. Moreover, these losses are too insignificant to affect these investments to a considerable extent. Finally, it must be stressed that the R&D budget of pharmaceutical companies, while important, only represents around 15 percent of their total budget. Losses stemming from parallel trade could just as well be deducted from the companies other budget items, such as marketing costs.*
>
> *. . . Any savings they might hypothetically make by preventing parallel trade would therefore not automatically lead to higher R&D investments. It is conceivable that these savings might merely be added to the companies' profits.*'[14]

An independent consultant[20] has put total direct losses to manufacturers from parallel trade across Europe at about Euro 500 million per year, roughly the same as one company's costs in discovering, developing and launching a single new active ingredient, he noted. Manufacturers also incur considerable self-inflicted costs (*e.g.,* lower sales volume, loss of customer goodwill, legal costs) in their attempts to prevent parallel trade.

There is no evidence that capital investment or competitiveness is affected either. Europe's pharmaceutical trade surplus with the rest of the world increased fourfold between 1985 and 1999.[19]

Myth: "It acts as a channel for counterfeit, pirated or substandard products".

Fact: Parallel traded medicines are the products of the original manufacturers, often from the very same plant that produces the domestic versions. They are either exactly identical, or with very small differences in colour or inert excipients, differences which the regulatory authorities verify have no therapeutic consequences. If a manufacturer criticises a parallel-traded product it amounts to criticism of its own product.

Handling, transportation and storage of medicines by parallel traders are strictly in accordance with the conditions given in the product's marketing authorisation, and this includes adhering to any cold chain or narcotic requirements.

Counterfeiting is a totally different subject to parallel trade. There is, in fact, very little evidence that counterfeit medicines are traded by any means in Europe. A 1999 survey published by the European Commission found the proportion actually

on the market was, after the U.S., the lowest in the world.[21] In 2001, the Medicines Control Agency described the level of pharmaceutical counterfeiting in the UK as "virtually undetectable".[22] One of the main reasons is that the system works effectively in a closed loop: Authorised manufacturers sell only authorised product to authorised wholesalers, who sell only to authorised pharmacies, hospitals and dispensing doctors. Parallel traders use the same distribution channels used by domestic products.

As far as can be ascertained there has never been a single, proven case of a counterfeit medicine leaving the parallel trade supply chain in Europe. Certainly, none has been reported in the two largest markets for incoming parallel trade—the UK and Germany; in the case of the latter, the government has recently verified this fact.[23]

Parallel traders take the strictest precautions. For a start, they source only from authorised, reputable wholesalers/traders in other EEA countries with whom they have had business dealings for many years. All incoming batches are compared against authentic reference samples, and multiple checks against photos of authentic products, package texts and leaflets are made at different stages of the process. In addition to the quality assurance procedures agreed between the trader's local medicines inspectorate and its Qualified Person, voluntary ones are often instigated, *e.g.,* UV detection of holograms on some packs from Greece, and re-assay of vaccines in Germany by the Paul Erlich Institute.

It is not unknown for parallel traders during their routine checks to detect defects in products and to report these to the manufacturer and regulatory authority concerned. As the only checks made in practice on a medicine after it leaves the manufacturer are those conducted by parallel traders, the likelihood of a patient receiving a counterfeit product is actually less not more with parallel trade.

Myth: "Parallel trade will damage Europe's industrial base"

Fact: For many years, leading manufacturers have predicted they will be damaged or even eliminated, not only by parallel trade, but by the likes of price controls, heavy-handed regulation and by generic competition, but the sector has not merely survived it has flourished.

> *"Conclusive information on the economic effect of this (parallel) trade on the British pharmaceutical industry is not available, given the uncertainty surrounding such factors as the profits made on sales to the country which is the source of imports and other discounts offered by manufacturers in the United Kingdom."*[24]

As well as offering competition to the domestic trade mark owner, the parallel trade sector is itself highly competitive, with up to 30 active players per country, each offering different terms. Together they provide employment to thousands of staff. Management is highly qualified, with extensive experience often gained in large pharmaceutical companies or in community pharmacy.

Many firms also have a strong platform to participate in the development of generic medicines, a sector that—with the active encouragement of several national governments—is forecast to grow strongly over the next decade, enhancing price competition with patent-expired molecules to the benefit of payers and patients. To further extend the continuum, some parallel traders have evolved into fully-fledged pharmaceutical companies, with a portfolio that includes original products and investment in R&D.

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Glossary of Abbreviations

EAEPC—European Association of Euro-Pharmaceutical Companies

EC—European Community

ECJ—European Court of Justice

EEA—European Economic Area

EMEA—European Agency for the Evaluation of Medicinal Products

EU—European Union

GMP—good manufacturing practice

R&D—research and development

The CHAIRMAN. Thank you for coming, Mr. MacArthur. I think you've contributed a great deal and given us perhaps some avenues that we might pursue, and we thank you.

And, from Fargo, North Dakota, Mr. Lubka. How cold is it in Fargo today?

Mr. LUBKA. It's like early spring.

The CHAIRMAN. Oh, good.

[Laughter.]

Mr. LUBKA. Global warming.

[Laughter.]

The CHAIRMAN. We're happy to see you here, sir. I think you have known Senator Dorgan in the past, so there are several things you don't want to reveal about him to the Committee.

[Laughter.]

Senator DORGAN. Mr. Chairman, if I might just say, again, that I went to Canada on a trip, and Mr. Lubka accompanied me and understands firsthand the differences in pricing between the U.S. and Canada on the identical prescription drug.

The CHAIRMAN. Thank you.

Mr. Lubka, you're welcome here, and we appreciate the input of people like yourself, who face these challenges on a day-to-day basis. Please proceed.

STATEMENT OF LEWIS LUBKA, SENIOR CITIZEN, ON BEHALF OF ALLIANCE FOR RETIRED AMERICANS

Mr. LUBKA. Chairman McCain and Members of the Commerce, Science, and Transportation Committee, thank you for holding this hearing today on the impact of prescription drug importation on consumers.

My name is Lewis Lubka. I live in Fargo, North Dakota. I am here today representing the Alliance for Retired Americans. The Alliance is a national organization of over three million members that works to create an America that protects the health and economic security of seniors, rewards work, strengthens families, and builds thriving communities. It was launched in January 2001, by a national coalition of labor unions and community-based organizations dedicated to improving the quality of life for retirees and older Americans.

I'm 77 years of age, and take at least three prescriptions at any given time. Between Myocalcin and Fosamax for osteoporosis, and Synthroid for my thyroid, I spend well over 2,000 a year on my prescriptions. I have purchased my drugs in Canada to help defray these costs. This was a trip that was organized by Senator Dorgan.

I saw my doctor, in Fargo, who wrote out my prescriptions, brought them to a doctor in the City of Emerson, which is a little ways over the border. After I saw the Canadian doctor, I took the prescriptions to a Canadian pharmacy located in the same building. I brought $300 in cash. I wished I'd a brought a lot more. I came back with about $800 worth of prescriptions. And I never got sick or—I mean, it was just like what I had been taking right along.

I feel completely safe in taking medications from Canada. The Alliance for Retired Americans has made more than 20 trips to Canada, from states stretching from coast to coast, serving hundreds of riders. No one has ever reported getting sick or had any adverse effects from taking these medications.

I'm a veteran of World War II. I was a paratrooper in the 82nd Airborne Division. As a former welder and then a professor, I am an ex-shipyard worker, ex-assembly line worker, and ex-steelworker, as well as retired member of the NEA, National Education Association. I have lived all over this country, seen many people, and witnessed a lot in my lifetime. I worked in a Hoboken, New Jersey, shipyards at Bethlehem Steel repairing the Stockholm after it collided with the Andrea Doria. I worked for General Electric, in Kentucky, before becoming a professor at North Dakota State University. I have always been a human rights activist, and was a part of Martin Luther King's civil rights movement. I'm still working for human rights.

Senators, I know right from wrong. The bill that is coming out of the conference committee is not good for retirees. It does nothing to contain the skyrocketing prices of prescription drugs. In fact, it forbids Medicare from using the purchasing power of 40 million beneficiaries to negotiate the best drug prices.

The Federal Government currently bargains for the best prices for the Department of Veteran Affairs, the Department of Defense, and the Indian Health Service Systems. There is no logic on why Congress would forbid Medicare from doing the same. Seniors and all taxpayers are the losers.

This bill caters to the pharmaceutical industry by unnecessarily preventing American citizens from getting their drugs in Canada, where they are safe and affordable. I have never seen anyone get sick from taking a drug imported from Canada, but I have seen many people suffering from high drug prices that they cannot afford. Drugs from Canada are just as safe as American drugs. In fact, many of the drugs from Canada were made in the USA.

Members of the Committee, I'm here today to ask that you enact a drug benefit that allows drugs to be imported from Canada, without loopholes that permit the Department of Health and Human Services to stop safe reimportation. To do anything else will make millions of seniors worse off.

Thank you for inviting me here.

[The prepared statement of Mr. Lubka follows:]

PREPARED STATEMENT OF LEWIS LUBKA, SENIOR CITIZEN, ON BEHALF OF THE ALLIANCE FOR RETIRED AMERICANS

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I have purchased my drugs in Canada to help defray these costs. I saw an American doctor, filled a prescription in the United States, and brought it to a doctor in the City of Emerson, right over the border in Canada. After I saw the Canadian doctor, I took the new prescription to a Canadian pharmacy that was located in the same building. I brought $300 in cash with me and purchased $800 worth of medications with the money.

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I have lived all over this country, seen many people, and witnessed a lot in my lifetime. I worked in the Hoboken, New Jersey shipyards of Bethlehem Steel repairing the Stockholm after it collided with the Andrea Doria. I worked for General Electric in Kentucky before becoming a professor at North Dakota State University.

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Senator DORGAN [presiding]. Mr. Lubka, thank you very much.

And, finally, Dr. Funderburk, thank you for joining us. Why don't you proceed.

STATEMENT OF DAVID FUNDERBURK, LEGISLATIVE COUNSEL, TREA SENIOR CITIZENS LEAGUE

Dr. FUNDERBURK. Mr. Chairman, I want to thank you for the opportunity to testify on behalf of S. 1781.

I serve as legislative counsel for the TREA Senior Citizens League, known as TSCL. It is a nationwide nonprofit education and lobbying organization with approximately 1.2 million members, which will be celebrating its 10th anniversary in a few months. TSCL's board of trustees is an all-volunteer group of retired military, headed up by its Chairman, George A. Smith. It sends out informative newsletters, stays in touch with its members via e-mail, publishes informational booklets, and it has an information-packed website, *www.tscl.org*.

TSCL has nearly 23,700 members and supporters in the state of Arizona, and, in your state of North Dakota, several thousand members, Mr. Chairman.

On the House side, TSCL has been working diligently in behalf of H.R. 2427, introduced by Congressman Gil Gutknecht, and is happy today to announce its support for S. 1781, your bill, the companion measure here in the Senate.

In TSCL's annual survey, in February 2003, fully 87 percent of the membership responding voiced their support for drug importation. The current high cost of prescriptions is crippling our seniors. One of our members, Lillian F., told us, "I don't get enough Social Security for my medication, and I had to quit taking a couple of them. I have Parkinson's. I take medication for that. It's very expensive. Now my husband had a heart attack, and he has to take a lot of medications, too, so I might have to quit taking more of my medicine." Unfortunately, since Lillian F. wrote that e-mail to us in April of this year, her husband has passed away, and she has had to cut back further on her medications.

It is on behalf of individuals such as Lillian that we support more affordable prescription drugs, and we believe S. 1781 is a good place to start. TSCL is absolutely committed to this drug reimportation legislation.

Prior to the vote in the House on H.R. 2427, TSCL ran a half-page ad in the *Washington Times,* urging Members of Congress to support passage of the bill. We also sent out e-mail alerts to thousands of our supporters urging them to contact their elected representatives. And we continue our efforts through similar grassroots activities.

As has been mentioned by many of those speaking previously, a drug that a senior or any American cannot afford and, therefore, cannot take is not a safe drug. TSCL Chairman, George Smith,

wanted me to tell you that seniors especially ask to be treated like responsible men and women, and seniors should have the right to assume the minuscule risk of using a drug obtained from Canada, rather than suffer the risk of not having the prescription drug at all.

William Hubbard, Associate Commissioner of the FDA, was quoted as saying, "It's not OK for an individual to bring in drugs," referring to these bus trips of individuals going to Canada, "but so much of the stuff is coming in, and it's so uncompassionate to go after patients." Well, should we then have compassion for Minnesotans who are able to make the trip, or North Dakotans, to Canada, but not for Mississippians and others who are not able to make such trips?

I want to thank the distinguished Chairman for holding a hearing on this critical legislation. And on behalf of TSCL and its members, I urge the Senate to join the House and approve this important legislation.

And, in closing, let me say, TSCL wants to work with you and the Committee on this issue and other issues of importance to seniors in the future, and I thank you for the opportunity to testify here today on behalf of TSCL and its members and supporters.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Funderburk follows:]

PREPARED STATEMENT OF DAVID FUNDERBURK, LEGISLATIVE COUNSEL, TREA SENIOR CITIZENS LEAGUE

Mr. Chairman, Members of the Commerce Committee, I want to thank you for the opportunity to testify today on behalf of S.1781, which would allow Americans to have increased access to prescription drugs at reasonable prices. I would ask permission that my entire statement be included in the record.

My name is David Funderburk, and I serve as Legislative Counsel for the TREA Senior Citizens League, known as TSCL. TSCL is a nationwide non-profit education and lobbying organization with approximately 1.2 million members and supporters, which will be celebrating its Tenth Anniversary in a few months. TSCL's Board of Trustees is an all-volunteer group of retired military headed up by its Chairman, George A. Smith. TSCL sends out an informative newsletter by mail and by e-mail to hundreds of thousands of seniors 10 times per year. It stays in touch with its members via e-mail alerts. TSCL publishes informational booklets such as those that help seniors better understand Social Security and Medicare, and other issues. And, TSCL has an information-packed website, *www.tscl.org,* with information on the drug re-import bill, and many other policy issues affecting seniors.

TSCL has nearly 23,700 members and supporters in your state of Arizona, Mr. Chairman. (I remember the Chairman coming to my hometown not too many years ago to campaign for me when I was in Congress. It's always nice to be with you, Mr. Chairman.)

On the House side, TSCL has been working diligently on behalf of H.R. 2427, introduced by Congressmen Gil Gutknecht (R–MN) and Rahm Emanuel (D–IL), and is happy to today announce its support for S.1781, the companion measure here in the Senate.

In TSCL's annual survey in February 2003, fully 87 percent of the TSCL membership responding voiced their support for drug importation. The current high cost of prescriptions is crippling our seniors.

One of our members, "Lillian F," told us "I don't get enough Social Security for my medication and had to quit taking a couple of them. . . . I have Parkinson's and I take medication for that and it is expensive. . . . Now my husband had a heart attack, and he has to take a lot of medications too, so I might have to quit taking more of my medicine." Unfortunately, since "Lillian F." wrote that e-mail to us in April of this year, her husband has passed away and she has had to cut back further on her medicines. It is on behalf of individuals such as "Lillian F" that we support more affordable prescription drugs, and we believe that S.1781 is a good place to start.

The disparity of drug costs in the United States, Canada and Europe is striking. In Canada, someone can purchase Zocor for $45.49; here in the U.S., the same prescription is $123.43. Pravachol purchased in Canada, 40.00; in the United States, $85.60. No wonder seniors like "Lillian F" aren't able to afford the medicine they need!

TSCL is absolutely committed to this drug re-import legislation. Prior to the vote in the House of Representatives on H.R. 2427, TSCL ran a half-page ad in the *Washington Times,* urging Members of Congress to support passage of the bill. We also sent out e-alerts to thousands of our supporters urging them to contact their elected Representatives. We continue our efforts through similar grassroots activities.

We may not have the visibility and presence of the pharmaceutical industry, but there are fully 1.2 million seniors represented by TSCL. TSCL is funded with small contributions from its supporters and members and today I want to share with you the views of those members and supporters.

Some who oppose S.1781 use the argument that measures such as S.1781 or H.R. 2427 will open the floodgates for unsafe drugs coming into the United States. But right now, some 1 million Americans buy medicines from Canada either through bus trips or via the Internet, according to the Manitoba International Pharmacists Association. There have been no reported deaths from those drugs, according to testimony provided from the U.S. Food and Drug Administration ("FDA") at a House hearing.

And as Katherine Greider wrote in her book, "The Big Fix: How the Pharmaceutical Industry is Ripping Off American Consumers," some 29 percent of seniors don't fill their prescriptions because they can't afford to. We see that in our own membership, as mentioned above. A drug that a senior—or any American—can't afford, and therefore can't take—is not a safe drug.

Please don't accept the nonsense that if this law is passed seniors might make the wrong choice in buying prescription drugs. Seniors do not need such protection from government. TSCL Chairman George Smith wanted me to tell you that seniors especially ask to be treated like the responsible men and women they are. And seniors should have the right to assume the miniscule risk of using a drug obtained from Canada, rather than suffer the risk of not having the prescription drug to take at all. Everything we do, including getting out of bed in the morning entails risk, and it is not the business of the Federal Government to take away our freedom to make decisions like these for ourselves.

Of course, the proposed legislation allows the importation of only FDA-approved drugs from FDA-approved facilities. Many drugs that Americans buy from Canada are actually made in New Jersey or Puerto Rico.

There is no guarantee of safety in any drug that you take. However, S.1781 provides for state of the art technology to protect imported medicines—the same anti-counterfeiting measures used to protect our new currency. Right now, an American has a greater risk of getting sick by eating imported food than he or she does getting sick from a drug purchased in Canada or Germany.

Americans over the age of 65 will spend some $1.8 trillion on prescriptions during the next 10 years, according to the Congressional Budget Office. Importing prescriptions could save them 35 percent, again according to CBO.

States and localities, too, want to save dollars in these tight economic times. Minnesota, Iowa, Illinois, all are looking at drug importation. Closer to home, Montgomery County, Maryland is beginning to study the issue. Governor Blagojevich released a study that concluded imports from Canada were safe and could save his state of Illinois tens of millions of dollars a year.

A study by Families USA found that marketing, advertising and administrative costs are much higher than what is currently spent on research and development, often twice as much. The pharmaceutical industry will still make a profit if S.1781 or H.R. 2427 were to pass, and pharmaceutical companies would still be able to devote sufficient funds to R&D if they chose to do so.

According to a statement by Senator Chuck Grassley, as cited in the *Washington Post,* "Imports create competition and keep domestic industry more responsive to consumers." (*Washington Post,* November 8, 2003)

The FDA has, in the past, looked the other way on Americans taking the bus to buy small personal supplies of medicines from Canada. This is changing. We have also recently seen a district judge grant an FDA request to shut down RxDepots in Oklahoma. The time to act is now.

William Hubbard, Associate Commissioner of the FDA, was quoted in a September 16, 2003 article from the *New York Times* as saying, "It's not O.K. for the individual to bring in drugs" (referring to bus trips of individuals going to Canada), "but so much of the stuff is coming in and it's so uncompassionate to go after pa-

tients." Should we then have compassion for Minnesotans who are able to make the trip to Canada, but not Mississippians who are not?

I want to thank the distinguished Chairman for holding a hearing on this critical legislation, and on behalf of TSCL and its members, I urge the Senate to join the House and approve this important legislation.

And in closing, let me say that TSCL wants to work with you and the Committee on this issue, and on other matters of importance to seniors in the future, and I thank you for the opportunity to testify here today on behalf of TSCL and its members and supporters.

Senator DORGAN. Mr. Funderburk, thank you very much.

Let me indicate, on behalf of Senator McCain, who had to leave for another engagement, that we very much appreciate the testimony of this panel. And I regret that the hearing took some long while this morning. As a result of that, my colleagues had other hearings to go to and other places to go.

And so let me make a couple of comments, if I might, about your testimony. I'm not going to ask questions, because we need to adjourn the hearing.

Mr. Catizone, I happen to feel very strongly that its very important to keep our Main Street pharmacists in the middle of patient healthcare, especially with respect to how prescription drugs act and interact. We have so many senior citizens who take multiple prescription drugs—four, six, sometimes 10 or 12 different prescriptions drugs every day. And if there's not a pharmacist somewhere watching all of these drugs to find out how they interact—and they might say to the senior citizen, "These two are dangerous if you take them together. These two, if you take together, nullify each other, so you're wasting your money." It's important that that be the case. There is so much now—so many circumstances in which there's not a pharmacist involved, and someone's seeing four different specialists, and they're ordering medicine from four different directions.

Our ultimate goal, my goal, is not to ask Americans to go elsewhere to buy prescription drugs. It is to force a repricing of prescription drugs in our country. But I value the role of the pharmacist. I feel very strongly about the viability and the need for Main Street pharmacists.

Mr. MacArthur, you described the issue of parallel trading in Europe, and it is identical to that which, in my judgment, we should be doing. We have taken a slightly different approach. But your description of parallel trading describes to us that all of the nonsense we are hearing about safety issues is just that, nonsense. It is, apparently, by your testimony, and I have heard this previously, it is easy for the countries in Europe to engage in a regime in which you are able to certify the prescription drugs in each other's countries, and also to monitor the drugs that are moving country to country. And so all of these safety issues here, I think, are just raised on behalf of those who don't want to do anything to interrupt the pricing strategy in the U.S. But I think you have raised, as Senator McCain has said, some important issues for us to consider with respect to parallel trading, itself, which is slightly different than that which we've been proposing.

And, Mr. Lubka, I've known you for some long while, and, as I indicated, on a snowy day in North Dakota, we rode in a van to Emerson, Canada. And, in a one-room pharmacy, you discovered

what all of us know, and that is, five miles north of a U.S. pharmacy you can buy exactly the same prescription drugs, FDA-approved, in the same bottle, the same pill, manufactured by the same company, for a dramatically lower price, and it describes what's wrong with this system and why we have these hearings. The U.S. consumer is paying the highest prices in the world for prescription drugs, and it's unfair.

Mr. LUBKA. Maybe I ought to make another run up to Canada. You think?

Senator DORGAN. Well, we maybe ought to do that, Mr. Lubka.

And Dr. Funderburk, I appreciate your organization's interest in this. I know that you make the case it ought not just be those who live contiguous to the border that have access to these lower-priced prescription drugs, and you're absolutely correct about that. Again, you heard me say, our ultimate goal is to force a repricing of prescription drugs in our country. There are no miracles from miracle drugs that people can't afford.

And let me finish by telling you of one evening in a little town in northern North Dakota, at the end of a meeting, a woman close to 80 years of age came up to me when the meeting broke up, and she grabbed me by the elbow, and she said, "Mr. Senator, can you help me?" I said, "I'll sure try. What's wrong?" And she began to describe to me, as her eyes welled with tears and her chin began to quiver, she said, "I have heart disease and diabetes, and my doctor says I have to take medicine to stay alive, and I can't afford it. I don't have any money. Can you help me?"

And she, at near 80, a widow with very little income, understood the dilemma. She didn't have the money, but she needed to take these prescription drugs to control her diabetes and her heart disease. And that's why we have to do something about this. And, you know, we have to do it in a way that makes sense for the consumers of this country.

Let me make one final point. This is not a search for villains. Our pharmaceutical industry is big, strong, and healthy. I want our pharmaceutical industry to do well. I want them to discover new medicines, and I want them to do research, but I also want from them fair pricing for the American consumers, and that is not the case today. And that's why we are pushing for legislation.

Let me thank this panel for being here. This hearing is adjourned.

[Whereupon, at 12:15 p.m., the hearing was adjourned.]

A P P E N D I X

PREPARED STATEMENT OF REPRESENTATIVE DAVID LEMOINE, CHAIR AND CHERYL RIVERS, EXECUTIVE DIRECTOR, NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES

Mr. Chairman:

The National Legislative Association on Prescription Drug Prices is a nonprofit bipartisan Legislative Association, which was formed in 1999,s Our mission is to win fair prices and comprehensive prescription drug coverage for all Americans. Though several of our member states, including our own states of Maine and Vermont have made valiant efforts and passed innovative and creative pieces of legislation, the situation with prescription drug prices in America remains a National disgrace. Americans are asked to pay the highest prices in the world for drugs, which were often developed with taxpayer dollars through government-funded research.

The Medicare Prescription drug conference report is the latest evidence of the failure of Congress to act to bring some balance and basic fairness to drug prices in America. It is clear that neither the current administration nor a majority in Congress have the political will to stand up to the pharmaceutical industry on behalf of ordinary Americans. Not only will the legislation fail to improve on the status quo for states, and seniors, but also it will severely curtail state efforts to use our clout in the market to negotiate for fair prices for states, seniors, and the uninsured. We understand that the Medicare Prescription Drug Conference Report contains industry-favored language that means it will never be implemented. Without a strong instructive statute this administration will continue to do everything in its power to protect the pharmaceutical industry at the expense of ordinary Americans.

Across America states, cities, businesses and individuals need your help. We need Legislation that allows businesses and individuals to freely acquire the prescription drugs they need in both the Canadian and European markets. This would allow a sufficient supply to thwart industry anticompetitive tactics currently being employed to try and limit the supply in Canada. Once before in American history there was a piece of legislation passed by the Congress known as the fugitive slave law. It was a bad law that Americans of conscience could not respect or follow. Thankfully it is a relic of history. A prohibition against letting people buy their medications in Canada and abroad endangers the life, liberty, and pursuit of happiness in the 21sr century just as that unjust and backward statute did in the 19th century. You have the power to eliminate this injustice and improve the health of millions of Americans in the process. It is past time to act.

Thank you for the opportunity to submit testimony.