S. HRG. 107–644

ERRATA
COMPARATIVE PRICING OF PRESCRIPTION DRUGS SOLD IN THE UNITED STATES AND CANADA AND THE EFFECTS ON U.S. CUSTOMERS

HEARING

BEFORE THE

SUBCOMMITTEE ON CONSUMER AFFAIRS, FOREIGN COMMERCE AND TOURISM

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION
UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

SEPTEMBER 5, 2001

Printed for the use of the Committee on Commerce, Science, and Transportation

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[Errata]

This errata sheet is being assigned because the hearing title was incorrect. The correct hearing title is Comparative Pricing of Prescription Drugs Sold in the United States and Canada and the Effects on U.S. Consumers

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WITNESSES

COMPARATIVE PRICING OF PRESCRIPTION DRUGS SOLD IN THE UNITED STATES AND CANADA AND THE EFFECTS ON U.S. CONSUMERS

WEDNESDAY, SEPTEMBER 5, 2001

U.S. SENATE,
SUBCOMMITTEE ON CONSUMER AFFAIRS, FOREIGN COMMERCE AND TOURISM,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:15 a.m. in room SR–253, Russell Senate Office Building, Hon. Byron Dorgan, presiding.

Staff members assigned to this hearing: Moses Boyd, Democratic Chief Counsel; David Strickland, Democratic Counsel; Carlos Fierro, Republican Senior Counsel; and Ken Nahigian, Republican Counsel.

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

Senator DORGAN. The hearing will come to order. This is a hearing of the Subcommittee on Consumer Affairs, Foreign Commerce and Tourism of the Senate Commerce Committee. I apologize for my delay. I was in a leadership meeting that began earlier this morning, and I'm sorry I'm late.

To begin, I would like to make a brief comment after which I will call on my colleague Senator Jeffords, who I think will also introduce someone he sponsors here today, followed by Senator Stabenow.

Let me describe the purpose of this hearing. The Congress has grappled with the question of the cost of prescription drugs for some time. Many of us feel, and many Americans feel for that matter, that the cost of prescription drugs has risen so rapidly that it is very difficult for some who need prescription drugs to be able to have access to those drugs. We are talking about a range of issues, including providing a prescription drug benefit through the Medicare program and other issues.

One of the issues that a number of us have worked on, Senator Jeffords, myself, Senator Stabenow and others, is to allow access to lower priced prescription drugs in other countries for the American consumers. We have enacted legislation in Congress that would allow pharmacists and licensed distributors to go to other countries and access a lower price prescription drug, the identical drug, the same pill put in the same bottle, produced in the same FDA-inspected plant, bring it back to this country and pass the savings along to the consumers.

The legislation had an amendment attached to it that said it must, if implemented, demonstrate cost savings and that it be safe.

Both the previous Administration and this Administration decided that they could not or would not implement this legislation. We will look at reasons for that during this hearing. I happen to disagree strongly with both the previous Administration and this Administration when they say there could not be demonstrated cost savings. In my judgment, that is false on its face. There are clearly cost savings demonstrated every day by those Americans who cross the border into Canada to access the identical prescription drug for a substantially lower price than they could acquire it for in this country.

The issue of safety is in my judgment equally specious. I do not think that, as an American, we will discuss some of that this morning, but we are holding a hearing to evaluate this from several perspectives. We need to get this done, and having the previous Administration and this Administration refuse to implement this law is a setback but it is not terminal.

Let me give you some examples of the price disparity. This is Zocor. The head football coach of the Atlanta Falcons talks about Zocor on television commercials nearly every day. He talks about how his life has improved because of Zocor. Zocor is a cholesterol lowering drug. It is purchased in this country for $3.82 per tablet, 20 milligrams, so it was $229.00 for this bottle. In Canada, for exactly the same pill purchased, made by the same company, in the same plastic bottle, the cost is $1.82 per tablet. The difference: the American consumer pays more than twice as much, no other difference.

This is Zoloft, commonly used for depression: the cost is $2.34 for the American consumer, $1.28 for the Canadian consumer.

This medicine is Norvasc, used for high blood pressure. When purchased in North Dakota, $1.25 per tablet; when purchased in Canada, 90 cents per tablet.

I went to Emerson, Canada one day and took with me a number of North Dakotans, one of whom was Sylvia Miller, a wonderful lady from Fargo, North Dakota. Sylvia Miller has diabetes, heart problems and emphysema. She takes seven different medications every day for her various ailments. Sylvia told me she receives $4,700 a year in Social Security benefits and she pays $4,900 a year for prescription drugs. On the way to Canada she said, "Things don't add up, do they?" But in Canada, she was able to cut her monthly prescription drug bill in half. The same FDA-approved medicine produced in the same plant.

Now, the question is, why should Sylvia, at age 70, have to go to Canada to access these cheaper drugs. In my judgment, she should not be required to do that. So legislation we have drafted would allow pharmacists to purchase in Canada and bring those drugs back and to pass those savings along to the American consumers. We have been stymied, during both the previous Administration and this Administration, by HHS refusing to implement it, and we will talk a fair amount about that today in this hearing.

That is the purpose of the hearing. Let me say again, prescription drug costs are increasing dramatically, 16, 18, 19 percent a year, year after year after year. Price inflation and increased utilization are the causes.

The fact that we have suffered setbacks from two Administrations who have refused to implement this legislation should not persuade people we are going to quit. Senator Jeffords and I offered this legislation in the Senate, and I would stay from my standpoint, and I assume from his, that we intend to continue this until we get it done.

And frankly, my goal is not to force people to go to Canada to access cheaper drugs. My goal is that when we allow that to happen, the pharmaceutical industry will be forced to reprice their pharmaceutical products in this country so that the American people are not paying the highest prices for prescription drugs of any other consumers in the entire world. That is the goal.

So, that is the purpose of this hearing. I appreciate those who have made an effort to be here today, and let me call first on Senator Jeffords. Senator Jeffords, let me say how much I appreciate your leadership on this legislation in the Senate. You have worked hard and long on this, and I know that this is the first chapter, that we are going to continue and we are going to complete it. Senator Jeffords.

STATEMENT OF HON. JAMES M. JEFFORDS, U.S. SENATOR FROM VERMONT

Senator JEFFORDS. Absolutely, and I can assure you that I have the same beliefs that you have and that we must proceed, and there is no reason why we cannot with this one. I want to thank you for holding the hearing and for letting me take a few moments to talk as you have about the unacceptable high cost of prescription medicine facing virtually all American consumers. Those high prices are even more unacceptable when they are compared to the relatively low prices paid by consumers of other industrialized nations.

I want to also applaud the leadership you and our friend Senator Stabenow have continued to show on this important issue. The hearing today is especially important because it keeps all of us focused on finding ways to reduce the high cost of medicine and making it more available to our citizens.

You will hear more about the pricing disparities from a number of witnesses today, but I want to take a minute to welcome one in particular. Beth Wennar, who is the President of the United Health Alliance in Bennington, Vermont, has been at the forefront of finding policy solutions to high prices experienced by Vermonters. Beth's experience and expertise has been invaluable to me in framing both the extent of the problem and the potential solutions for addressing it, and I urge the Committee to pay close attention to this.

Last year we were able to enact the Medical Equity and Drug Safety, or MEDS Act. It was designed to allow safe FDA-approved medicines that are manufactured in plants approved by FDA and sold abroad to be purchased by American pharmacists and wholesalers to reimport them to the United States. We worked closely with the FDA.

I want to emphasize that. We worked closely with the FDA in developing this law. We sought the agency's advice about provisions which were necessary to insure safety and quality of these medicines. We accepted that advice and included stringent controls in the MEDS Act, but now we are essentially being told that the goal posts have moved. We are now being told that what FDA then said would have worked to ensure safety now no longer would work, that the controls FDA advised us to include in the MEDS Act are now inadequate.

Mr. Chairman, I can accept that the MEDS Act was not flawless. I can accept that there were some disagreements about whether and how it would work, but few doubted the notion that it should work. No one argued that the Americans should continue to pay prices higher than those of other consumers in other countries.

President Clinton supported and signed the MEDS Act, and then Presidential Candidate George Bush supported it during the campaign. This is not a partisan issue. It is supported by Democrats, Republicans and Independents in the House and Senate, all of whom are looking for the right answers.

So today I would argue that the FDA must stop telling us what will not work and must now tell us what will work. I hope that your witness from the FDA can begin to tell us what is necessary, what conditions are needed to make this program available to our citizens. We can then take that advice, write the necessary law and get to the matter at hand, to insure that Americans have better access to more fairly priced medicine.

Mr. Chairman, I apologize, but I have to attend another Committee hearing that is examining the issue of stem cell research, but before I go, I want to again comment you and Senator Stabenow for your leadership on this issue, and thank you for holding this hearing. I know the Committee will listen closely to my friend and fellow Vermonter, Beth Wennar, and I will look forward to hearing the answers FDA is prepared to share with you about how to move forward with this program, and we must move forward. Thank you, Mr. Chairman.

Senator DORGAN. Senator Jeffords, again, let me say thanks for your leadership. You offered the amendment, I was proud to join you in the Senate, that actually launched the effort to get this in law, and we have been thwarted with respect to its administration at this point, but we will get it done. Your leadership is very important on this, and I deeply appreciate it.

Let me also say that, Senator, you are welcome to go to your other hearing.

Senator JEFFORDS. Thank you.

Senator DORGAN. Senator Stabenow, you of course were a leader in the U.S. House on this issue, and we are delighted that you have now joined us in the Senate. As I indicated to Senator Jeffords, I look very much forward to working with you on this issue. Although the Administration has not seen fit to implement this legislation, we will get this done and, in my judgment, the sooner the better. I feel more confident in getting it done in the Senate with you here, and we very much appreciate your efforts.

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

Senator STABENOW. Thank you, Mr. Chairman. I very much appreciate the opportunity to testify today on an issue that can dramatically lower health care costs for all of our citizens, and that is the issue of allowing Americans to purchase safe FDA-approved prescription drugs from other countries.

I want to particularly thank you, Mr. Chairman, for your leadership, as well as Senator Jeffords. You have been the leaders in the Senate, I am very proud to have the opportunity to be in the Senate and to join you in that effort. As you indicated, I was involved in cosponsoring this legislation in the House of Representatives and this has been an issue that has been very very important to people that I represent in Michigan.

It affects every American family, particularly our seniors, who as we know, use the majority of prescription drugs. Frankly, Mr. Chairman, too many seniors got up, sat down at the kitchen table, and have to decide do I eat today, do I pay the utility bill, or do I take my medicine. I know you join me in saying that this is simply not acceptable in the United States of America.

I find it ironic, Mr. Chairman, that in an era of free trade, that we have effectively erected barriers on our borders that force our citizens in the United States to pay prices for prescription drugs that are often twice those paid by our neighbors even in Canada, as well as around the world.

Particularly coming from Michigan, we look at the Canadian border, it is a 5-minute trip across the bridge or by tunnel, and there is such a dramatic difference in price, it is absolutely unacceptable.

As you may remember, during my Senate campaign last year I organized bus trips to Canada, took a number of seniors who went to physicians and pharmacies in Canada to be able to demonstrate the differences in prices. It was a quick 5-minute trip, and we saw night and day price differences, and I would like to share those with the Subcommittee at this time.

Mr. Chairman, you have spoken to some of the prescriptions as well that we have, but in our trips, we found the differences in Michigan, Zocor, a drug to reduce cholesterol, cost $109.73 for 50 5-milligram tablets. In Canada the exact same prescription cost just $46.17, a 138 percent difference in price.

In Michigan, Prilosec, a drug to treat ulcers, cost $115.37 for 20 20-milligram tablets. In Canada the same prescription cost just $55.10, a 109 percent difference in price.

In Michigan, Procardia XL, a drug to treat heart problems, cost $133.36 for 100 30-milligram tablets. In Canada the same prescription cost just $74.25, an 80 percent difference in price.

And there are certainly, Mr. Chairman, other examples that are on the chart. This literally is the difference between a senior being able to eat or be able to pay the utility bill, pay the telephone bill, pay the rent, pay the mortgage, and I found as I was at home this month again, over and over again, the No. 1 issue people want to speak about is the struggle that they are having being able to pay the high cost in the United States of prescription drugs.

All of these drugs were manufactured in the United States and met all the FDA requirements for manufacturing, safety and purity.

Furthermore, we should note that Americans paid for much of the research that led to the breakthroughs in many of these prescription drugs. I support the R&D tax plan, the efforts at federal labs through NIH to provide critical research and funding for that research, and yet we in America pay twice as much as anyone else around the world while supporting this research. It only makes sense that Americans should get the best possible prices on these life saving medicines as a return on their investment.

Mr. Chairman, as you know, the very first bill I introduced into the Senate as the junior Senator from Michigan was a bill that would eliminate this health care tariff, and it builds on the legislation that you and Senator Jeffords introduced into the Senate, the amendment that was passed.

We have looked at concerns raised by the previous and current Secretaries of Health and Human Services, and made some corrections to address what we felt were legitimate issues that could be put into this bill to make it crystal clear that there are no safety issues, and clearly there is a price savings.

I welcome anyone who does not believe that there is a price savings to join me in Michigan, it is a beautiful time in the fall, the leaves are turning, we welcome it, and I would be happy in a 5-minute trip across the border to show you the difference.

Mr. Chairman, I look forward to working with you, to working with Senator Jeffords, members of the Committee, and Senator Wellstone I know is very involved in legislation as well, to make sure that we can finally address this issue. The problem is clear and frankly, we have an immediate solution at hand. I know that, Mr. Chairman, you join me in a commitment to modernizing Medicare for prescription drugs, but I also know that in the Budget Committee that we are going to have a difficult struggle within the confines of this budget this year to really put forward the comprehensive prescription drug benefit that we all want.

And most importantly, that we take the time to do that, time our seniors and families do not have. We need to have the same sense of urgency in our Congress that our seniors and our families have at home when the are trying to pay for life saving medicines that they need. We can do something now that does not involve a large amount of dollars. We can do something immediately to lower costs, and I know Mr. Chairman, that you have that same sense of urgency that I have that this needs to be done immediately, and I look forward to working with you. Thank you again for providing this critical hearing.

Senator DORGAN. Senator Stabenow, thank you very much. In my comments, I failed to mention that Senator Snowe and former Senator Slade Gorton also were actively involved in introducing and sponsoring legislation in this area. We appreciate your testimony and thank you for being with us.

We are joined today by Senator McCain. Senator McCain, do you have a statement?

STATEMENT OF HON. JOHN McCAIN, U.S. SENATOR FROM ARIZONA

Senator MCCAIN. Thank you, Mr. Chairman. I want to thank you for convening the hearing on the explosion of prescription drug prices. This is of critical importance, and I thank you for your decision efforts on this issue for several years now.

I joined with my colleagues Senator Dorgan, and Senator Schumer in introducing a bill that would, among other things, streamline FDA approval of generic drugs by closing the loophole that allows brand name manufacturers to receive an automatic 30 month stay by simply filing a patent infringement suit against a generic manufacturer's patent challenge or application. The bill would also prevent brand name manufacturers from using financial advantage to keep generic products from entering the market.

Mr. Chairman, I think this is a multifaceted issue. I think there are a number of parts and pieces of legislation that have been introduced, but the issue of delaying generic drugs from entering the marketplace is an important part of this discussion. It is unconscionable on the part of both the patent drug manufacturers as well as the generic manufacturers that there are cases where a patenting drug company will pay a generic drug company not to introduce that product into the market. There are records of that, and they have also used various other legal tactics in order to delay entry as well.

I think that is a fairly easy thing for us to at least make some fixes on, but I still have been unable to explain to my constituents, and I know you have the exact same situation in the north, why they can drive to Mexico and buy a prescription drug at considerably less cost than in the United States of America. I would like to ask our witnesses that question because I still do not get it. And frankly, nor do a lot of the seniors who live in my state who by a simple trip down to Mexico, can buy the exact same drug for sometimes half or less than half the price of its brand name counterpart.

Thank you, Mr. Chairman.

Senator DORGAN. Senator McCain, I share your concern about the issue of generics, and it does come to the same point, it is all about the price and pricing practices, in most cases the American consumers are paying the highest prices anywhere in the world.

And your point about borders, if this truly is a global economy, then why doesn't it work for ordinary folks to give them access to prescription drugs made in the same plant, inspected by the FDA? In short, why should Americans be prevented from crossing a border to access a prescription drug that was made in America, for a fraction of the cost that was charged in their retail outlet. Those are the right questions and that is why we are determined to do something about this issue. I appreciate your comments and support them.

We have two panels today. The first consists of Mr. William Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation of the FDA. Then we will have a second panel with five persons, and I will introduce them as we ask them to come forward.

First let me welcome Mr. William Hubbard, Senior Associate Commissioner, Policy, Planning and Legislation of the Food and Drug Administration. Mr. Hubbard, thank you for joining us. Why don't you proceed.

STATEMENT OF WILLIAM K. HUBBARD, SENIOR ASSOCIATE COMMISSIONER FOR POLICY, PLANNING AND LEGISLATION, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY DAVID HOROWITZ AND MATTHEW ECKEL

Mr. HUBBARD. Thank you, Mr. Chairman. If I may, we are cluttering up the table here with drug samples, to complement those that you have.

I would like to introduce my co-witnesses if I may, Mr. Chairman, David Horowitz, in charge of our compliance branch in the Center for Drugs, and Matt Eckel is in our counsel's office. I, of course, have written testimony but, I won't read that today. I will just make some comments.

You are holding these hearings to examine drug pricing and while prices are not FDA's responsibility, we agree with you that prices in other countries are a little lower than in the United States. As Alan Sager and others have pointed out, prescription drugs are sold in Canada and Europe for up to one half of the U.S. price. This is because most developed countries have controls on drug prices and the U.S. does not. We are the only major developed country that does not set such price limitations.

It is also apparent that the patient paying cash pays more than those who are third party payers and who negotiate a lower price. Thus, folks like the elderly, who often lack drug insurance coverage and must pay cash for their prescriptions, are often hit the hardest, and I think for the Senators from areas with large rural populations, there is even more concern because the rural people get hit even harder than that because they don't have the access to several competing pharmacies.

So, clearly, your constituents' needs here are real and significant, and we do not at all at FDA disagree with them. We have great sympathy for that. The question that gets asked of us as a drug safety regulatory agency, is whether we can find a way for patients to access these cheaper drugs if, in fact, they are clearly there.

The answer unfortunately from our perspective is that Congress can change the law to let these drugs in, but only at the risk of lowering safety assurances for the drugs. The current drug regulatory system in the United States is highly protective.

We believe, Mr. Chairman, that Congress got it right in 1938 and 1962 when it set up a system that said that drugs had to be approved for a demonstrated safety and efficacy before marketing and, therefore, we have the safest and most technologically advanced drug system, in both development and manufacturing, in the world.

The current system is fairly closed, it requires high standards of drug manufacturing. It utilizes a network of highly skilled pharmacists and other professionals to control the movement of these drugs, and it requires that imported drugs meet those same high standards.

This system means that drug counterfeiting is a rare event in the United States, despite the fact that, worldwide, counterfeiting is endemic. In some countries, there are estimates that perhaps half of the drugs on the market are counterfeited.

I will just give a few examples. These are counterfeit drugs that we found in FDA, and it is very very rare we find these. This is a recent one, an injectable called Serostim. One of these is counterfeit and one of these is real. If they weren't marked as counterfeit and genuine, none of us in this room could tell the difference, no pharmacist could tell, no physician could tell. That is part of the problem.

These particular drugs are hormones and they were brought in from overseas and introduced into the market here, and in the package are vials of a saline solution and a powder. You pull the saline solution into a syringe and then you inject it into the other ampule which contains the powder, and you shake it up to actually formulate the drug for the person. Well, the problem is the drug was counterfeited, and it may be pharmacologically effective, but the problem with this drug is that the saline solution was not sterile. It was contaminated with bacteria and endotoxins so using it would inject people with septicemia.

So, this is the problem we worry about with counterfeiting. These are very very real counterfeiting issues, although they are, and I will repeat, they are rare in this country.

Now these examples are drugs that people have bought on the Internet from other countries.

This probably was bought by a weight lifter, it is a human growth hormone. This purports to be an Eli Lilly product. We have no idea whether that's really an Eli Lilly product or not but it says it is. Then in other cases, we just have bags of pills.

Now, we can look at some of these and try to determine what these are, but it is virtually impossible for any pharmacist or physician or anyone else to know what's in these packages.

This one apparently is a Roche product called Valium, or at least it's marked that way. But we don't know if it really is Valium or not, and of course Valium is a controlled substance and should not be sold in this country without a prescription.

So, these products are coming in every day. We estimate that perhaps as many as two million of these small shipments are being purchased by American citizens every year.

Senator DORGAN. Mr. Hubbard, sorry to interrupt you, but when you say these products, you're not saying these products here, every day there is counterfeiting. When you are referring to these products, you are talking about products coming in from other countries.

Mr. HUBBARD. Right.

Senator DORGAN. You had been talking about counterfeit drugs, so I just don't want people to misunderstand what you just said.

Mr. HUBBARD. Right. We know that some of these are counterfeit. These that I have most recently displayed were ones we pulled out of the Dulles mail facility just yesterday. They come in every day, and we have no idea whether they're counterfeit. We don't know.

And so, the FDA's job is to make sure that when you go to your doctor and get a prescription and take it down to the pharmacy and get the drug, that you're getting the real drug, a drug that will be safe, a drug that will treat your condition. Of course we believe in that, and I'm sure you believe in that too.

The problem is, we have no way of insuring, when they're coming in from these other countries in this way, to know whether they are the real drug or know whether they are safe, know where they are coming from, or know where they have been, or whether the drug may have been held in some sort of poor condition or in high heat, or cold, or it expired and was repackaged, or whatever.

So while we understand the Senators' concerns about drug prices, we think that opening the doors to these foreign drugs undermines the safety and protection that has served us so well, and that's been the FDA's concern because our job is safety, and the drug price issue is one that we feel ill suited to solve. Thank you.

[The prepared statement of Mr. Hubbard follows:]

PREPARED STATEMENT OF WILLIAM K. HUBBARD, SENIOR ASSOCIATE COMMISSIONER FOR POLICY, PLANNING AND LEGISLATION, FOOD AND DRUG ADMINISTRATION

Introduction

Mr. Chairman and Members of the Committee, I am William K. Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation, Food and Drug Administration (FDA or the Agency). I appreciate the opportunity to discuss our mutual concerns related to the importation of drugs into the United States. This topic encompasses a range of issues, including the importation by individuals of prescription drugs at land borders or through the mail; the introduction into the U.S. of controlled substances from foreign sources under the guise of personal importation; the potential introduction of counterfeit bulk drugs into the U.S. drug supply; and the purchase of drugs from foreign sources over the Internet. Let me begin by discussing one of our greatest challenges in this area.

Personal Importation of Drugs Through the Mail

The amount of prescription drugs for personal use imported through the mail has increased in recent years. According to testimony by the U.S. Customs Service (Customs) before the Government Reform Committee in May of last year, seizures of parcels containing scheduled or controlled substances at international mail facilities increased by 450 percent in FY 1999, primarily due to drug sales over the Internet. We estimate that approximately two million parcels containing FDA-regulated products for personal use enter the U.S. each year through international mail facilities that Customs could set aside for FDA review for possible violations of the Federal Food, Drug, and Cosmetic (FD&C) Act. This estimate is based on an extrapolation of data obtained during a pilot project conducted at the international mail facility in Carson, California (see below).

Under the FD&C Act, unapproved, misbranded, and adulterated drugs are prohibited from importation into the U.S., including foreign versions of U.S.-approved medications, as is reimportation of approved drugs made in the U.S. In general, all drugs imported by individuals fall into one of these prohibited categories.

From a public health standpoint, importing prescription drugs for personal use is a potentially dangerous practice. FDA and the public do not have any assurance that unapproved products are effective or safe, or have been produced under U.S. good manufacturing practices.

U.S.-made drugs that are reimported may not have been stored under proper conditions, or may not be the real product, because the U.S. does not regulate foreign distributors or pharmacies. Therefore, unapproved drugs and reimported approved medications may be contaminated, subpotent, superpotent, or counterfeit. In addition, some foreign websites offer to prescribe medicines without a physical examination, bypassing the traditional doctor-patient relationship. As a result, patients may receive inappropriate medications because of misdiagnoses, or fail to receive appropriate medications or other medical care, or take a product that could be harmful, or fatal, if taken in combination with other medicines they might be taking.

Personal Importation Policy

Under FDA's personal importation policy, as described in guidance to the Agency's field personnel, FDA inspectors may exercise enforcement discretion to permit the importation of certain unapproved prescription medication for personal use.

First adopted in 1954, the policy has been modified several times over the succeeding years. It was last modified in 1988, in response to concerns that certain potentially effective treatments for AIDS patients were not available in the U.S., but were available in other countries. The Agency expanded the guidance for humanitarian purposes to allow individuals suffering from serious medical conditions to acquire medical treatments legally available in foreign countries but not approved in the U.S.

The current policy permits the exercise of enforcement discretion to allow entry of an unapproved prescription drug if:

- the product is for personal use (a 90-day supply or less, and not for resale);
- the intended use is for a serious condition for which effective treatment may not be available domestically (and, therefore, the policy does not permit inspectors to allow foreign versions of U.S.-approved drugs into the U.S.);
- there is no known commercialization or promotion to U.S. residents by those involved in the distribution of the product;
- the product is considered not to represent an unreasonable risk; and
- the individual seeking to import the product affirms in writing that it is for the patient's own use and provides the name and address of the U.S. licensed doctor responsible for his or her treatment with the product or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

FDA has not officially permitted the importation of foreign versions of U.S.-approved medications, even if sold under the same name, because these products are unapproved, and the Agency has no assurance that these products are safe or effective, while safe and effective versions are already available in the U.S.

FDA believes that the need for its personal importation policy is far less now than it was when the current version of the policy was developed in 1988. Now, due to faster review times and various regulatory mechanisms through which patients can obtain unapproved treatments for humanitarian purposes, the need to import therapies not available in the U.S. has diminished. According to a Tufts University study presented in September 2000, 80 percent of new molecular entities approved in the U.S. in 1996 through 1998 received that approval within a year of its first introduction on the world market, almost double the rate during the years 1991 through 1995.

Implementation of the Personal Importation Policy

At mail facilities, Customs officials identify parcels that may be violative of the FD&C Act. FDA inspectors then determine if these products should or should not be permitted to enter the country. If detained, FDA must issue a notice to the addressee describing the potential Federal violation and provide the individual with an opportunity to respond. If the addressee does not respond or provides an inadequate response, FDA will give the parcel back to Customs to have it returned to the exporter. Due to the requirements for notice and the opportunity to respond, the process for detaining and further processing mail parcels consumes large amounts of FDA resources. In addition, much storage space would be needed to hold the large number of detained parcels pending replies from the addressees.

FDA's personal importation policy, as written, is difficult to implement. This is due, at least in part, to the difficulty faced by FDA inspectors, or even health care practitioners, in identifying a medicine by its appearance, and labeling may falsely identify a product. From a practical standpoint, FDA inspectors cannot examine drug products contained in a mailed parcel and accurately determine the identity of such drugs or the degree of risk posed to the individual who will receive these drugs.

FDA detains and refuses few mail imports for personal use. As a consequence, the tens of thousands of parcels that FDA does not review are eventually released by Customs and sent on to their addressees, even though the products contained in these parcels may appear to violate the FD&C Act and may pose a health risk to consumers. We do not believe this is an acceptable public health outcome and are working to develop a solution.

HHS Plan to Address Mail Imports for Personal Use

Due to the inability of FDA to cope with the volume of medications imported for personal use through the mail, and because of the public health risks associated with these products (as discussed below), FDA has been working to develop a more effective personal importation policy. In addition, we recognize that Customs is dependent on guidance from FDA, and one of our goals is to provide clear and simple standards for assessing parcels containing drug products. We are discussing options for revisions to the Agency's personal importation policy with Secretary Thompson.

Carson Mail Facility Pilot

Earlier this year, FDA and Customs conducted a survey of imported drug products entering the U.S. through the Carson City, California mail facility (the Carson pilot). The Carson pilot was proposed by Customs as a means to examine incoming mail shipments of pharmaceutical products over a specified time frame in order to identify both the volume and the types of drug products entering the U.S. We also hoped to better assess the efforts required to cover drug importations at a mail facility, and to gain a better understanding of the public health implications these importations may have for U.S. consumers.

The Carson pilot ran for a five-week period, with FDA inspectors present for 40 hours per week. At the onset, Customs took a "baseline" sample in the first week by setting aside all international packages that were suspect, or that they would have set aside for FDA review had FDA been able to process them. The number of packages set aside was approximately 3,300. Multiplying that number by five weeks provides an estimated total of 16,500 international packages (650 packages per day) that Customs could have set aside for FDA review during the Carson pilot, if the ability to process them was not a factor. After the first week, however, Customs actually set aside the number of packages they believed FDA would be able to examine. In general, during each week of the Carson pilot, more packages were set aside than FDA was able to handle.

FDA was actually able to examine 1,908 packages during the five-week pilot, an average of approximately 381 packages per week. Neither FDA nor Customs kept a count of the packages that were set aside but not examined. Unexamined packages were sent on to the addressees.

Of the 1,908 packages examined by FDA, 721 parcels were detained and the addressees notified that the products appeared to be unapproved for use in the U.S., misbranded and/or a drug requiring a doctor's prescription. The parcels were shipped from a total of 19 countries, and overall, there was no obvious evidence of the products being imported for further commercial distribution. On average, the Agency was detaining at a rate of 144 packages per week, or about 38 percent of those examined.

Clearly, the Carson pilot demonstrated that the rate of packages coming into the U.S. exceeds FDA's capacity to manage, thus, Customs is left with little choice but to forward the majority of packages to addressees. As we stated, we do not believe this is an acceptable public health outcome, and we are working to develop a solution.

Analysis of the Carson Pilot Drug Parcels

In order to define better the nature of the risk to public health from the types of products coming into the U.S. through personal importation, FDA's Center for Drug Evaluation and Research (CDER) reviewed listings of the products detained during the Carson pilot. CDER's review demonstrates that there are serious public health risks associated with many of the 721 drug shipments (composed of 197 different drugs) intercepted at Carson. In general, there are two types of risks that consumers of these drugs would face. The first type of risk is that associated with taking drugs of unknown origin or quality. Second are the very significant risks associated with taking many of these drugs without first obtaining a physician's prescription and without the continued oversight of the physician.

Risks Associated with Drugs of Unknown Origin or Quality

In general, FDA has no information to establish where these drugs were actually manufactured and whether necessary current Good Manufacturing Practice requirements were followed. There is also no assurance that the drugs were packaged and stored under appropriate conditions to avoid degradation or contamination.

Approximately eight percent of the shipments contained drugs that could not be identified because they contained no labeling; some of these contain only foreign language labeling. Most of these drug shipments were contained in plastic bags; one shipment contained drugs taped between magazine pages.

Several drugs do not appear to correspond with any U.S.-approved drugs and the risks are therefore difficult to assess. One drug was evaluated for FDA approval but was denied approval. This drug is associated with cardiac abnormalities and its efficacy could not be successfully demonstrated. Another drug approved abroad but not in the U.S. is associated with medically serious gastro-intestinal complications. Several shipments contained three drugs that were once approved by FDA but have been withdrawn from the market based on serious safety concerns, including:

- fatal arrhythmia and dangerous drug interactions;
- loss of white blood cells (agranulocytosis) associated with fatal infections; and
- hemorrhagic stroke.

Risks Associated with the Absence of Physician Oversight

The vast majority of the shipments were identified as containing prescription drugs, which by definition, have serious toxicities and risks associated with them such that they are "not safe for use except under the supervision of a practitioner licensed by law to administer such drug." (Title 21, *United States Code*, section 353(b)). Although some foreign Internet sites might offer an online questionnaire, we believe that very few, if any, require a prescription from a practitioner licensed in the U.S. before dispensing such drugs to U.S. residents. Moreover, after detention notices were issued to the intended recipients of the 721 drug shipments, fewer than four percent presented evidence of prescriptions to document their relationship with a physician in association with the drugs purchased from abroad. The lack of adequate English language labeling accompanying many of these shipments exacerbates the risks associated with the absence of physician oversight.

During the Carson pilot, as in normal practice, Customs generally separated out controlled substances for processing by the Drug Enforcement Administration (DEA) before the remaining shipments were provided for FDA review. However, in FDA's review, six controlled substances were identified, including lorazepam, codeine sulfate, loperamide, chlordiazepoxide, chloral hydrate, and diphenoxylate. These drugs have the potential to cause addiction or be abused. Life-threatening overdoses are possible. A physician's prescription and oversight are essential for managing these risks.

There are numerous drugs identified on the Carson list that are intended to treat conditions that consumers need physicians to properly diagnose. As a result, consumers who bypass physician diagnosis and prescribing may be exposing themselves to risks and toxicities that cannot be justified by offsetting benefits to those patients.

- For example, almost ten percent of the shipments were for antibiotics, despite the fact that consumers are generally not able to diagnose whether their symptoms are caused by bacterial infections. The overuse of antibiotics continues to be a serious public health concern because it is linked to the growth of antibiotic resistant-bacteria.
- Several drugs listed are potent steroids, which are generally prescribed for conditions that are not self-diagnosable. In addition, potential adverse events associated with these drugs, including diabetes, hypertension, and serious infection require prompt attention and careful monitoring.

There are many drugs on the list for which it is essential that the proper dose be delivered into the bloodstream at the proper rate. Some of these drugs have a narrow range in which they can safely achieve their therapeutic effect. At least seven such drugs were identified on the Carson list. Without FDA oversight, there is the risk that these drugs may not have been manufactured with the necessary quality controls to ensure a consistently safe and effective product.

- One seizure medication on the Carson list, for which there were three shipments, could be very dangerous if not manufactured to these rigorous standards. Any change in potency could render the drug ineffective or highly toxic.
- Another seizure drug on the list for which physician monitoring is also essential has a narrow therapeutic range and FDA labeling provides a black-box warning for hepatoxicity, teratogenicity, and pancreatitis.

More than 30 drugs on the list have serious contraindications and/or drug interactions for which physician oversight is essential. For instance, almost 20 percent of the shipments were for various estrogen products for which there are multiple serious contraindications that a physician needs to consider before making prescribing decisions and in monitoring the patient.

It is impossible to make a scientifically definitive statement on the public health impact of the drug shipments encountered during the Carson pilot without extensive chemical testing and analysis of the incoming pharmaceuticals, which would be prohibitively expensive. Based on the observations noted above, however, FDA believes that these drugs pose substantial risks to the public health, and we further believe that significant changes to the policies governing personal importations through the mail are warranted.

Border Surveys

Over the last year, FDA has initiated three other surveys to gather data on drug products imported by individuals into the U.S. Although these border surveys involve land traffic rather than mail importation, the results of these surveys show some similarities to the findings from the Carson mail pilot, as well as some significant differences.

Southwest Border Survey (August 2000)

A survey of prescription drugs being brought by pedestrians into the U.S. at eight ports of entry along the 2,000 mile border with Mexico was conducted by FDA's Southwest Import District (SWID) with the assistance of other agencies including Customs, the DEA, the U.S. Department of Agriculture, and others. The survey looked at activity during four hours on a Saturday (August 12, 2000) at eight border ports in California, Arizona, and Texas. The purpose of the survey was to interview individuals walking across the border into the U.S. from Mexico who had purchased prescription drugs in Mexico to determine 1) what specific types of products are being imported, and 2) who is importing these products.

The data collected from over 600 interviews indicated that the most common importer of prescription drugs during the survey was an older male Caucasian with a prescription from the U.S., bringing back primarily antibiotics or pain relievers for his own use. Prescriptions were held by 63 percent of the persons interviewed (59 percent U.S. prescriptions and 41 percent Mexican). The most common drugs and their indications that were purchased in Mexico during the survey were as follows: Amoxicillin (antibiotic), Glucophage (diabetes), Premarin (estrogen), Dolo Neurobion (vitamin supplement), Vioxx (inflamation), Retin-A (acne), Tafil (anxiety), Celebrex (arthritis), Penicillin (antibiotic), Viagra (impotence), Carisoprodal (analgesic).

Canadian Border Survey

On January 6, 2001, in cooperation with Customs, FDA conducted a survey to obtain a snapshot of prescription drug products being brought into the U.S. from Canada via passenger vehicles. During the eight-hour survey at three ports of entry in New York, Michigan and Washington, a total of 10,374 passenger vehicles and 58 buses crossed into the U.S. Of these, 33 passenger vehicles (35 individuals) were referred by Customs to be interviewed. These individuals brought in a total of 47 containers of drug products from Canada.

The types of products included pain medicines—primarily "222" (a combination of acetaminophen, caffeine, and codeine) or similar products. The indicated reason for import was that the products were available over-the-counter (OTC) in Canada and cost less than in the U.S. The next largest group of products was herbal products, with the reason for importation being that the products were not available in the U.S. Other products included Tobradex (antibiotic/steroid opthalmic for individuals having laser eye surgery); Claritin and Allegra (allergies) purchased OTC in Canada; Sibelium capsules (calcium channel blocker); and a variety of OTC products sold in Canada and not available in the U.S.

Southwest Border Survey (April 2001)

On April 11, 2001, FDA, Customs, and other agencies conducted a survey of prescription drugs being brought into the U.S. at seven ports of entry along the U.S./Mexican border. This survey coincided with both Easter vacations from many colleges and the end of the "snowbird" season, when tourists from Northern states visiting along the Southern border return home.

During the four hour "blitz" a total of 586 persons brought in a total of 1,120 drugs. Approximately 56 percent had a prescription for the medicines (61 percent were U.S. prescriptions, 39 percent were Mexican). The most common drugs purchased in Mexico were: Amoxicillin (antibiotic), Premarin (estrogen), Claritine (allergy), Terramicinia (antibiotic), Ampicillin (antibiotic), Ibuprofen (analgesic), Penicillin (antibiotic), Vioxx (inflammation), Tafil (anxiety), Dolo Neuorobian (vitamin supplement), Glucophage (diabetes), Celebrex (arthritis), Naproxen (analgesic), Retin-A (acne), Ventolin (pulmonary disease), and Valium (controlled substance/nervous system depressant).

Controlled Substances

Although we do not know, nor is it possible to clearly determine, the amount of controlled substances brought into the U.S. purportedly for personal use, it is likely that such medicines are frequently imported for resale and pose a public health risk. The Agency has been working with both Customs and DEA to streamline and clarify Federal import policies specifically related to the importation of controlled substances.

Internet Drug Sales

Based on surveys conducted in early 2000 by Office of Criminal Investigations (OCI) and subsequently by the General Accounting Office (GAO), it appears that there are roughly 300 to 400 Internet sites selling prescription drugs, with approximately half located domestically and half located outside the U.S. FDA has long taken the position that consumers are exposed to a number of risks when they purchase drugs from Internet sites or other mail order outlets that dispense foreign drugs. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong product, a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. FDA cannot provide consumers with any assurance that these products were manufactured under current good manufacturing practice standards. Taking an unsafe or inappropriate medication puts consumers at risk for dangerous drug interactions and other serious health consequences.

Internet sites that provide prescription drugs by having consumers fill out a questionnaire rather than seeing a doctor pose serious health risks. A questionnaire generally does not provide sufficient information for a healthcare professional to determine if that drug is appropriate or safe to use, if another treatment is more appropriate, or if the consumer has an underlying medical condition where using that drug may be harmful.

FDA has undertaken widespread public relations efforts to warn consumers about the dangers of buying drugs online, and we have provided extensive information on these dangers on FDA's own Internet site. FDA's Buying Medical Products Online web page is one of the most frequently requested pages on FDA's website. It consistently ranks among the top twenty requested pages, averaging almost 13,000 hits per month.

Currently, FDA has 90 sites under active review for possible regulatory or civil action. Warning letters have been sent to 48 domestic online sellers. Additionally, FDA has sent 121 "cyber letters" to operators of Internet sites offering to sell online prescription drugs or unapproved drugs. These sites may be engaged in illegal activity such as offering to sell prescription drugs to U.S. citizens without valid (or in some cases without any) prescriptions. Cyber letters are sent over the Internet to the suspect websites to warn the operators that they may be engaged in illegal activities, and inform them of the laws that govern prescription drug sales in the U.S. Cyber letters have a deterrent effect and FDA has seen positive results from using them. FDA has received positive responses from 20 percent of the cyber letter recipients and we are continuing to monitor these sites.

FDA also sends copies of its cyber letters to the home governments of targeted websites, when the locations can be identified. Follow-up depends on the ability and willingness of the foreign regulatory bodies to investigate and take actions against website operators who are illegally shipping drugs to other countries.

In cooperation with the Department of Justice (DOJ), five preliminary injunctions have been imposed on the sale of illegal products, including one product marketed as a weight-loss aid containing a potent thyroid hormone which could cause heart attacks or strokes, and an unapproved cancer therapy. FDA and DOJ also are pursuing an injunction against the sale of another unapproved cancer therapy over the Internet. Additionally, 15 product seizures, 11 product recalls, and the voluntary destruction of 18 violative products have been achieved, generally pertaining to unapproved new drug products including gamma hydroxybutyric acid, gamma butyrolactone, Triax, 1,4 butanediol, and laetrile. Thirty-six foreign shippers have been placed on Detention Without Physical Examination and added to Import Alert 66–57 for targeting sales of unapproved new drug products to the U.S.

During FY 2001, FDA's OCI initiated approximately 40 Internet-related investigations and will continue to conduct investigations involving suspected criminal activity related to Internet drug sales as well as other Internet-facilitated criminal violations of the FD&C Act. Of the 133 currently open Internet-related investigations, 64 are Internet pharmacy cases, where the focus is on the possible dispensing of prescription drugs without a prescription.

In recent years, OCI has initiated 285 Internet investigations and each of these investigations have involved a variable number of actual websites—typically ranging from one to 25 or more. OCI has effected 88 Internet-related arrests, 70 of these in drug-related investigations. Of the 70 drug-related arrests, 11 have involved Internet pharmacy cases. These arrests have resulted, thus far, in 48 Internet-related convictions, 42 of these in drug-related investigations. Of the 42 drug-related convictions, five have involved cases involving the sale of prescription drugs without a valid prescription.

In addition, OCI has an ongoing initiative at the Dulles International Airport Mail Facility that had its genesis in their first Internet case, which began in 1994. The case, which involved a site selling steroids over the Internet, resulted in a successful prosecution and shutdown of the website. The partnership resulting from this case has continued, and in the past 18 months, OCI has been involved with local law enforcement in the Washington metropolitan area in 98 drug seizures. The seizures represent dozens of types of drugs coming in from 13 different countries. Of the 98 seizures, 87 of the drug seizures were ordered over the Internet and mailed to U.S. citizens; six were mailed to the U.S. by family or friends living abroad; four were ordered via a 1–800 telephone number from Canada and mailed to the U.S.; and one was transported via an airline passenger in two suitcases from Romania. The efforts of OCI, Customs, and local law enforcement have yielded the execution of eight search and seizure warrants and led to the arrest and prosecution of nine people.

Conclusion

Mr. Chairman, FDA remains concerned about any possibility that unsafe drugs may find their way into the American drug supply. We will remain vigilant as we refine and improve the programs and procedures that we use to ensure the availability of safe medications for consumers.

We appreciate the Committee's interest in assuring that the American public has access to safe and affordable medicines. We look forward to continuing to work with you. Thank you again for the opportunity to participate in today's hearing. I will be happy to answer any questions.

Senator DORGAN. Mr. Hubbard, thank you very much. I have read your entire testimony. Let me ask you some questions about this, because I am curious. You have spent most of your time referring to counterfeit drugs and the issue of safety. We have about $14 billion worth of drugs imported into this country by manufacturers; is that correct?

Mr. HUBBARD. I don't know the number, but generally a majority of the raw material for drugs come in from foreign sources and the finished pharmaceuticals are made in this country.

Senator DORGAN. Now let me ask you a question about the Canadian system, and I want to focus on that just for a moment, if I might. Do we have a system in this country that is substantially safer than Canada's?

Mr. HUBBARD. I'm not well prepared to describe the safety or conditions in any other country. We certainly believe that, we certainly believe that we have the safest.

Senator DORGAN. Let me just focus on Canada for a moment, because if you are saying the reimportation of prescription drugs from Canada by the pharmacist or licensed distributor compromises safety, then you must be prepared to tell me whether you think our system is safer than Canada's. Let me tell you why I am asking the question.

Some, perhaps sometime in the next hour up in Binford, North Dakota, a truck is going to come across the border from Canada, it is going to have a load of fresh meat on it, cows or hogs have been slaughtered and they come over in the form of fresh meat. We are not going to inspect that fresh meat. You know why? Because our country decided that the Canadian inspection system is fine for us, and so we will not inspect that meat. And that is an FDA and USDA decision.

I am asking a question about Canada. If a pill is produced, a tablet is produced in an FDA approved plant either in the U.S. or Canada, it goes to a distributor or pharmacist in Canada and ends up in a one-room pharmacy in Emerson, Canada, and then a pharmacist from Binford, North Dakota wants to go to that one-room pharmacy in Emerson and pay one-tenth the cost for Tamoxifen and bring it back across the border and pass the savings along to the senior citizens or the women who have breast cancer in Binford, and they are told no, they are not allowed to do that because there is a safety issue.

The question is, what is the safety issue? I want to specifically talk about Canada. What is the safety issue?

Mr. HUBBARD. Let me say in the case of the meat situation that you mentioned, by law the Canadian meat processor in Canada has to be approved by the U.S. Department of Agriculture and inspected by the Department of Agriculture, and must be what is known as equivalent. It is under a very rigorous U.S. set of standards in meat processing. It is likely to be inspected again at the border by a USDA inspector.

Senator MCCAIN. That is not likely.

Mr. HUBBARD. In the case of drugs, that is not true, that is not required for drugs sold in Canada. It may be in fact that the same manufacturing plant assigned to a Canadian pharmacy and to a U.S. pharmacy can manufacture the medicine, so you are correct on that point. The problem is when the drug leaves the manufacturing facility and arrives, and goes out into the Canadian market, it is outside FDA's jurisdiction and therefore, when the pharmacist procures that drug, we would have no way of knowing if, in fact, that was the real drug.

Senator DORGAN. Mr. Hubbard, I understand that, but the same is true with the cow, or the steer that's slaughtered in Canada. That is outside the U.S. inspection system. We have simply determined that the Canadian inspection system is sufficient for us to allow that meat to come in uninspected.

Now the question is this: If an FDA inspector finds—and this is all our legislation deals with, FDA-approved drugs manufactured in an FDA-inspected plant, if an FDA-inspected plant produces a bottle of medicine and sends it to a pharmacy in Winnipeg, Canada, you are saying that you cannot determine whether the Canadian system of providing safety in the chain of supply is sufficient to allow us to have confidence in it? We do it in a dozen other areas, but you cannot do it with respect to medicine?

Mr. HUBBARD. We are not authorized to do that. In your example, USDA is authorized to go to Canada and inspect and set standards for the Canadian meat packing and, in fact, the Canadians do not send meat until they meet those standards. In the case of drugs, that is not the case at all.

Senator DORGAN. But you are answering a question I am not asking. I am not asking you whether you are authorized, I am asking whether you have the capability to determine whether the chain of supply in Canada is sufficient so that we have confidence in it just as we do in this country. Why would you not be able to do that, and then allow only pharmacists and distributors to be able to reimport only those drugs that are produced in an FDA approved plant and only those drugs that are FDA approved? How on earth can that be rocket science?

That does not seem to me to be difficult, and yet, the FDA and HHS keep saying there is this huge safety problem. I understand there could be a safety problem from some areas, but I am trying to take the most logical instance here of Canada, where we have a lot of reciprocal agreements on what both sides are doing. I am assuming that the chain of custody in Canada is equivalent to ours with respect to——

Mr. HUBBARD. Well, you can make that assumption and I can make that assumption as well.

Senator DORGAN. Do you know it is not?

Mr. HUBBARD. I do not know whether it is or not. We don't have authority, we have not looked at the Canadian system, that's not our job.

Senator DORGAN. So you are telling me that you, you say there are safety concerns but you have not looked at the treatment of prescription drugs in Canada?

Mr. HUBBARD. Mr. Chairman, there are safety concerns about any drug that goes outside the approval process, and is subject to the intermingling of counterfeit drugs, to abuse of the drug or to some sort of diversion. Diversion is a very real problem for us in the world. Drugs get moved around and go places that, where they just lose control, and all kinds of malevolent things can happen to them in that process, and that's our concern. Sure, you or I might go to Canada today on a trip and get sick, go to a doctor and get a drug and feel confident that that drug from that Canadian pharmacy is good, but the FDA can't assure that.

And once you have said Canada is the entree to this big U.S. market where the real money is, as it were, then the Canadian system becomes vulnerable to the sorts of international charlatans that deal in counterfeit drugs. So even if the Canadian system is every bit as good as ours, and I don't know whether it is or not, you are certainly saying that the Canadian system then is open to vulnerabilities by people who will try to enter the U.S. market because, again, that's where the money is.

Senator DORGAN. Mr. Hubbard, I think from the first moment I have understood that the position of both the last Administration and this Administration is that there are safety concerns and you have made that judgment without understanding what the circumstances are in other countries, especially Canada. I mean, you are making it without knowledge of what is happening in Canada, and that concerns me.

Mr. HUBBARD. I think we're saying that there are 200 countries that import products into this country and we are neither authorized nor empowered nor resourced, nor interested in examining the systems in those countries because that's not what we do, Mr. Chairman.

Senator DORGAN. We do it for other products. I just mentioned meat, fresh meat, we do it in fresh meat. Right now there is a truck stopping at the border coming through, and you know what they will do? They will look at a strip that was cut to lay on the back. They don't inspect the meat. They look at a strip that is cut. Why? Because we have already been to Canada, and we have said your plants meet our standards. We are willing to accept that. Your trucks come through, and we are not going to stop you.

Mr. HUBBARD. That's right, Mr. Chairman.

Senator DORGAN. Now why can that not work with respect to prescription drugs that are made in a U.S. manufacturing plant, sent to a pharmacy in Winnipeg, Canada, and then brought back across the border by a pharmacist in Binford, North Dakota, why can that not work?

Mr. HUBBARD. I suppose that it could be designed and situated in a way where the Canadian manufacturing plant would have to meet U.S. requirements.

Senator DORGAN. What if it is a U.S. manufacturing plant that makes the pill and sells it to Winnipeg through a distributor, and a pharmacist brings it—don't talk about a foreign pill, let's just talk about an American pill made in an American plant, FDA-approved plant that is then through a distributor sent to a pharmacy in Canada, and you are saying that you cannot assure safety if a registered U.S. pharmacist goes to a Winnipeg pharmacy and brings it back and passes the savings along to the consumer.

Mr. HUBBARD. That's correct, Mr. Chairman. Our concern is that once that U.S. manufactured product that we would give an FDA seal of approval to leaves the United States, it goes wherever it goes, whether it be 10 miles across the border in Canada, or 10,000 miles to Asia, we have lost control of it. We do not know if it comes back what it is, where it came from, whether it's safe. That's our problem, Mr. Chairman.

Senator DORGAN. Well, you have more problems than that. I want to come back in a second round. Senator McCain.

Senator MCCAIN. Mr. Hubbard, I am sure you are aware of the North American Free Trade Agreement.

Mr. HUBBARD. Yes, Mr. Chairman.

Senator MCCAIN. That free flow of goods and services between three countries has been a spectacular success. I am sure you are aware of that. Why should prescription drugs be an exception to the North American Free Trade Agreement?

Mr. HUBBARD. Well, the free trade agreements with both the GATT arrangement and the North American are to give the individual countries the right to set specific safety standards for any product for that country. So for instance, a contaminated food in Honduras could be sold legally in Honduras but could not come into the United States.

Senator MCCAIN. Mr. Hubbard, I am talking about the North American Free Trade Agreement.

Mr. HUBBARD. The point is that those agreements allow countries to set safety standards that may be different from——

Senator MCCAIN. But not so as to impede the flow of goods and services between——

Mr. HUBBARD. Right, they can't be a so-called trade barrier.

Senator MCCAIN. Exactly. And clearly what you are talking about is a trade barrier, because you are saying that Canadian manufacturers cannot manufacture a product or drug that is the same whether it goes to the United States or Canada, or certainly not one that would allow it to flow freely into the United States.

Is there a manufacturing facility of a U.S. drug company located in Canada?

Mr. HUBBARD. There probably is, I don't know.

Senator MCCAIN. What do you do about—you don't even know that?

Mr. HUBBARD. Oh, drug manufacturers register with the FDA, and if there is one there that is registered with the FDA, we inspect it.

Senator MCCAIN. You don't know.

Mr. HUBBARD. I don't know. There is a registration with thousands of manufacturers, so I don't know.

Senator MCCAIN. You don't know if any of them are from Canada. You come to this hearing well informed, Mr. Hubbard.

Let me just say, or ask this question. If a U.S. drug company has a manufacturing facility, obviously it has to be approved by the FDA in Canada, could that product then meet all of your requirements if it were sent to the pharmacy in Canada and then sent to the United States?

Mr. HUBBARD. Well, there is a specific law passed by Congress in 1988 that prohibits the reimportation of a drug made in this country that goes to another country and then attempts to return. It can only be returned to this country if it was by an original manufacturer who basically never lost control of it. So the answer to your question is no, it cannot come back in.

Senator DORGAN. Might I just point out that that specific law is the one that we repealed effectively and asked you to implement, and you refused to implement it based on what you say are safety and cost issues. So I think that I might point out, Senator McCain, that you are asking the right question here. If a U.S. pharmaceutical company is manufacturing in Canada, the FDA is up there inspecting the plant because they are going to ship those drugs down to Grand Forks, Minnesota, to sell them, the question is, can a Grand Forks pharmacist go up to Canada and access those drugs for half the price and bring them down and pass the savings along to the consumer. The answer from Mr. Hubbard is no, they cannot do that because we do not think we can assure safety. Is that it?

Mr. HUBBARD. Well, there are certain requirements that relate to safety of drugs and in order for it to be technically feasible for us to do that, there are certain requirements.

For instance, a Canadian drug will have a foreign label on it and we would require the American label so the patient can be warned of whatever. Also, in other countries, manufacturers may change the product slightly, the milligrams may be slightly more or less, the color may be different, there may be so-called inactive ingredients. There may be lots of changes that occur in the drug that make it not the drug that the U.S. patient receives.

Senator MCCAIN. I don't know why they would want to do that if they are manufacturing a product that is being sent to the United States of America. It seems to me it would cost them more to do all those things.

Mr. HUBBARD. In fact, that's a business decision and, in fact, they do do that.

Senator MCCAIN. Why is it, do you think, that the cost is so much lower in Canada and Mexico for the same drugs?

Mr. HUBBARD. In Canada they use a system called a reference price in which they take the lowest price the drug is sold across seven countries, that's mostly European countries and the United States. In the United States they use what is called the federal supply schedule, which is the price paid by the Defense Department and the VA and other public hospitals. They then say to the manufacturer, you can charge no more than the average of these seven countries' prices, so it is a price controlled system, and they are maintaining the price that can be charged. They may say, you can make so much profit.

In France they set a price of their own. Different countries set their prices differently, but they say this is the price you can sell that drug at.

And of course, generic drugs in this country are competitive on the world market. I think the biggest problem is the so-called brand name drugs that are still patented. When generic competition occurs, as you yourself said, Mr. McCain, the prices do in fact drop dramatically.

Senator MCCAIN. I am a deregulator, I do not believe in price control, but it seems to me that if it costs one-tenth for the same drug in Canada, do you think then, that we should look at price controls?

Mr. HUBBARD. I don't think that's—I mean, our job is safety. I think price controls are an issue for others in the Administration to consider.

Senator MCCAIN. Do you not have obligations to the consumer here?

Mr. HUBBARD. Well, we do. I think we care a lot about this in the sense that we try to get generics on the market as soon as we can, we work with drug companies to get newly developed drugs on the market as rapidly as possible. I think we do try to do things to provide access to patients, but this issue of how much they charge for a drug is outside our area of expertise.

Senator MCCAIN. Are you aware of the abuses that are being exercised by some drug companies with the generic drug manufacturers?

Mr. HUBBARD. Yes, Mr. McCain.

Senator MCCAIN. Do you think that ought to be changed?

Mr. HUBBARD. We have expressed willingness to work with committees in Congress to discuss those issues. I don't believe that we have been specifically asked about the particular legislation at this point, but we are certainly willing to discuss it.

Senator MCCAIN. We would like to have your opinion on the legislation, specifically where patent drug companies pay generic drug companies to keep a particular generic drug from being manufactured. Are you aware of that?

Mr. HUBBARD. Yes.

Senator MCCAIN. I would like to know your opinion on this legislation. It would be helpful.

I want to say Mr. Hubbard, that disparity in pricing, particularly where our two neighbors are concerned, for the exact same drug today, forces seniors all over America to make a choice between their health and their income, because of the high cost of prescription drugs. So I hope you understand why we are so concerned about this particular situation and why it is hard for us to respond to our constituents as to why it is that the citizens of our two neighboring countries pay less for prescription drugs, as opposed to our own constituents. I hope you understand the problem we're trying to address.

Mr. HUBBARD. Absolutely.

Senator MCCAIN. I thank you for your forthright testimony.

Senator DORGAN. Senator McCain, thank you. Let me just observe that I think there are price controls on restricted drugs in this country by the pharmaceutical companies; they control the price, and they do that with this law that prevents the reimportation. And when Dan Reeves, the coach of the Atlanta Falcons, goes on television every night and says Zocor is a lifesaving drug, he will describe the miracles of modern medicine of lowering cholesterol and so forth. The problem is that the Canadian that buys Zocor pays $1.82 per tablet and the American pays $3.82 per tablet. The question the American consumer asks, as Senator McCain asked, why can they not go to a pharmacy in Winnipeg and pay the $1.82?

You say, Mr. Hubbard, it is because of your concern about safety. Let me again focus just on Canada, and I think what we would like to do is reintroduce this legislation and pass it dealing just with Canada, just taking a first step.

Let me read to you Dr. David Kessler's letter. He says, "The Senate bill"—and he's talking about our bill that we passed that is now law—"allows only the importation of FDA-approved drugs manufactured in approved FDA facilities and for which the chain of custody has been maintained, addresses my fundamental concerns. I believe the importation of these products can be done without causing a greater health risk to American consumers." I would be interested in your response to Dr. Kessler's letter.

Mr. HUBBARD. I think as a potential patient, were I to be ill and purchase a drug from Canada, I think I would have a relatively high degree of confidence in Canadian drugs, speaking personally, because they are close by, our approval systems work together, we know them, people go there and purchase drugs, so you know——

Senator DORGAN. What do you mean, our approval systems work together?

Mr. HUBBARD. Well, we often talk to our counterparts in Canada when we approve drugs, they will approve them at the same time, and there is——

Senator DORGAN. You have more knowledge than you were allowing earlier.

Mr. HUBBARD. Well, the scientists talk. We talk with the Europeans quite a bit, and there is a lot of collaboration on the underlying data about whether a drug should be approved and its safety, so sure, the Canadian system is one we have some knowledge of, and I would have some degree of confidence to say as opposed to a Third World country.

But the problem is the system is set up, the way the law is and the FDA implements it is designed to deal very specifically with the production of drugs and their movement, and drugs in Canada are not part of that system, and therefore, we're saying that we cannot provide the assurance of safety. And I will repeat that I am concerned that any country that became the entree to the United States could then become a trans-shipment point for problem drugs.

Senator DORGAN. Mr. Hubbard, in a global economy, every country has entree to every other country, that's a given.

Let me ask you how you respond to Dr. Kessler's evaluation, if we just deal with Canada. Just dealing with Canada, is he correct that really that dissolves the issue? Because we are going to give you a chance to do that, we are going to pass this legislation again, and we are just going to take the first step, just Canada, and then see if the Administration or the previous, or anybody else involved in this thing can honestly say there are safety issues.

Mr. HUBBARD. I just don't think that we would be able to provide the same assurances of a drug imported from Canada or any other country as we could for American drugs. On some level, or some scale of——

Senator DORGAN. So you think Dr. Kessler is wrong?

Mr. HUBBARD. I would never second-guess any former commissioner, I'm sure they are all right about anything they say.

Senator DORGAN. First of all, I am really disappointed that you seem to suggest that the only way you can assure the safety of the drug supply of FDA-approved drugs produced in FDA-approved facilities, the only way you can assure that safety is if reimportation is only by a manufacturer. What makes the manufacturer such a much better importer than a licensed pharmacist?

Mr. HUBBARD. I think it is possibly the closeness issue, but as I said earlier, when this product appears in a North Dakota pharmacy, how do we know, it came from Canada, how do we know it's not a counterfeit? In fact, this one appeared in a pharmacy in Chicago and it was a counterfeit, and no one knew.

Senator DORGAN. And how did you find that?

Mr. HUBBARD. I believe there were some questions raised by physicians and our criminal investigators inspected, and found some very difficult to find variations in a label, and then after some follow-up testing and all, discovered that a Long Island, New York drug wholesaler was purchasing counterfeit drugs from the Middle East and bringing it in. It wasn't really a counterfeit drug, and working out of a storeroom in the back, just using water out of a tap that wasn't sterile and, therefore, introducing a very dangerous product.

Senator DORGAN. You are saying it happens rarely here?

Mr. HUBBARD. It happens very rarely here.

Senator DORGAN. And it happens more often in Canada, is that your point?

Mr. HUBBARD. We know that in the world it happens——

Senator DORGAN. I am talking about Canada.

Mr. HUBBARD. I can't specifically speak to counterfeiting in Canada, I will have to do some research and get back to you on that.

Senator DORGAN. Well, we are going to give you a chance to implement a piece of legislation dealing specifically with Canada, and my hope is that we will have the FDA and HHS support on behalf of consumers, and support consumers both by assuring safety and assuring reduction in costs by being able to access the same drug, the same company, and that we import it to this country.

Now let me tell you, I respect your opinion, I do not mean to bring you here to cast disrespect on your opinion. We disagree about this, but I am convinced, as are many many experts in this country, that we have the will and we can do with prescription drugs, just as we have with many other sensitive products, provide a safety net with respect to the chain of supply, and allow our American consumers to be able to access the identical drug produced in an FDA-approved plant from a Canadian pharmacist and to be able to allow the pharmacists in this country on behalf of consumers to do the same thing.

Let me make just one additional point through a question about costs. I have not spent a lot of time on costs, there will be some testimony about that, but it is also the case that the HHS and FDA, I think primarily HHS, saying that there cannot be a demonstrated cost savings, that on its face will fly in the face of reality. Anyone who has purchased drugs in Canada understands that there is a very dramatic cost savings for the identical drug produced in an FDA-approved plant.

So, can you just describe for me if the Administration still believes that you cannot demonstrate a cost saving, and if so, why?

Mr. HUBBARD. When Secretary Thompson was asked to relook at this issue, he asked his Office of Planning and Evaluation, which has cognizance over this, to look at the cost issue. And while it's very clear, as you pointed out, that the purchase price in a foreign country and the purchase price here is different, the Secretary's staff also included concerns about the various middlemen that would want profit from this, and concluded that it was basically inconclusive that cost savings would be as great, the costs that you would have in this country. For instance, the wholesaler who received the drug perhaps from the Canadian pharmacy, the pharmacist himself in the United States, would add to the price they would pay, assuming they paid what they would view as a wholesale price, which might be a retail price in Canada, and that the ultimate saving to the consumer at the end of the line might not be anywhere near what the price would be if the citizen actually traveled to Canada and actually bought it in Canada.

And so, that was I think their concern that there would be costs in the system to get the drug here and move it around and, therefore, these middlemen would be taking their 10 or 20 profit would eat up much of the savings. I think that was their concern, so therefore, they concluded that they couldn't really determine whether these cost savings that would seem to be apparent are really there.

Senator DORGAN. And who are they again?

Mr. HUBBARD. Well, it was the Office of Planning and Evaluation in the Secretary's office who did the study essentially. FDA did not do that particular examination. We examined the MEDS Act from more of the process of the testing and the documentation and those other requirements from the act.

Senator DORGAN. Well, I will not dwell on this. I think it is quite apparent there are very substantial savings and for the very reason that you indicated in your written testimony today, that there are limits on what can be charged by the pharmacies in the other countries, and the result is, our consumers pay the highest prices in the world for prescription drugs. The ability to access the identical drug from an FDA-approved plant for a fraction of the price, it seems to me, clearly demonstrates savings, but we will leave that for another day for experts in that particular area.

Let me again say that I think we will give you the opportunity to deal just with the issue of Canada, and the issue of safety and chain of supply and cost. It will be my intention, along with my colleagues, to pass legislation in this Congress, and I am confident that we will do it, that focuses just on Canada for the moment. We will just take the first step, and then we are going to have another hearing if there is not an implementation, and I will not be nearly as gentle in my nature.

I should tell you, I am very frustrated by this, enormously frustrated, largely because I think that both the previous Administration and this Administration have gone out of their way to find ways not to implement this. The Clinton Administration and the Bush Administration have both tried to find ways to not do something.

Now, I have a lot of folks from my home town, and I come from a real small town, and I can identify folks who sit around and find ways not to do things, you know, they are crabby all day, and every community has people like that. The people that make things happen and make changes in this country are the people that are looking for ways to get things done and make progress.

I do not want to compromise the safety of our drug supply, that is not my intention. Nor do I want our consumers to be handcuffed to the highest prices for prescription drugs of anyone in the world and then be told that they are prevented from going across the border to purchase a prescription drug made in an FDA-approved plant, an FDA-approved drug made in an FDA-approved plant, and pay 50 percent or 10 percent of the price because of some arcane piece of legislation was passed that represents, in my judgment, a sweetheart deal for the pharmaceutical industry. I am hopeful that we can change this.

Mr. Hubbard, you have answered our questions, and I again respect your opinion. I am not disrespectful to someone who disagrees with me, but I expect we will go at this again at some point because we are going to pass some legislation in this Congress and have additional hearings. I hope that our paths will cross again, and I hope perhaps you will be able to say to me that you all have taken a good look at the Canadian system, you have some confidence in that system, you have engaged with the Canadians with respect to the chain of supply issues, and tell us that there are no safety concerns with respect to the way we have reconstructed this law.

So let me give you my thanks for coming here today with other members of your staff.

Mr. HUBBARD. Thank you, Mr. Chairman. We certainly understand that your interests are in protecting the patients as well, and obviously we will continue to do this the best that we can.

Senator DORGAN. Thank you very much, Mr. Hubbard.

We will call the next panel forward. Ms. Elizabeth Wennar, President and CEO of United Health Alliance in Bennington, Vermont; Mr. John Marvin, member of the Alliance for Retired

Americans; Ms. Marjorie Powell, Assistant General Counsel, Pharmaceutical Research and Manufacturers of America; Mr. Stephen Giroux, Community Pharmacist, Middleport Family Health Center, and Member of the National Community Pharmacists Association in Middleport, New York; and Dr. Alan Sager, Professor of Health Services and Co-Director of Health Reform Program, Boston University School of Public Health.

We appreciate all of your being with us today. We have received the testimony that you have prepared, and we ask that you present a summary of your testimony. We will begin with Elizabeth Wennar, the President and CEO of United Health Alliance. Ms. Wennar, as you know, Senator Jeffords was here and spoke of you earlier. Welcome.

STATEMENT OF ELIZABETH A. WENNAR, PRESIDENT AND CHIEF EXECUTIVE OFFICER, UNITED HEALTH ALLIANCE

Ms. WENNAR. Thank you very much for having me here. As you mentioned, I am the President and CEO of United Health Alliance. By way of a little background, I have a nursing background, I have a masters in public health from Yale University, I have a doctorate from the Medical University of South Carolina in health administration and policy, and I completed my doctoral dissertation on the importation of prescription drugs, particularly looking at Canada.

Having said that, quite a few things that I have in my testimony have already been covered so I will try and not be repetitive, and I understand I only have about 5 minutes, so stop me when you think you've heard enough.

Senator DORGAN. We have a light system, actually. When the red light comes on, a trap door opens.

Ms. WENNAR. Well then, let that trap door fall into Canada, please.

Mr. Chairman and Members of the Committee, as you are aware, today's healthcare market presents many challenges for consumers, purchasers and our political leaders. None is more controversial than that of technology in the form of a pill. More often than ever, our policymakers and physician providers are being queried as to why it is that Americans, particularly senior citizens, must pay many times more than their Canadian counterparts for the same drug.

By way of background, what I'm going to do is to share with you a little bit of what we have done from a grass roots level in Bennington, Vermont.

United Health Alliance is a nonprofit physician health system organization located in the southwestern corner of Vermont. Our partners include a rural hospital and nursing home, a home health agency, and just over 100 community-based physicians. We serve residents in Vermont, Massachusetts, and New York. Our mission is to promote a physician-driven organization whose principal services are to provide advocacy and leadership in the areas of care management, contracting, performance improvement and educational programs to maximize value for our membership.

Although we have committed to 10 guiding principles, none is more important to us than assisting the communities we serve at becoming the healthiest in the nation. Approximately one year ago we found although this was an admirable objective, this objective was going to be difficult to achieve given the circumstances that existed for some of our elderly. Very simply, they did not have access to affordable prescription drugs and, therefore, they were not able to comply with the treatment plans prescribed by their physicians.

Although we had individuals that we knew were seeking their medications affordably via bus trips to Canada, this was not an option for the majority of the elderly in the communities we serve by virtue of either their medical condition or their financial ability of doing so.

One of our physicians came to us and requested our assistance at investigating how we could help a patient of his with breast cancer access her medications from Canada without having to get on the bus. Today that patient takes her medication because she can afford it. It cost her 90 percent less.

We compared the costs for 145 seniors for 6 months, and I have provided copies of that graph in my testimony. We compared the cost for the 145. As you can see, these individuals would have paid $81,000 in the U.S. and they paid approximately $22,000 for their medications in Canada. Our understanding is that there were no substitutes made for these medications, all medications accessed were for the treatment of chronic diseases such as diabetes, heart disease and cancer.

A price comparison of more commonly prescribed medications is also included in my testimony and you can see here, they are significant. Although there are minor variations across Canada, the savings are still significant, and have been reported anywhere from 30 to 95 percent.

Although the majority of the individuals using what we call MedicineAssist are the elderly on fixed incomes with no prescription drug coverage, we are beginning to see individuals that have depleted their pharmacy benefits also attempting to access their medications from Canada.

We have had multiple conversations with employers located in our communities and they have told us that they now must consider cutting benefits because they no longer can afford to supply the coverage that they have historically. The implications are frightening to all of us.

I'm now going to move to quality. I have heard quite a bit discussed concerning quality. Clearly as a provider network, our major concern is the ability of our patients to comply with a given treatment plan. When a patient cannot afford their medications, it's costly for all of us. Are we concerned about quality? Absolutely, Mr. Chairman, we are concerned about quality, and there is a quality issue and it exists on this side of the border, we would propose.

When a patient cannot take their medications, they most definitely will consume services elsewhere in our system such as the emergency room or by being admitted to the hospital. That is simply not rational. This is not about people that won't comply with a treatment plan, this is about individuals that can't afford to purchase prescription drugs in the country they live in.

Also, let's keep in mind that we are talking about Canada, not a Third World country. Having said this, these individuals are looking to take the risks associated with crossing the border. Many of them have told us that they are willing to take these risks.

I'm going to skip over the portion on why we think that drugs are less costly in Canada, but I will tell you clearly, there is no simple answer with regard to these issues. Barring any type of regulation of the pharmaceutical industry on this side of the border, personal reimportation from Canada under controlled circumstances can provide an interim solution for those who need access to a prescription drug.

I do believe with the cooperation of the industry, the FDA, the Canadian regulators and the U.S. physicians, that under a controlled demonstration project we could achieve a policy that would prove beneficial for all the stakeholders until we can produce a better solution.

In conclusion, I was asked to share something with you by a physician who recently called me. He basically had a patient that came to him and asked him to help him get his medications in Canada for his high cholesterol. The physician reached into the trash can and retrieved a prescription with a note attached to it that had been delivered to him earlier that day by his staff. The note read: Dear Doctor, Thank you for the prescription but I am returning it to you because I went to the pharmacy to get it filled today and when they gave it to me, I could not afford it.

According to the physician, this was a diabetic amputee that he had given samples to and had responded extremely well. He did what came next, he wrote a prescription. He had no idea that this one medication would cost this gentleman on a fixed income over $140 a month. He [the physician] noted that that man was on the medication and had done extremely well on it. As this patient's caregiver, he felt that instead of solving a problem for his patient, he had indirectly created one. Not a good feeling to know your patient will not be able to comply with a treatment plan you prescribe for them because he or she cannot afford it, and that you unknowingly contributed to that situation. His answer to the patient sitting in front of him was you bet.

The medication for that amputee would have cost $65 in Canada versus $140 here.

Thank you very much for this opportunity.

[The prepared statement of Ms. Wennar follows:]

PREPARED STATEMENT OF ELIZABETH A. WENNAR,
PRESIDENT AND CHIEF EXECUTIVE OFFICER, UNITED HEALTH ALLIANCE

Mr. Chairman, and Members of the Committee:

Thank you for inviting me to discuss the issues associated with the pricing of pharmaceuticals for U.S. consumers.

As you are aware today's healthcare market presents many challenges for consumers, purchasers and our political leaders. None is more controversial than that of technology in the form of a "pill." Pharmaceutical spending has almost doubled in less than a decade. More often than ever, our policymakers and physician providers are being queried as to why it is that Americans, particularly the elderly, must pay many times more than their Canadian counterparts for the same drug.

Background on United Health Alliance and MedicineAssist

United Health Alliance is a nonprofit physician health system organization located in Southwestern Vermont. Our partners include a rural hospital, nursing home, home health agency and just over one hundred (100) community physicians. We serve residents of Vermont, New York and Massachusetts. Our mission is to promote a physician-driven organization whose principle services are to provide advocacy and leadership in the areas of care management, contracting, performance improvement and educational programs to maximize value for our membership and customers. Although we have committed to ten (10) guiding principles, none is more important to us than assisting the communities we serve at becoming the healthiest in the nation. Approximately one year ago we found that although admirable, this objective was going to be very difficult to achieve given the circumstances that existed for some of our elderly. Very simply, they did not have access to affordable prescription drugs, therefore they were not able to comply with the treatment plans prescribed by their physicians. Although we had individuals that were seeking affordable medications via bus trips to Canada, we knew that this was not an option for the majority of the elderly in the communities we serve by virtue of their medical condition and/or their limited resources. One of our physicians came to us and requested our assistance at investigating how we could help a patient of his with breast cancer access her medications from Canada without having to get on a bus. Today that patient takes her medication because she can afford them. It cost her ninety (90) percent less in Canada. We compared the costs for 145 seniors for the first six months to see if what we had heard about the differences in pricing was in fact true. While these individuals would have had to pay just over $81,000 in the U.S., they paid approximately $22,000 for their medications in Canada. Our understanding is that there were no substitutions for the medications they were currently on. All medications accessed were for the treatment of chronic diseases such diabetes, heart disease and cancer. A price comparison of some of the more commonly prescribed medications for the treatment of these diseases has been provided along with this testimony. Although there is minor variation with some pricing in Canada, the savings are still significant and have been reported anywhere from thirty (30%) to (95%) percent. Although the majority of the individuals using MedicineAssist are the elderly on fixed incomes, with no prescription coverage, we are beginning to see individuals that have depleted their pharmacy benefits also attempting to access their medications from Canada. As we have conversations with employers located in the communities we serve about benefits and coverage for their employees we find many are concerned about how to continue the level of coverage they currently provide, particularly with the growth in their expenditures for prescription drugs. The implications are frightening for all of us.

Quality

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

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

To put it in the simplest of terms: the Canadian government is the purchaser, therefore they have implemented controls over the costs. Next, they do not allow direct-to consumer advertising. My understanding is that this type of marketing is only allowed in the United States and New Zealand. Essentially our major mode of control is through the approval process by the FDA that essentially controls entry into the market, not pricing. In the U.S. with its non-universal coverage structure, cost containment is undertaken by a myriad of public and private decision-makers, each with their own agenda and objectives. The price differential is of course going to appear even greater when you compare a group that has no coverage and pays out of pocket. They have no purchasing power, because they have no coverage. This is particularly true for about one-third (30 million) of the Medicare population.

I recently visited with health care providers in France and in Canada and they seemed quite perplexed by how we could rationalize the cost/benefit of allowing the prescription drugs to be advertised in the manner that they were on television. Their point was well taken on two fronts: (1) someone has to pay for the costs associated with this advertising and (2) when I proposed that it was intended to educate consumers so that they could be more informed about what was available for their treatment: they asked where's the data to support that this was anything more than "marketing" the drugs the industry wants to sell or promote. They used the example of a drug for chronic indigestion allowing you to continue to eat foods that are clearly not good for you.

Reimportation/Importation from Canada

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

Conclusion

Before departing to attend this hearing, I received a call from a physician that requested that I share a recent situation that he was presented with. He had a patient that asked if he [the physician] would help him get his medications from Canada so that he could afford to take them? The physician said he listened as the patient began to explain the differences in pricing for the medication recently prescribed for his high cholesterol. The physician reached into his trash can and retrieved a prescription with a note attached to it. The note had been delivered to him earlier in the day by one of his staff. The note read: Dear Doctor, Thank you for the prescription, but I am returning it to you because I went to the pharmacy to get this filled and when they gave it to me, I couldn't afford to pay for it. According to the physician this was a diabetic amputee that he had given samples to and had responded extremely well, so he did what came next, wrote a prescription. He had no idea that this one medication would cost this gentleman on a fixed income over $140 for a one-month supply. He noted that the man was on other medications as well. As this patient's caregiver, he felt that instead of solving a problem for his patient he had indirectly created one. Not a good feeling to know your patient will not be able to comply with the treatment plan that you prescribed because he or she can't afford it and that you unknowingly contributed to the situation.

His answer to the patient that was now sitting in front of him requesting help with purchasing his medications . . . you bet.

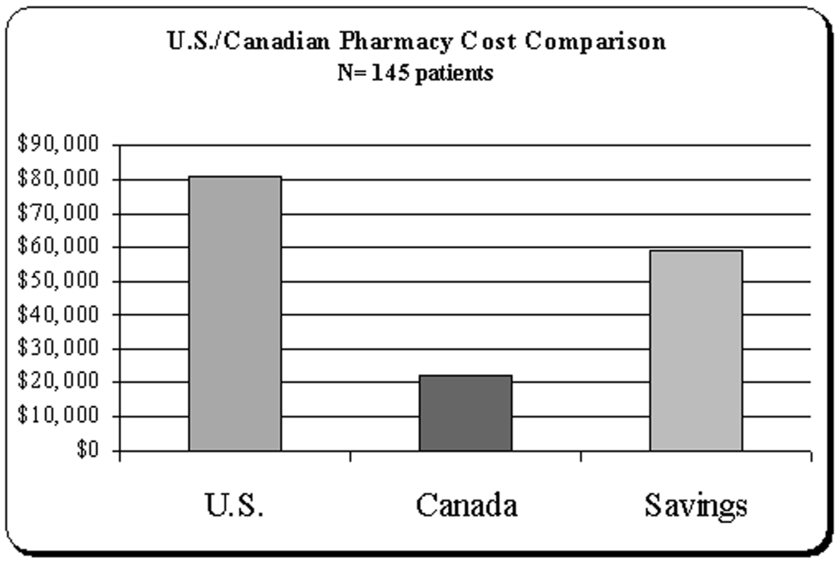
By the way the medication for the diabetic amputee would have cost approximately $65 in Canada.

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

UHAMedicineAssist

Six-month Summary Analysis

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



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

Source: United Health Alliance 2000 (MedicineAssist)
Note: U.S. prices are based on AWP plus 30%. The actual cost of U.S. prescriptions will vary based on geographic area and by individual pharmacies.

Sample Drug Pricing

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

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

Senator DORGAN. Ms. Wennar, thank you very much. We appreciate your testimony.

Mr. John Marvin, a member of the Alliance for Retired Americans.

STATEMENT OF JOHN MARVIN, MEMBER OF THE ALLIANCE FOR RETIRED AMERICANS

Mr. MARVIN. Thank you, Senator Dorgan. I appreciate the opportunity to testify today. I am representing the Alliance for Retired Americans, where I serve as a Regional Board Member for the northeastern part of the nation. The Alliance, which was established on January 1 of this year, now has 2.6 million members across the nation. It is made up of retirees from affiliates of the AFL–CIO, community-based organizations, individual seniors who joined the Alliance to fight for social and economic justice and civil rights for all Americans. I am also representing the Maine Council of Senior Citizens.

Today I submitted testimony which I hope you will read. I really want to testify from the gut, if you will. You are talking—you've heard of the angry young man. Today you're going to hear from an angry old man. The current policy seems to result in a kind of people export into Canada act instead of a workable reimportation act into this country.

This is the fourth year that I have spent organizing bus trips to Canada for prescription drugs run on an average of one-third to one-half cheaper than here. Last year 25 people caught a bus, saved $10,000 from the costs over what they would have paid in this country had they bought those same drugs here.

We always have on most trips at least one person and usually more, women who are suffering from breast cancer, which means they must take Tamoxifen for virtually the rest of their lives. At my local drug store in Augusta, Maine, a month's supply of Tamoxifen costs $114.99. Last August, that same month's supply in St. Stephen's, New Brunswick, just across the border, cost $14.50. That's why I am an angry old man about the situation as it relates to prescription drugs.

The trips do two things in addition to being of immediate help to those fortunate enough to be able to ride the bus. They highlight the fact that persons without drug coverage in this country literally pay the highest prices in the world, as you were pointing out, for drugs made mostly in Puerto Rico and heavily subsidized by the U.S. taxpayer.

In that respect, I want to point out that the major reason why the drug prices in the United States are so high is the pharmaceutical industry has a lock on the supply of needed drugs, backed up by law and power. It controls the development process for new drugs both here and throughout the world. The laws of this nation then protect the market power of the industry by providing patent protection for almost two decades.

To make sure this patent protection stays secure, we add in public financing of the highest risks of development process. The industry spends hundreds of millions of dollars to influence government at all levels. The result is the exploited pricing policies that we are discussing here today.

A publication of the Alliance, *The Profit in Pills: A Primer on Prescription Drug Prices,* documents why prescription drug prices have increased so dramatically, and the various ways that the pharmaceutical industry protects its interests at the expense of the American public. Most affected are older persons and those with disabilities who take more medications than other segments of the population and are most likely to pay the full retail prices.

I respectfully request that this report be included in the hearing record and I would also ask that you, Senator Dorgan, put it into the Congressional Record so that all of your can colleagues may also have an opportunity to read it.

Senator DORGAN. Without objection, the publication will be part of the hearing record.

[The information referred to follows:]

THE PROFIT IN PILLS: A PRIMER ON PRESCRIPTION DRUG PRICES, A REPORT BY THE ALLIANCE FOR RETIRED AMERICANS

[Reprinted from *The Profit in Pills: A Primer on Prescription Drug Prices* with permission of the Alliance for Retired Americans.]

Dear Reader:

Our purpose in producing this report is to make the public aware of how price gouging by the pharmaceutical industry is allowing industry profits to soar at the expense of every American citizen and every American company with health benefits. Even the health plans covering younger and working citizens are being squeezed because of hyperinflation of prescription drug prices.

Unfortunately, those ages 65 and older and persons with disabilities suffer the most because they take more medications than other segments of the population. More than 40 percent of all prescriptions written are for retired Americans, who make up 13 percent of the U.S. population. While more than 13 million older Americans and people with disabilities have no prescription drug coverage at all, the coverage other Medicare beneficiaries have is often very expensive (some policies cost more than $3,000 a year), inadequate and unreliable. Almost half of all Medicare beneficiaries lack coverage for at least part of each year. In addition, health maintenance organizations (HMOs) have dropped more than two million Medicare beneficiaries, many of whom have been unable to find another HMO, and employer-provided health and prescription drug insurance is declining.

The Alliance for Retired Americans believes the time has come for the federal government to act decisively to resolve the crisis. There is overwhelming support for the government to provide prescription drug coverage for the elderly and persons with disabilities and to confront drug prices. That support must be translated into political action.

The more than 2.5 million members of the Alliance for Retired Americans, organized in 2001 and growing rapidly, are making the fight for prescription drug coverage for all Medicare beneficiaries their No. 1 legislative priority in Congress. Including pharmaceuticals as a basic, defined Medicare benefit would equip the Centers for Medicare and Medicaid Services, the agency of the U.S. Department of Health and Human Services that administers Medicare, to use its national purchasing power to bring outrageously high prescription drug prices under control and set national standards for reasonable prices. Medicare drug coverage also would provide current workers with the peace of mind of knowing they will be able to get the medicines they need when they retire. Even such corporate giants as General Motors are calling for the addition of a universal prescription drug component to Medicare. Other approaches to use government authority to control and moderate drug prices also must be explored and adopted.

The Alliance believes that drug benefits, like other Medicare benefits, should be available to all Medicare beneficiaries with no income test; all medically necessary and approved treatments should be covered; enrollment must be voluntary so people who now have plans can keep them; provision should be made to encourage current employer retiree plans to maintain at least their current levels of benefits; premiums, deductibles and co-payments must be affordable; there must be reasonable limits on beneficiary out-of-pocket expenses; and lower-income beneficiaries should have all costs covered. Most importantly, to make the benefit affordable to taxpayers and beneficiaries, drug price cost controls are essential.

In the longer term, the Alliance believes the enactment of a universal health system that includes pharmaceutical treatments as a basic benefit is required to fully address the challenge of availability and reasonably priced drugs.

Our immediate challenge on behalf of older and retired Americans is to serve as a strong voice for the enactment of a drug benefit under Medicare, and for strengthening and improving Medicare and Social Security. For more information on the Alliance and to find out what you can do to help put an end to the outrageous price gouging by the pharmaceutical industry, we invite you to visit our website at www.retiredamericans.org.

Sincerely,

GEORGE J. KOURPIAS,
President

EDWARD F. COYLE,
Executive Director

Serious Choices

Too many older Americans are forced to choose between paying for their prescription drugs and buying food. But one woman's choice was even more critical.

Ms. H had moved recently into Council House, a housing project for seniors in Maryland. One day at the elevator she met a neighbor awaiting a delivery from her pharmacy. The deliveryman arrived—but when the woman saw how much her drugs cost she sent them back. She said she didn't have enough money to pay for them.

Two weeks later she was dead.

Summary

Prescription drug prices are rising rapidly and are projected to continue to do so through at least the next decade. This increase has the most adverse effect on the segments of the population without some type of insurance protection.

Drug spending overall is increasing largely because of three factors: utilization or volume increases; availability of new drugs for treating diseases; and rising prices for existing drugs. While a number of new drugs have extended and enhanced the quality of everyday life for many Americans, they remain too costly and out of the reach of millions.

The pricing chain for drugs is complex and difficult to trace because much of the information regarding prices is considered proprietary and hence is not publicly available.

The pharmaceutical market is unique in several ways. Manufacturers charge different prices for different customers and allow for discounts and rebates in order to maintain inclusion of their products on the formularies of large purchasers. It is the individual consumer without insurance coverage who pays the highest prices for prescription drugs.

Drug manufacturers also enjoy a lower tax rate than other industries. And although they maintain that high prices for new drugs are justified as their recovery for research and development expenses, most core research for drugs is funded by the federal government, primarily through the National Institutes of Health. Much of the companies' development of drugs actually is for derivatives of existing drugs rather than new drugs.

While the precise cost of drugs is difficult to pinpoint, the profit levels are not. In 2000, pharmaceutical companies had after-tax median profits of 18.6 percent, compared with 4.9 percent for all other Fortune 500 companies combined.

Drug manufacturers spend more of their revenues on profits than on research and development—and even more on marketing. They dedicate more than 18 percent of revenues to profits and 30 percent to marketing and administration, compared with 12 percent to research and development.

Promotional spending is directed toward doctors primarily through distribution of samples. Since 1997, direct-to-consumer (DTC) advertising has become a more significant part of marketing, accounting for $1.3 billion in advertising outlays in the first half of 2000 alone. Drug companies also spend millions in contributions to political candidates and to lobby Congress.

Almost half of all prescription drugs sold in the United States are generic drugs—but this accounts only for about 10 percent of the costs of all pharmaceuticals. Generic drugs, which cost less than brand-name drugs, are able to enter the market only after the brand-name company's patent expires. These patents often are extended by various means, including deals with generic companies.

Since the enactment of Medicare 36 years ago, prescription drug treatment has become an essential component of medical treatment for older people and those with disabilities. For Medicare beneficiaries with serious chronic medical conditions, access to drugs is critical to survival and to the maintenance of an acceptable quality of life.

The most comprehensive approach to providing affordable prescription drugs for all Americans is to enact a universal, national health care system that includes a prescription drug benefit. Among Medicare beneficiaries, however, a crisis over both declining coverage and price escalation has been a top political and medical issue. National and state lawmakers are exploring a variety of interim approaches. This primer responds to the immediate need of Medicare beneficiaries and discusses a number of measures being pursued toward the goal of affordable, comprehensive drug coverage for such beneficiaries.

Introduction

The high costs of prescription drugs in the United States are not new but in recent years have made it to the front of the nation's radar screen. Prescription drug prices are rising rapidly, having the most adverse effect on the segments of the population without some type of insurance protection, including Medicare beneficiaries. As a policy issue, coverage of prescription drugs for Medicare beneficiaries became a major component in the 2000 presidential campaign and in many congressional races; it continues to be a major issue in the 107th Congress.

This report attempts to present the trends and reasons why prescription drug prices have increased so dramatically, where the money goes, examine proposals to address the issue and present recommendations from the Alliance for Retired Americans.

Principles for a Medicare Prescription Drug Benefit

The Alliance for Retired Americans is committed to the enactment by Congress of a universal, comprehensive and affordable defined prescription drug benefit under Medicare.

The Medicare program is a vital and effective program on which more than 98 percent of older Americans and millions of persons with disabilities depend. However, Medicare lacks a core component of any comprehensive medical system—prescription drugs.

Prescription drug prices are rising rapidly, having the most adverse effect on the segments of the population without some type of drug coverage. Older Americans spend more out of pocket than the rest of the population because they have more acute and chronic illnesses, use more prescription drugs for treatment and are less likely to have insurance coverage.

Older Americans, 13 percent of the U.S. population, account for 34 percent of all prescriptions dispensed and 42 cents of every dollar spent on prescription drugs. Employer-provided health coverage for retirees is declining, and managed care plans are capping or dropping drug benefits and dropping out of the Medicare+ Choice program.

The recent proposal to give block grants to the states to create prescription benefits for low-income seniors would be ineffective for the following reasons:

- It would leave millions of moderate-income older and disabled persons without protection;
- It would take years to create;
- It would give states wide latitude to restrict benefits;
- It would delay the passage of a true universal and defined Medicare drug benefit; and
- The record of states in enrolling persons in the QMB and SLMB programs gives little cause for optimism for expanded coverage.

The Alliance for Retired Americans believes that a Medicare pharmaceutical benefit must incorporate the following principles:

- Universal coverage for all who qualify for Medicare benefits;
- The benefit must be comprehensive and include the most current and effective treatments and quality controls;
- Enrollment in the benefit should be voluntary so that those who have superior benefits can remain in their employer's plan while assuring enrollment later for persons facing erosion or loss of current drug benefits;
- The benefit must have affordable premiums and co-pays and should protect all beneficiaries from high out-of-pocket expenses;
- The benefit must not be means-tested; however, low-income persons should have all costs covered;
- Dollar coverage of the benefit should be high enough to protect the out-of-pocket costs of average-to-higher pharmaceutical users and contain a reasonable cap on costs for those with catastrophic bills;
- Employers should be required and/or provided with incentives to maintain and expand the level of coverage of current, employer-provided prescription drug benefits; and
- Pharmaceutical prices for all consumers must be brought under some system of control, including, for example, enforcement of patent limits; negotiations on fair prices by the federal government where there is significant public investment in drug development; and provisions to achieve price discounts for Medicare beneficiaries based on the Federal Supply Schedule and comparable to prices charged to larger HMOs and hospital chains. Without action on the rising price of pharmaceuticals, the cost of a Medicare benefit will not be affordable and millions of Americans of all ages will be denied their right to first-class health services.

Recent Trends in the Price of Prescription Drugs

- According to Bureau of Labor Statistics figures, drug prices rose 306 percent between 1981 and 1999, while the consumer price index (CPI) rose 99 percent during the same period.[1]
- In 2000, total spending in the United States for prescription drugs was $116 billion—more than twice the $51 billion spent in 1993. And that amount is expected to more than triple to $366 billion by 2010.[2]
- Older Americans and people with disabilities spend more out of pocket than the rest of the population because they have more acute and chronic illnesses, use more prescription drugs for treatment and are less likely to have insurance coverage. Older Americans, 13 percent of the U.S. population, account for 34 percent of all prescriptions dispensed and 42 cents of every dollar spent on prescription drugs.[3] The average Medicare beneficiary fills 18 prescriptions a year.
- Annual spending per capita in the Medicare population for prescription drugs has jumped from $674 in 1996 to $1,539 in 2000 and is expected to climb to $3,751 in 2010, an average rate of increase of 9.3 percent. Total prescription spending in the Medicare population will rise from $61.2 billion in 2000 to $174.4 billion in 2010, an average annual rate of increase of 11 percent.[4] The Congressional Budget Office (CBO) estimates prescription drug spending for Medicare enrollees will total nearly $1.5 trillion over the next decade.[5]
- Although nearly one-third (30 percent) of Medicare beneficiaries are expected to incur less than $250 in drug expenses in 2001, more than four in 10 (43 percent) will have drug expenses greater than $1,000—and 8 percent will have expenses of at least $4,000.[6]
- Out-of-pocket spending for prescription drugs by Medicare beneficiaries in 2001 is estimated to average about $686, with 20 percent expected to spend more than $1,100.[7]
- Medicare beneficiaries without prescription drug coverage spend on average 83 percent more for their medicines than those with drug coverage. About half of

Medicare beneficiaries without any form of prescription drug coverage have incomes less than 175 percent of poverty, which is $15,000 in 2001.[8]

- As Social Security benefit increases are tied to the CPI and prescription drug prices are increasing much faster than the CPI, these trends make prescription drugs increasingly less affordable for Social Security beneficiaries.

Why Are the Prices Going Up So Rapidly?

Toward the end of the last century, changes were made in the way hospitals were compensated that prompted them to reduce the length of stay of patients. This "quicker and sicker" discharge from hospitals led physicians to increasingly rely on prescription drugs for treating patients. Drug interventions, in turn, forestall the hospitalization of many other older persons and help them to maintain lives outside of institutions. Consequently, the role prescription drugs play in the lives of older persons, in particular, has become much greater.

There is no doubt the introduction of many new drugs has extended and enhanced the quality of everyday life for millions of Americans. Technological advances in treating diseases include the utilization of new drugs that can arrest or cure many cancers, heart disease, high blood pressure, AIDS and other life-threatening conditions. Drugs have contributed to reducing costs of hospitalizations and surgeries, but new drugs are more expensive than older drugs, and three times more costly than generic drugs.

The spending increases for prescription drugs are attributed largely to three factors:

- Utilization increases;
- Availability of new drugs for treating diseases; and
- Rising prices for existing drugs.

The volume of drugs sold has increased dramatically. Between 1992 and 1998, the number of prescription drugs sold has increased 37 percent. The 3 billion prescriptions sold in 2000 are expected to rise to 4 billion by 2004.[9]

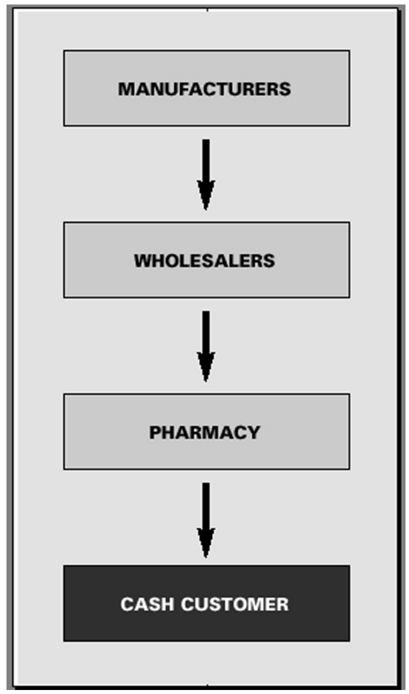
The increase in utilization or volume of drugs prescribed is greatly affected by promotional advertising by manufacturers.

Manufacturers promote the use of new drug therapies in a number of ways. The most common practice is for thousands of drug company representatives to leave samples when visiting physicians and hospitals. Advertising directed at consumers is a relatively new practice that has grown considerably over the past 15 years. Promotional spending by drug companies reached $13.9 billion in 1999, an 11 percent increase from 1998 levels. Of that total, direct-to-consumer (DTC) advertising accounted for $1.8 billion, a 40 percent increase from 1998.[10]

The price of older drugs is increasing also, but at a rate of less than 4 percent per year. Additionally, in order to extend patents, drug manufacturers often will issue older drugs in new dosage forms or with other minor changes and charge higher prices. A Congressional Budget Office study found the average list price of brand-name drugs increases faster than inflation even after the entry of other therapeutically equivalent ("me too") drugs on the market.[11]

Distribution Chain

Generally, the chain of distribution begins with the manufacturer who distributes the drug by selling it to drug wholesalers, the middlemen between the manufacturer and the pharmacies. The wholesaler sells the drug to the retail pharmacy at the price of obtaining the drug plus a markup, usually between 2 percent and 4 percent. The pharmacist sells to the consumer at the acquisition price plus a markup of 20 percent to 25 percent. If the customer is insured, he or she will not pay the full amount, but rather a copayment of differing amounts depending on the insurance plan. If the customer is uninsured, he or she will pay the full cost or highest price for the drug.[12]



For every dollar that a consumer pays for a prescription drug at the pharmacy, 74 cents goes to the drug manufacturer, 3 cents goes to the wholesale distributor and 23 cents to the pharmacy.[13]

Pricing Chain

It is extremely difficult to identify the actual cost of a drug because the pricing chains are more complex than the distribution chain. This table summarizes key pricing terms and the levels at which prices are and are not publicly accessible. Some prices are not publicly available, as they are considered to be manufacturers' proprietary information.

PRICE	DEFINITION
Retail price	The price charged by retail pharmacies to individuals without insurance, known as "cash-paying" customers.
Average wholesale price (AWP)	The average list price that a manufacturer suggests wholesalers charge pharmacies. AWP typically is less than the retail price, which will include the pharmacy's own price markup. AWP is referred to as a "sticker" price because it is not the actual price that large purchasers normally pay. For example, in a study of prices paid by retail pharmacies in 11 states, the average acquisition price was 18.3 percent below AWP. Discounts for HMOs and other large purchasers can be even greater. AWP information is available publicly.
Average manufacturer price (AMP)	The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. Federal Supply Schedule prices and prices associated with direct sales to HMOs and hospitals are excluded. AMP has a benchmark created by the Omnibus Budget Reconciliation Act (OBRA) in 1990 to use in determining Medicaid rebates and is not publicly available. The Congressional Budget Office (CBO) estimated AMP to be about 20 percent less than AWP for more than 200 drug products frequently purchased by Medicaid beneficiaries.
Nonfederal average manufacturer price (NFAMP)	The average price paid to a manufacturer by wholesalers for drugs distributed to nonfederal purchasers. NFAMP is not available publicly.
Federal Supply Schedule (FSS)	The price available to all federal purchasers for drugs listed on the Federal Supply Schedule. FSS prices are intended to equal or better the prices manufacturers charge their "most-favored" nonfederal customers under comparable terms and conditions. Because terms and conditions can vary by drug, the most-favored customer price may not be the lowest price in the market. FSS prices are available publicly.
Federal ceiling price (FCP)	The maximum price manufacturers can charge for FSS-listed brand-name drugs to the Veterans Administration, Department of Defense, Public Health Service and the Coast Guard, even if the FSS price is higher. FCP must be at least 24 percent of NFAMP. FCP is not available publicly.
Medicaid rebate net price	The effective outpatient drug price after manufacturer rebates to state Medicaid programs. The basic rebate on brand-name drugs is the greater of 15.1 percent of the AMP or the difference between AMP and the lowest or "best" price the manufacturer charges any purchaser other than Medicaid. Rebates for generic drugs are 11 percent of the AMP. Rebates are larger for brand-name drugs whose AMP increases exceed inflation in the consumer price index. Information on rebate amounts is available publicly; AMP and best price are not available publicly.
VA national contract price	The price the VA has obtained through competitive bids from manufacturers for select drugs in exchange for their inclusion on the VA formulary. Contract prices are available publicly.

Source: GAO, *Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes,* August 2000

Variations in the price can take place because of the power the drug companies have in their market and also because purchasers can be separated into groups that vary by their price sensitivity. This practice is known as price discrimination. Price-sensitive group health maintenance organizations (HMOs, see glossary), for example, would decrease the amount of a particular drug they purchase if the price of that drug increased, particularly if there are equivalent substitutions available. Doctors who prescribe medications and consumers with insurance coverage that covers most of the costs of drugs are considered to be price insensitive. An individual consumer without coverage and without bargaining power would be "price sensitive" to costs and more willing or forced either to use a substitute or decrease use.

Consequently, drug manufacturers charge different prices to different purchasers for the same drug. Agencies of the federal government, state Medicaid programs and many nonfederal public health entities have access to substantially lower prices through the Federal Supply Schedule (FSS) for pharmaceuticals.

Under the Omnibus Budget Reconciliation Act of 1990 (OBRA), drug manufacturers must provide rebates to state Medicaid programs for their outpatient drugs in exchange for Medicaid coverage. The minimum rebate for a brand-name drug is 15.1 percent of the average manufacturer price (AMP). Medicaid pays the pharmacy its acquisition price plus a dispensing fee and gets an average cash rebate of 19 percent to 21 percent from the manufacturer. Favored private purchasers with their own outpatient pharmacies, such as HMOs and hospitals, may deal directly with the manufacturers and consequently pay a price lower than that offered to wholesalers.

Insurers and pharmacy benefit managers (PBMs, see glossary) obtain both a retail discount and a rebate from the manufacturer wielding their bargaining power through the use of formularies, i.e. lists of drugs approved for use and reimbursement. It is of significant economic importance to manufacturers to have their drugs included in the formularies of large purchasers. The amount of rebates can vary considerably by type of arrangement and by drug. Thus, together with co-pays from covered beneficiaries, discounts and rebates, an insurer and PBM likely would pay between $30 and $44 for a drug for which the uninsured cash customer would pay $52. With rebates, Medicaid would pay about $34 for the same drug.

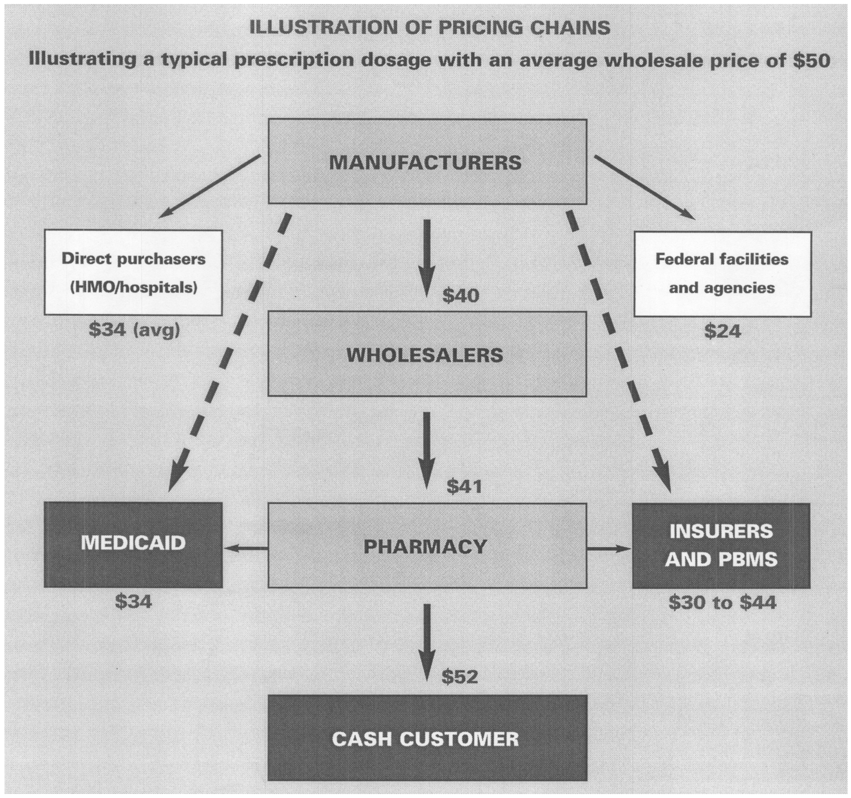
Most retail pharmacies, however, do not have the bargaining power for discounts that other favored purchasers have, as they must stock a full range of drugs, not just those in specified formularies, in order to fill all prescriptions presented to them. At the bottom of the chain, it is the noninsured consumer who pays the most for a prescription drug.[14]

Who Pays?

On average, Americans use about 10 prescriptions a year, but most do not pay full price for them. Slightly more than three in four (77 percent) of the non-Medicare population have prescription drug coverage. Sixty-one percent have coverage from their employer; 11 percent have coverage under Medicaid and 5 percent have private coverage. Nearly one-fourth of the non-Medicare population has no drug coverage, primarily because they do not have health insurance.

Since Medicare does not have an outpatient prescription drug benefit, at least one in three people in the Medicare population—approximately 13 million—have no drug coverage at all in the course of a year; nearly half have no coverage for at least part of an entire year. Employers cover prescription drugs for 24 percent of the Medicare population. Seventeen percent are covered by Medicare HMOs. Others rely on Medicaid (12 percent) and other sources (5 percent) for coverage.[15] Another 8 percent purchase Medigap plans, but they must pay for the coverage and are subject to high administrative costs and high premiums as well as adverse selection.

The prescription drug benefit has been a major reason many Medicare beneficiaries are attracted to Medicare HMO plans. However, many of them are losing their prescription drug benefit either because of the withdrawal of HMOs from Medicare or a decline in the number of plans covering the benefit. Many rural counties now have either no carriers or only one noncompetitive plan. At the end of 2000, more than 900,000 Medicare beneficiaries were dropped from their HMOs; they encountered more difficulty finding an alternative HMO than the 700,000 who were dropped in 1998 and 1999. Of 237 HMOs once in the Medicare program, only 90 continue.[16] A study of benefits under Medicare+ Choice plans during the 1999–2000 period shows there was a decline in the number of contracts covering prescription drugs from 73 percent to 68 percent.[17]



Source: Adapted from Jack Hoadley, Ph.D., Office of the Assistant Secretary for Planning and Evaluation (ASPE), DHHS. Presentation to ASPE Conference on Pharmaceutical Pricing, Utilization and Costs, Washington, D.C., Aug. 8–9, 2000.

There also is evidence of decline in either the generosity of the benefit or an increase in cost-sharing. Seventy percent of plans have an annual $1,000 or less limit on drugs and 32 percent have caps of $500 or less per enrollee.[18] A survey of enrollees in Medicare HMOs found that 72 percent of them saw their annual HMO premiums increase by at least $500 within one year.[19]

Similarly, employer coverage for retirees and the scope of their benefits has been declining in the past decade because of rising costs. Among employers with more than 200 workers offering retiree health benefits, 67 percent offered them to Medicare-eligible retirees in 2000, down from 80 percent in 1999, a 16 percent decline. Sixty-seven percent of firms of all sizes report that higher spending for drugs contributed "a lot" to increases in health insurance premiums in 2000.[20] Another survey of employers reports that drug costs represented 40 percent to 60 percent of employers' retiree plan costs. Large employers (1,000 employees) are most likely to offer retiree health plans. However, 40 percent of them are seriously considering cutting back on drug benefits for their retirees in the next three to five years and 30 percent would consider terminating coverage prospectively for retirees ages 65 and older.[21]

Consequently, the number of Medicare beneficiaries without prescription drug coverage can be expected to grow considerably, leaving millions more to pay the highest prices for their prescriptions.

The Money Chain: How Are Drug Revenues Spent?

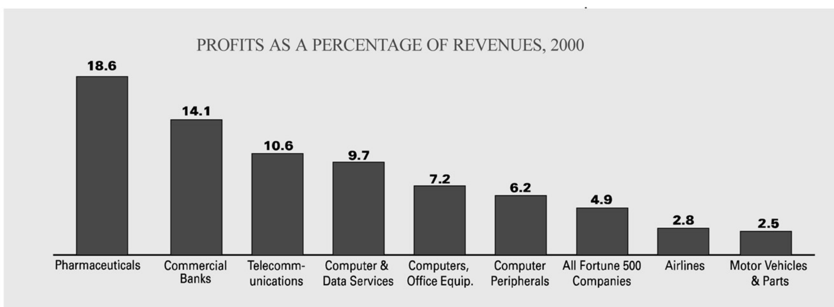
Drug manufacturers devote more of their revenues to profits and marketing than to research and development (R&D). The 12 drug companies with the highest revenues spent three times as much on marketing as on R&D in 2000. More than 18 percent of revenues are dedicated to profits, compared with 12 percent spent on R&D and 30 percent on marketing and administration.[22]

Profits

The pharmaceutical market differs from other markets in a number of ways:

- There is a ready demand for the old as well as the higher-priced new therapeutic products, so marketing is intense;
- There is insurance coverage and subsidization for the product;
- Government pays for a substantial share of research that leads to drug development;
- There is government compliance in supporting drug monopolies through allowing market exclusivity under a patent and the extension of patents; and
- There are hidden prices, discounts and rebates.[23]

The pharmaceutical market differs also in the profits the industry makes compared with others. As can be seen in the following chart, data from the list of Fortune 500 companies show that in 2000, the after-tax median profits of pharmaceutical companies was 18.6 percent, higher than any other industry and considerably higher than the median after-tax profit level of 4.9 percent for the other Fortune 500 companies combined. This translates into $192 billion in revenues and $28 billion in profits in 2000 for drug companies. In fact, Fortune magazine places the pharmaceutical companies at the top in two of three categories—returns on revenues and returns on assets—and second in returns on shareholders' equity.[24]



Source: *FORTUNE* magazine

Not only are pharmaceutical companies more profitable than other industries, they also have a lower tax rate. There are five federal tax provisions that result in greater tax savings for the drug companies than other major industrial categories. A Congressional Research Service report found that while the average tax rate for all industries was 27.3 percent between 1993 and 1996, the rate for drug companies was only 16.2 percent.[25]

Research and Development

Although pharmaceutical companies claim the prices of new drugs are necessary to fund ongoing research and development, it is the federal government, primarily through the National Institutes of Health (NIH), that pays for the majority of the initial drug research in the United States.

A congressional committee found that of the 21 most important drugs introduced between 1965 and 1992, 15 were developed using knowledge and techniques originating in federally funded research.[26] A team of journalists from The Boston Globe looked at 50 top-selling drugs approved by the FDA over a five-year period. Thirty-five were new bestseller drugs that the FDA considered most important or most unique, and 15 were so-called "orphan" drugs that treat rare diseases. Thirty-three of the 35 new drugs and 12 of the 15 orphan drugs received money from NIH or the FDA to help in discovery, development or testing.[27]

Drug manufacturers also maintain that the most expensive aspect of their research is in the clinical trials,[28] yet NIH and other federal agencies are sponsoring 60 percent of current clinical trials and the industry is sponsoring just 11 percent.[29]

During the 1980s and early 1990s, NIH required drug companies to charge a "fair and reasonable" price for drugs originally developed by taxpayer-funded research and development. This requirement was dropped by NIH in 1995. Reinstatement of this requirement is part of a proposal now in Congress, but it may not have sufficient support in the face of intensive industry lobbying.

In addition, a review of the government's invention reporting system shows NIH does not keep track of the drugs invented with taxpayer monies; NIH tracks its spending by disease, not by drug.[30, 31]

Much of drug manufacturers' development of drugs is not for new drugs but rather copies of existing drugs. This is particularly important to them, as a number of patents are expiring between 2000 and 2004.

Until 1992, the FDA classified every new drug it approved according to its significance for human health. One classification was 1C, meaning little or no therapeutic gain, since a drug so ranked was a duplicate of products already available. During the period from 1982–1991, more than half of newly approved drugs (53 percent) were 1C or copycat drugs, indicating that much of drug manufacturers' so-called research and development of drugs is actually of the "me too" variety—therapeutically equivalent drugs. Thirty-one percent of the approved drugs were classified as modest therapeutic gain, such as a change in formulation, so the drug could be taken less frequently. Only 16 percent were ranked as important therapeutic gain or a breakthrough drug. Because of industry pressure, the Bush administration eliminated these rankings in 1992.[32]

In the 1990s, the FDA approved 857 new drug applications. More than one-third (311) were new molecular entities (NMEs), compounds that have never been sold on the U.S. market. Nearly half (426) were "new formulations" or "new combinations" of compounds already approved. New formulations consist of active ingredients already on the market that have been modified; new combinations contain two or more previously approved active ingredients in a new single medicine.[33]

Marketing

Pharmaceutical companies' promotional spending directed toward doctors and consumers topped $8 billion in the first six months of 2000, up 14.3 percent for the same period in 1999. The industry employs one of the largest sales forces among all manufacturing sectors. Distribution of prescription samples to doctors accounted for nearly 50 percent of promotional spending. Nearly half of the samples (45.1 percent) were given to patients over the age of 60.[34]

Changes to FDA policy in 1997 have allowed drug manufacturers to expand advertising via mass media to consumers. Direct-to-consumer (DTC) advertising, primarily through television ads, totaled $1.3 billion for the first half of 2000 only, compared with $1.3 billion for all of 1998 and $1.8 billion for 1999.[35]

The direct-to-consumer advertising and dispensing of free brand samples by physicians generate market demand whereby consumers are introduced to and encouraged to request the brand-name drugs from their physicians. In a telephone poll conducted in 2000, 91 percent of Americans said they had seen or heard an advertisement for prescription drugs in the past year; 34 percent said they had talked with their doctor about a specific medicine they saw or heard advertised; and 7 percent said they asked their doctor to prescribe a medicine they saw advertised.[36] DTC ads can produce significant returns. In the first 10 months of 2000, pharmaceutical companies Merck and Pfizer together spent $206 million combined on advertising for their arthritis drugs, Vioxx and Celebrex respectively, resulting in combined sales of $3.7 billion.[37]

Lobbying

The drug industry spends a considerable amount on lobbying efforts to protect their interests. Overall, the industry spent $278.5 million from 1997 to mid-2000 lobbying the Clinton administration and members of Congress on both sides of the aisle. During this period, nearly 300 lobbyists, many former members of Congress or former congressional/administration staffers, were hired to fight bills that would control their prices and limit their profits.[38] During the 2000 election cycle, pharmaceutical companies contributed $26 million to congressional and presidential campaigns, about 30 percent to Democratic candidates and 70 percent to Republican candidates.[39]

In addition, drug companies are financial backers of such front groups as "Citizens for Better Medicare." In 2000, CBM waged a $50 million ad campaign against a prescription drug benefit under the Medicare program.[40] Also, at least $20 million was funneled through the U.S. Chamber of Commerce during the 2000 election cycle for ads defending candidates who oppose governmental solutions to the high costs of drugs and attacking members of Congress who favored a universal Medicare benefit and systems designed to moderate drug prices.[41]

Why Not Have More Substitution of Generic Drugs?

During the 1950s and 1960s, drug manufacturers persuaded doctors to prescribe brand-name drugs and state legislatures to prevent pharmacists from substituting generic drugs. Those laws were repealed during the 1970s and the drug companies then turned their attention to protecting their interests by obtaining patent extensions and using loopholes to stall the introduction of generic drugs.[42] For example, many patents on drugs can be extended beyond the 17 years of a patent by altering dosages or shapes of the drugs for the sole purpose of obtaining another patent on essentially the same drug. Companies also are able to acquire 30-month extensions on brand patents when they obtain FDA approval to switch the patented prescription drug to an over-the-counter drug. During the extension periods, generic drug makers thereby are prevented from introducing their products.

In 1984, Congress attempted to keep drug prices down through the Drug Price Competition and Patent Term Restoration Act—also called the Hatch-Waxman Act. The intent of this legislation was to speed up the entry of generic drugs and encourage competition between companies producing generic and brand-name drugs. When the first generic is allowed to enter the market after expiration of a patent, it has six months' exclusivity and its price is 75 percent to 80 percent of the brand. After other generics are allowed to enter the market, within a 12- to 18-month period, the average generic drug price will be one-third the price of the brand-name drug price.[43] As part of a legislative compromise, the Act allows for brand patent extensions based on time spent in the FDA review process.

Today, more than 40 percent of all prescription drugs sold in the United States are off-patent generic drugs, but the dollar share of the market is less than 10 percent, indicating how far less costly generic drugs are.[44] However, a Congressional Budget Office study shows that increased competition from generics has not reduced the profitability of the prescription drug industry.[45]

In recent years, the intent and benefits of the Hatch-Waxman law have been undermined by generic as well as brand companies. Through federal investigations or lawsuits, several cases have come to light in which brand companies have made agreements with generic companies. Typically, the generic company agrees not to produce the generic drug in return for substantial compensation from the brand-name company.[46, 47]

In applying for approval from the FDA, generic drug firms are hampered by having to address nearly every aspect of a brand-name patent in the FDA's registry, including patents on such nonessential features as color, size, shape and types of containers. Another obstacle is the practice by brand-name companies of filing "citizens petitions" that require FDA investigation of issues raised in the petition. Citizens petitions originally were created to allow individuals to voice concerns to the FDA about the safety or efficacy of a generic drug. However, the drug firms abuse this provision by filing petitions for the purpose of delaying entry of generic competition.

Currently, drug patents in force prior to June 8, 1995, have a term of either 17 years from date of issuance of the patent award or 20 years from the date of filing an application for a patent, whichever is longer, plus allowance for up to a five-year extension under the Waxman-Hatch Act. Under the Uruguay Round Agreements Act (URAA) of 1994, patents issued after June 8, 1995, have a term of 20 years from date of filing plus allowance for a five-year extension for court appeals, interference actions and certain other delays. The effective patent life, the portion of patent term remaining after clinical testing and FDA review, generally is less. Nevertheless, the average effective patent life of many drugs has increased by 50 percent over the past two decades. The Hatch-Waxman Act, URAA and other laws could add 4.4 to 5.9 years to effective patent lives of some new drugs, for a total of 13.9 to 15.4 years.[48]

Proposed Solutions

Aside from plans that would expand or provide an affordable prescription drug benefit for seniors, a number of proposals have been made to alleviate the high cost of prescription drugs and check the growth in prices. A partial list includes:

- Allow the re-importation of drugs by pharmacies and health plans;
- Require drug companies to give local pharmacies the "best" price they give their most favored customers, or the average foreign price;

- Enact state initiatives to control prices;
- Close loopholes in the Hatch-Waxman Act that allow brand-name drug companies to obstruct entry of generic competitors;
- Elevate cost-consciousness of doctors and patients;
- Reinstate requirement for "reasonable pricing" on products that were researched and developed using taxpayer monies via NIH;
- Authorize the federal government to buy drugs in bulk and at discount for Medicare beneficiaries;
- Open the market to more competition by shortening the length of patents and/or eliminating the practice of patent extensions;
- Enact compulsory licensing; and
- Authorize the NIH to develop a yardstick for comparing prices.

Allow the re-importation of drugs by pharmacies and health plans.

In the past, only drug manufacturers were allowed to re-import drugs made in the United States from countries where the drugs are available at lower prices.

A provision allowing the re-importation of FDA-approved prescription drugs was included in the FDA and Agriculture Department appropriations bill (H.R. 4461) passed by Congress and signed by President Clinton Oct. 28, 2000. It included $23 million in funding for FDA implementation in the first year. However, Health and Human Services Secretary Donna Shalala did not request the monies to begin the program because of "flaws and loopholes." Some members of the 107th Congress have asked President Bush to proceed with implementation.

Many in Congress and others have opposed the measure on the basis of the "loopholes" rather than the concept. That is, drug companies can refuse to allow re-importers to use the FDA-approved labels on their products, effectively blocking re-importation. The measure also does not prevent drug companies from imposing restrictive contract terms on foreign distributors, and a sunset stipulation ending the re-importation system after five years is seen as a disincentive for public and private investment in the program. There is also concern that the benefits of the Prescription Drug Marketing Act (PDMA) of 1987 are undermined. PDMA protects consumers from foreign counterfeits and improper storage in foreign countries. Legislation (H.R. 1512) has been proposed in the 107th Congress to close most of the loopholes.

Require drug companies to give local pharmacies the "best" price they give their most favored customers, or the average foreign price.

Legislation introduced in the 107th Congress (S. 125, H.R. 1512) would make it possible for pharmacies to purchase drugs for seniors and disabled persons on Medicare at the lowest price pharmaceutical manufacturers give to such federal agencies as the Veterans Administration and military treatment facilities. A report from the federal General Accounting Office concluded that enactment of this proposal would not necessarily control the increase in drug prices overall, because drug companies likely would raise their prices to the federal agencies to offset losses in the reduction of prices to Medicare beneficiaries.[49] However, an increase in the volume of drugs sold would be sufficient to compensate the drug firms for the reduced prices. One analysis of a similar bill estimates that after adjusting for increased utilization, the net drop in total pharmaceutical industry revenues would be just 3.3 percent.[50] A variation on this proposal, also introduced in the 107th Congress (S. 699, H.R. 1400), would allow pharmacies to purchase the drugs at the average price at which the drugs are sold in other developed nations.

Enact state initiatives to control prices.

A number of states have taken on the problem of high prescription drug costs, largely because of inertia on the national level. More than 40 states considered legislation to lower prescription drug costs in their 2001 sessions.

The state of Maine enacted the "Maine Rx Program" in 2000, which would have allowed the state to negotiate lower drug prices with drug manufacturers for Maine residents who lack prescription drug coverage. Drug companies found guilty of overcharging for drugs or restricting supplies would have incurred fines. The law also authorized the state to establish price caps. The Pharmaceutical Research and Manufacturers of America (PhRMA) filed a lawsuit challenging the constitutionality of the law. The case has subsequently moved through the courts. In May, 2001, a federal appeals court ruled in favor of Maine. PhRMA has appealed the case to the U.S. Supreme Court.[51]

Legislation has been introduced in a number of other states focusing on lowering pharmaceutical costs by various means. Thirty-four states plan to create rebate or discount prescription drug cards in 2002 and 32 states are considering purchasing pools.[52]

Several states have already formed bulk purchasing alliances to negotiate lower prices for segments of their populations, such as Medicaid recipients or public employees. Attorneys general in several states are considering or taking legal action to require drug companies to lower prescription drug prices. At least two states have filed lawsuits charging pharmaceutical companies with illegally inflating prices.[53]

Close loopholes in the Hatch-Waxman Act that allow brand-name drug companies to obstruct entry of generic competitors.

Legislation introduced in the 107th Congress (S. 812) would streamline the approval process for generic drugs from the FDA. If a brand-name firm pays a generic firm to stay off the market, that company's 180-day market exclusivity as first generic would roll over to the next generic applicant. The measure also addresses abuse of "citizens petitions."

Elevate cost-consciousness of doctors and patients.

Survey data indicate that current Medicare beneficiaries rely on their physicians for guidance regarding selection of drugs. Furthermore, generic companies do not promote their products to doctors as brand-name companies do.

To enhance doctor and patient decision making and to ensure patient safety, Rx Health Value, a coalition of insurers, unions, private employers, academics and consumer and senior advocacy groups, recommends independent research to provide usable, reliable data for practitioners and consumers in deciding on the use of new drugs and how to evaluate relative merits of different drugs within the same class.[54] Another recommendation is to publicly fund an independent organization as a reliable source of information on the quality of generic drugs and the equivalence across brand-name drugs in the same drug categories.[55] Presumably, doctor and consumer education also will lead to increased price sensitivity without coercion.

Reinstate requirement for "reasonable pricing" on products that were researched and developed using taxpayer monies via NIH.

In effect, this would eliminate the subsidy supplied to the drug makers. An amendment to that effect was passed in the House in the 106th Congress by a vote of 313–109. It is included in other drug cost-containment legislation (H.R. 1512) introduced in the 107th Congress. However, reinstatement of the requirement may not allow for retroactivity, meaning it would not apply to products already on the market. Additionally, NIH's reporting system needs to be shored up considerably for this requirement to be effective.

Authorize the federal government to buy drugs in bulk and at discount for Medicare beneficiaries.

The Health Care Financing Administration (HCFA), which administers the Medicare program, could be given the authority to negotiate price reductions with pharmaceutical companies much as it does with such providers as hospitals, doctors and nursing homes. HCFA also could be authorized to use the prescription drug fee schedule the Veterans Affairs Department and other federal agencies have negotiated with the drug makers.[56]

Open the market to more competition by shortening the length of patents and/or eliminating the practice of patent extensions.

This approach actually might produce greater technological breakthroughs because, without the 17 to 20 years of exclusivity on patents, the drug manufacturers would have greater incentive to develop the next money-making drug. Patents spur innovation, but so do their expiration. Once a drug manufacturer has a blockbuster drug, it is inclined to protect the patent on that drug as long as possible, including making copycat drugs, in order to continue reaping substantial profits. Closing loopholes on patent extensions could shift attention to new research.[57]

Enact compulsory licensing.

This option is discussed most recently in regard to measures African countries and Brazil are taking to obtain drugs for treating citizens with AIDS and HIV. A 1994 international trade agreement protecting intellectual property grants 20-year patents to drug manufacturers. However, compulsory licensing allows a government in a national emergency to license local or other manufacturers to produce cheaper versions of drugs whose patents are held by multinational companies. Compulsory licensing in the United States could take the form of allowing the originator of the drug to have a monopoly for a few years with no extensions, then compelling that company to license the drug to other manufacturers in return for a royalty payment.

Authorize the NIH to develop a yardstick for comparing prices.

The NIH could be designated the federal agency for developing, testing and producing new medicines. Using this experience to measure costs of research and development, NIH would be in a position to gauge whether prices charged by manufacturers are reasonable or excessive. Federal and state agencies then would contract only with manufacturers whose prices were reasonable.[58]

A variation on this would be to endow a private, nonprofit institute as an independent source of research to verify whether drugs are new or just variations of old drugs.[59]

Conclusion

Whatever solution or solutions are devised and implemented, the excessive rise in prices indicates that immediate action is necessary.

All developed countries that have lower drug prices than the United States also have some form of universal health insurance coverage. While the presence of insurance coverage increases utilization and expenditures for prescription drugs, it also provides the means and incentives for governments to control expenditures. For Medicare beneficiaries, the urgent need for such coverage is self-evident, as is the need for mechanisms to assure the affordability of such a benefit.

Ultimately, the best and most comprehensive approach to providing affordable prescription drugs for all the American people is to enact a universal, national health system based on a single-payer financing model.

Glossary of Key Prescription Drug Pricing Terms

Average manufacturer's price (AMP). Average price paid by wholesalers to manufacturer. Established by manufacturers as a suggested list price for wholesalers selling to pharmacies. Also called the wholesaler acquisition cost (WAC).

Average wholesale price (AWP). Published wholesale price ("list price") suggested by the drug manufacturer. It is comparable to a sticker price on an automobile.

Cost-sharing. Consumers pay a portion or percentage of the price. Co-payments are consumer payments of a fixed cost per prescription (for example, $5); co-insurance is payment of a proportion of costs (perhaps 20 percent). (See Tiers below.)

Discount. The price lower than the base price paid by certain purchasers to the retail pharmacy; amount is negotiated.

Formulary. List of drugs approved for use or payment—in other words, covered or reimbursable drugs. An open formulary includes all drugs; a restricted or closed formulary covers only the listed drugs. A partially closed formulary specifies drugs covered but allows exceptions with prior approval and/or with increased co-payments.

Generic drug. A generic drug is one that is chemically identical and bioequivalent to the brand-name drug. FDA approval requires that a generic drug must be absorbed into the body at essentially the same rate and to the same extent as the brand-name drug.

Health maintenance organization (HMO). A structure for providing managed care resulting in lower costs. HMOs under the Medicare+ Choice program are paid a fixed monthly amount adjusted for beneficiary's age, gender, institutional status and Medicaid enrollment. They typically yield lower costs and provide benefits, such as prescription drugs, not covered under Medicare for enrolled participants.

Indemnity coverage. As it pertains to prescription drugs, the insured pays for the prescription and then is reimbursed or indemnified by the insurance plan.

Launch price. The price of a new drug as established by a manufacturer when the drug is introduced on the market.

Market power. The degree to which a company exercises influence over the price and output in a particular market. Market power is related to the availability of substitute products. A drug manufacturer with a patent on an unrivaled drug has great market power.

Monopoly. A market in which there is only one supplier. A drug manufacturer with a drug patent has a monopoly on that drug. The patent protects the manufacturer from competition of chemically identical (but not therapeutically equivalent) drugs and allows it to set the market price.

Oligopoly. A market in which relatively few firms have significant influence over the price of a product in the market, such as when two or three drugs dominate a therapeutic category.

Patent. A patent on a drug protects it from replication competition for a number of years. The effective patent life is the portion of the patent term remaining after safety and efficacy testing, clinical trials and FDA approval for marketing.

Pharmacy benefit managers (PBMs). Private companies that contract with health plans to arrange discounts from retail pharmacies and manage distribution of drugs. They may also perform such functions as paying claims and negotiating price discounts via rebates.

PhRMA. Pharmaceutical Research and Manufacturers of America, an association of prescription drug manufacturers.

Price discrimination. The selling of the same product to different purchasers at different prices.

Price sensitivity. Refers to the extent to which a purchaser would change the amount of a product it would buy if the price of that product should rise or fall.

Rebate. Money that is returned to the purchaser by the seller after the purchase has taken place. Usually a percent of the value of the drug dispensed.

Retail price. The price charged by retail pharmacies to individuals without insurance, known as "cash-paying" customers.

Therapeutically equivalent drugs. Drugs that perform the same function as another drug even though they may be different chemically. Therapeutically equivalent drugs can be in competition with each other for listing on formularies.

Tiers of co-payments. Refers to the co-payment amount health plans may require for purchasing drugs from a formulary with the purpose of encouraging the use of generic drugs. The first tier co-payment would be for generic drugs and require the lowest co-payment, for example $1; the second tier would be for brand-name drugs listed on the formulary with a co-payment of $10, for example; the highest co-payment would be for drugs not listed on the formulary, perhaps $20.

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About the Alliance for Retired Americans

The Alliance for Retired Americans is a new senior advocacy organization that was created in January 2001 by national and local affiliates of the AFL–CIO, together with community-based organizations, to provide a voice for the rapidly growing numbers of union retirees and older Americans.

The mission of the Alliance for Retired Americans is to ensure social and economic justice and full civil rights for all citizens so they may enjoy lives of dignity, personal and family fulfillment and security. The Alliance believes that all older and retired persons have a responsibility to strive to create a society that incorporates these goals and rights; and that retirement provides them with opportunities to pursue new and expanded activities with their unions, civic organizations and their communities. The Alliance's public policy and legislative goals will be achieved through mobilization of members in an extensive grassroots network in every region, state and district in the country.

Acknowledgments

This report was researched and written by Dianna M. Porter, public policy analyst with the Alliance for Retired Americans. Ms. Porter previously worked as public policy director at the Older Women's League and National Council on the Aging, and as a professional staff member with the U.S. Senate Special Committee on Aging. More recently, she assisted the government of Macedonia in the development of a private pension system. Ruby Scott and Brenda Brooks assisted Ms. Porter in preparing the original manuscript for this report.

Case Studies

Coverage Doesn't Mean Full Coverage—Ms. M of Suitland, Md., has congestive heart disease and is required to take 10 medications. Even though she is under a Medicare HMO, she pays full payments and co-payments of about $300 per month. The HMO plan has a cap of $1,000 per year for prescription drugs. When Ms. M surpasses that amount in June, she must assume the total costs of her prescriptions. She is ineligible for her state's drug assistance program because her income is just above the allowable level of 116 percent of poverty.

Prescription Drug Costs Lead to Impoverishment—Ms. FM of Rossville, Ga., is 73 and widowed. Her annual prescription drug costs are about $4,200 ($350 per month). Her income is $608.50 a month—$569 from Social Security and $39.50 from her husband's pension. She has had both a heart attack and a hiatal hernia. She lost her insurance coverage and used her savings to pay for prescriptions, to the point where she doesn't have enough to pay her Medicare premiums. Fortunately, Family Services pays for her Medicare premiums now.

Limited Coverage Lost When HMO Fails—Ms. D of Lebanon, Tenn., has annual prescription drug costs of $2,900. In September 1998, Ms. D was forced to join an HMO or pay for all of her supplemental insurance, which she could not afford. She had a minimal prescription drug benefit, but the HMO folded in January 2001. Ms. D's pension is $322.50 a month and her Social Security is $538 a month. "It isn't always easy skimping and scraping to stay on top," she says.

Health Plan Coverage Not Enough—Mr. and Ms. R of Lansing, Ill., have annual prescription drug costs of more than $4,000. They do not have prescription drug coverage because it would cost about $2,000 to $3,000, while the policy would only pay about $1,600.

Some Must Rely on Samples—Ms. N of Los Angeles is 87 and widowed. She pays $135.99 for an antibiotic and $59.69 for prescription eyedrops. She is only able to take two other prescriptions her doctor has recommended by getting free samples.

Dosage Decreases, But Prices Stay the Same—Mr. S of Yarmouthport, Mass., is 87 and married. His annual prescription drug costs are about $4,500. Originally, Mr. S's doctor prescribed 10 mg. of one of the drugs, which cost $251.99. The dosage was later decreased to 5 mg., but the cost remained $251.99 for the prescription.

Prescription Drug Costs Wipe Out Life Savings—Ms. H of Springfield, Ill., has prescription drug costs of $4,000 per year. Over a decade, this has amounted to $40,000, depleting most of her life savings.

Food Comes Last—Ms. H of Monroe, Ga., is 83 and widowed. Her annual prescription drug costs are about $3,400 ($283 per month). Ms. H's monthly income is $691 from Social Security. Her daughter, who was born with cerebral palsy, lives with her. After paying for utilities (about $250 a month) and her prescriptions, Ms. H has only $158 for food and other necessities.

Returning to Work Only Way to Pay for Prescription Drugs—Mr. S of Medford, Ore., is 71. His prescription drug costs per year are $2,760 ($230 per month). Social Security benefits cover the cost of rent, utilities and food, but not prescriptions. He has diabetes, high blood pressure and high cholesterol, all of which require medication. His savings were depleted by treatments for his wife's ovarian cancer. To pay for the drugs they need, Mr. S has gone back to work. "Our budget would be in serious trouble if this old 71-year-old man couldn't put on his boots and overalls and go to work every day," he says.

Mr. MARVIN. The trips remind the public of how serious the drug problems are for seniors and their families, but bus trips are not the answer. While there are dozens of people riding the bus and going across to Canada, there are literally hundreds of others who physically cannot ride a bus to Canada and have even greater needs for prescription drugs than those who are fortunate enough to be going three.

Getting drugs through the mail is sketchy at best, thanks to the FDA, which always seems to imply that somehow, as we have heard this morning, that the Canadians have lesser standards than we do. Some diplomacy that represents with our Canadian brothers across the border.

Senator you can help seniors by finding out just what the U.S. Customs policy really is. Can we go to Canada and bring out a 3-month supply? We do that on the bus and the U.S. Customs Service has no problems with our bringing it across, but what about getting drugs through the mail? Sometimes they come and sometimes they are intercepted by the FDA. We need to get some firm information even now as to what the correct policy is.

Our people in Maine are well aware that the Canadian government represents its citizens in dealing with the most profitable industry in the world. They want to know why the American government cannot do the same. Our people in Maine know well that the Canadian government bans advertising in professional journals, it bans advertising in other than professional journals. That's not done in the United States and our people want to know why the U.S. Government doesn't reinstitute the ban on advertising which contributes heavily to the cost of drugs in this country.

Our people want to know why the government in the name of health and safety of its citizens cannot regulate the drug industry in the same way that the government is involved with regulating the utilities.

I am proud to be a part of Medicare and the Medicare insurance program. But I want to demonstrate for you what's wrong with the program. This stool that I brought is a milking stool, and I know some of you will be concerned about what happens to the milk program, but nonetheless, it represents the Medicare program, if you will. This first leg is Part A of the Medicare program, it deals with the hospitals. I happen to have hepatitis B and through Part A, the tests are taken care of, if I wind up in a hospital because of deterioration of the liver, it will be taken care of through Part A of the program.

Part B, this is supposed to be white, if you will, represents the heart of the Medicare program providing for expenses for the doctors.

But you will notice that my $750 pill bottle, which is the cost that I pay for a 6-month supply to deal with hepatitis B, Eupaverin HB, that won't stand on this platform, it falls over.

There really needs to be a third leg, and I would suggest to you that that third leg which is absolutely essential for a total Medicare program is a Medicare prescription drug program.

The ARA, the Alliance for Retired Americans, has some ideas on how to approach this issue and how the Congress could make positive steps. We are calling for enactment of a new Medicare pharmaceutical benefit using the $300 billion reserved in the tax cut legislation for an affordable benefit program.

Congress should consider a change in Medicare sending by spending these funds over a 6-year period as opposed to the proposed 10-year period. By doing that, we could deepen the benefit, make it more affordable for the average income persons in the Medicare program, but let's do it and stop debating. That's what the seniors I know in Maine and across the country are saying.

Senator this angry old man begs you to do something so that I can get out of the bus tour business. Thank you for the opportunity.

[The prepared statement of Mr. Marvin follows:]

PREPARED STATEMENT OF JOHN MARVIN, MEMBER OF THE ALLIANCE FOR RETIRED AMERICANS

Thank you, Senator Dorgan and all of the Members of this Subcommittee, for this invitation to testify today. I am John Marvin representing the Alliance for Retired Americans where I serve as a Regional Board member for the northeastern part of the nation. The Alliance, which was established on January 1 of this year, now has 2.6 million members across the nation. Retirees from affiliates of the AFL–CIO, community-based organizations and individual seniors have joined the Alliance to fight for social and economic justice and civil rights for all Americans. I am also representing the Maine Council of Senior Citizens.

I am here today because of my work in Maine and New England to organize bus trips to Canada so that seniors can buy prescription drugs at much lower prices than are available in the U.S.

In Maine, we are now organizing our 4th annual trip to Canada which is scheduled for September 19–20. On the first trip, I saved $400 on a 12-month supply of 40 mg. Zocor. I now take Epivirim HB 100 mg. instead. While the savings are not nearly as dramatic, I will still pay $150 less in Canada than at my local pharmacy. That adds up to about a $300 annual savings to me alone.

On our second trip, we hit the jackpot. We were well aware of the festering problems for seniors caused by the price of prescription drugs. But Mike Wallace and the 60 Minutes television program which featured our trip two years ago escalated awareness of the seriousness of the problem by putting a human face on it. In the recent elections, it was the rare candidate indeed who did not pledge to do something about the problem even if little has been done.

This work organizing trips and advocating for programs to meet the prescription drug needs of seniors puts me in almost daily contact with people like Vi Quirion of Waterville, Maine. She retired from a shirt factory there and has a very modest retirement income—primarily from Social Security. Instead of paying $1290 at her local pharmacy, she will pay $660 in Canada for a 6-month supply of Prilosec and Relaten.

Another couple who will ride with us are Pauline and Leopold Nolette of Biddeford, Maine. Between the two of them, they have prescriptions for drugs like Anucil, Zocor and Celebrex. Their Canadian bill will be right around $1162. Their local pharmacy in Biddeford would charge $3,879 for the same drugs, an incredible savings of $2,717.

And we will have on the bus at least one breast cancer patient who must take Tamoxifen. A year ago, a month's supply at her pharmacy in Augusta was $115. The same quantity cost $15 in St. Stephens, New Brunswick, an astounding 79% savings.

What infuriates Vi Quirion, the Nolettes, myself and all the others on the bus is that we are buying these drugs in Canada which are for the most part manufactured in the United States of America and shipped there.

Seniors are upset and we have a right to be. Fewer of us have access to retiree drug benefits and frequently our incomes exceed that which would qualify us for state low-income drug programs. We are asked to pay literally the highest price in the world for prescription drugs. It is even more insane when you realize that most people with substantial incomes in this country have prescription benefits from their employers. So seniors wind up paying even more for drugs than do the relatively well-to-do. Now that's wrong.

In Maine we grew impatient with federal inaction. We pushed the legislature into passing the Maine Rx program which will ultimately result in price controls applied to the products of the most profitable industry in this country. Is it unreasonable for U.S. citizens to think that we might pay about the same price for prescription drugs as our Canadian neighbors?

PhRMA, Pharmaceutical Research and Manufacturers of America (which badly underestimated the citizen power behind this Maine legislative initiative), chose to fight the law rather than to see if there is any truth to Professor Alan Sager's proposition that lower prices for prescription drugs will induce more volume in business so that profits should remain constant. However, it will be unlikely that this law—even with tremendous citizen support—will yield much help for consumers for several years.

Bus trips get a lot of publicity. We filled two buses in less than 48 hours this year. They highlight the problem. Laws providing for re-importation are interesting ideas. But neither solves the fundamental problem. To begin with, for every person making the trip there are others far worse-off physically who need the lower-priced medications even more, but they cannot physically board a bus. Ultimately, we want our local pharmacies to serve as they are intended—community sources of affordable drugs.

This hearing to review the cost of pharmaceuticals in this country in contrast with prices in Canada is right on point. The more information that hearings like this provide to the Congress and to the public, the closer we will come to agreement on what can and should be done. For the Alliance, and I think that I can speak for most seniors in Maine and across the northeastern part of this country, the reasons for these contrasts in price are clear.

Why are prices better in Canada? Well in part, Canadians have a national health care system and people of all ages obtain a more comprehensive system of health care beginning in childhood and continuing into their older years. Only about 10% of Canadian seniors do not have either public or private coverage for drugs while up to half of U.S. seniors lack coverage during some time of the year. Only about 4% of Canadian seniors pay more than $100 in out-of-pocket costs for drugs per month while 20% of U.S. seniors do.

More important, Canadians pay less for drugs because their government bargains on their behalf with the pharmaceutical industry. Their drug prices are cheaper because the Canadian government believes, as should this government, that the role and impact of pharmaceuticals in people's lives are too important to leave to market forces. On behalf of the Canadian people, their government forces the pharmaceutical industry to bargain and to peg prices close to the average prices of pharmaceuticals in other industrial nations or face a denial of opportunities to market the drug in Canada. We should take the same direction on behalf of all U.S. citizens needing medications.

We are also forced to go to Canada to purchase lower cost drugs because of the lack of a pharmaceutical benefit within the Medicare program.

I, and the Alliance for Retired Americans, have some ideas on how to approach this issue and how the Congress could take positive steps. The Alliance for Retired Americans is calling for the enactment of a new Medicare defined pharmaceutical benefit using the $300 billion reserved in the tax cut legislation for an affordable benefit. Congress should consider a change in Medicare by spending these funds over a shorter period of time than 10 years. By doing that, we can deepen the benefit and make it more affordable for average income persons in the Medicare program. But let's do it and stop debating—that is what the seniors I know in Maine and across the country are saying.

To emphasize the contrast between Canadian and U.S. prescription drug prices, members of the Alliance for Retired Americans will board buses later this month and travel to Canada from every State that borders our northern neighbor to have their prescriptions filled. We hope to show that seniors can save hundreds of thousands of dollars in just one week of short trips. But, we also want to demonstrate the absurdity of having U.S. Citizens go to Canada to get the savings. Your enactment of an affordable, comprehensive Medicare drug benefit will end these burdensome trips north and end this national embarrassment.

The major reason that prices are so high in the U.S. is that the pharmaceutical industry has a lock on the supply of needed drugs backed up by law and power. It controls the development process for new drugs both here and throughout the world. The laws of this nation then protect the market power of the industry by providing patent protection for almost two decades. To make sure this patent protection stays secure, together with public financing of the highest risks in the development process, the industry spends hundreds of millions of dollars to influence government at all levels. The result is the exploitative pricing policies that we are discussing here today.

The inaugural publication of the Alliance, *The Profit in Pills: A Primer on Prescription Drug Prices,* documents why prescription drug prices have increased so dramatically and the various ways that the pharmaceutical industry protects its interests at the expense of the American public. Most affected are older persons and those with disabilities who take more medications than other segments of the population and are the mostly likely to pay full retail prices. I respectfully request that this report be included in the hearing record. I would also ask that you, Senator Dorgan, put it into the Congressional Record so that all of your colleagues may read it.

As I mentioned earlier, some states, like Maine, have become frustrated by the lack of action here in Washington. They are trying to take steps on behalf of their own citizens to curb prices. But, they are being fought all of the way by the industry in the courts and in the press. We support state action to push prices down but this is a national policy problem. Most states cannot take on a global industry that so vigorously holds on to its privileged economic position. The industry has spent millions of dollars lobbying against a Medicare drug benefit because they believe that such a benefit may cut into their profit margins and lead to greater public regulation of their industry.

Why is it that the Federal Government is so vigorous in bargaining with all parts of the health industry to set prices but not with the pharmaceutical industry? Why does the Department of Health and Human Services force hospitals and doctors and other health providers to take lower payments or compete for government business but not force the same constraints on the prices we pay for out-patient pharmaceuticals? There is something wrong with the process and millions of citizens—older people and persons with disabilities—are paying the price for government's timidity. It's got to end.

In short, we don't have the luxury of time to wait while nothing happens. Thousands of us face continued deterioration of our health, loss of savings, increased burdens on our families, unnecessary institutionalizations, and, yes death, while the pharmaceutical industry seems to be able to stop Congress from acting. Please—listen to our plea.

I, for one, want to get out of the tour bus business.

Thank you.

Senator DORGAN. Mr. Marvin, thank you very much for your testimony.

Ms. Marjorie Powell represents the Assistant General Counsel of the Pharmaceutical Research and Manufacturers of America, and I imagine you are really excited to follow Mr. Marvin, but why don't you proceed? We are glad you are here.

STATEMENT OF MARJORIE E. POWELL, ASSISTANT GENERAL COUNSEL, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Ms. POWELL. Thank you, Senator Dorgan. My name is Marjorie Powell, I am the Assistant General Counsel of the Pharmaceutical Research and Manufacturers of America, PhRMA, and I represent the companies who discover and develop and secure FDA approval to market the innovative drugs.

I actually am quite pleased to follow Mr. Marvin this morning because he did a much more effective job than I could of illustrating what we believe is the primary source of the problem and the primary reason why this hearing is being held, which is that seniors do need access to prescription medications. They have access to health care through the existing Medicare system, but if anybody designed Medicare today, they would definitely include a prescription drug benefit, because drugs are the most cost effective, beneficial portion of the health care system and we would urge this Committee and Members of Congress to enact a Medicare drug benefit.

We think that the issue of importing drugs from Canada or from any other country has come up in part because of the political debate about the need for and how to structure a Medicare drug benefit.

When you look at prescription drug costs within Canada and the U.S., you do need to look at the context within which prescription drugs are provided in Canada. They are part of a government-run health care system where the government imposes price controls on drugs, hospital services, physician services, medical specialist services. Those restrictions result in shortages of not only physician services and specialist services, access to a variety of medical care treatments, but also restrictions on drugs. These restrictions have an effect on the health care of people in Canada.

A recent study found that 20 percent of the physicians in British Columbia said that they had admitted patients to either emergency rooms or hospitals because those patients had been switched from one drug to another because of the restrictive system in British Columbia on the cost and availability of drugs.

The price controls don't actually have the effect of lowering the proportion of health care expenditures for drugs. A study found, in 2000, 15.5 percent of Canadian health care expenditures went for prescription drugs. In the United States, in the same year, 2000, approximately 8.6 percent of health care dollars were spent on prescription drugs.

There are a variety of reasons why some drugs are less expensive in Canada. One of those reasons is that it takes a longer time to get new drugs approved to go on the market in Canada today. It takes anywhere from one to 2 years longer in Canada than in the United States. We used to, back when I first became involved with this industry, talk about an FDA drug lag, and because of at least two actions by Members of Congress, and because of FDA monitoring this issue, there is no longer a drug lag between the United States and Canada, or the United States and a variety of other countries.

And those two Congressional actions, Senator, are the Prescription Drug User Fee Act of 1992, allowing the FDA to hire additional reviewers, and the FDA Modernization Act of 1997.

Let me talk for about a minute about the approval process in Canada. There is in Canada a review of drug safety and effectiveness just like there is here. Once the Canadian authorities have approved a drug for marketing, however, that drug must go through two additional steps that do not occur in the United States.

First they must go to the PMPRB, the Prescription Medicines Price Review Board, which is a national board that decides on the maximum price that a manufacturer can charge to wholesalers. Once that happens, and that can take anywhere from 2 weeks to 2 years, then the manufacturer must go province by province and determine a price that the province will reimburse for that drug, if the province will reimburse for that drug at all.

Back in the period from December 1997 to November 1999, Health Canada approved 134 new drugs. During that same period, Manitoba authorized 36 of those drugs to be on the Manitoba formulary.

Quebec, which was the most generous of the various provincial plans, approved 64 of them. So more than half of those products are not available to people in Canada or to U.S. citizens going to Canada today attempting to purchase drugs.

There have been a number of studies of price differences between the United States and Canada, and most of the studies are seriously flawed because of selection of products to be sampled, comparisons of retail prices in the United States and wholesale prices in Canada, ignoring discounts given to large U.S. purchasers, such as insurers, HMOs or PBMs, changes in value of the U.S. dollar.

But, I come back to my starting point, that the issue of seniors having to take buses to Canada is an issue of seniors having coverage for prescription drugs just as they have coverage for hospital expenditures, and we have been urging Members of Congress to enact a Medicare drug reform benefit. Thank you.

[The prepared statement of Ms. Powell follows:]

PREPARED STATEMENT OF MARJORIE E. POWELL, ASSISTANT GENERAL COUNSEL, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Mr. Chairman and Members of the Subcommittee:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I want to thank you for providing the opportunity to testify on pharmaceutical price differences between the United States and Canada.

As part of the Medicare reform debate, the cost of some drugs for American seniors and price differences between Canada and the U.S. have attracted the attention of U.S. legislators and the media. Before I address these two topics, however, I think it is important to briefly discuss in a general way the Canadian health-care system. Members of Congress should be aware of the Canadian experience with health-care cost-containment policies for pharmaceuticals and other health-care services when considering changes to the U.S. health-care system.

The unintended, adverse consequences of government-driven cost-containment policies on access to appropriate medical and pharmaceutical care are not widely known. However, the results of such government intervention have been widely felt by patients. With respect to pharmaceuticals, cost-containment and price-control mechanisms have led to less choice and delays in access to the newest and most innovative medicines. In addition, these policies have also led to increases in other forms of more costly health care, such as hospitalization.

Canadian Health-Care System

Health care in Canada is administered through the Ministry of Health in each of the Canadian provinces and territories. The Canadian system is primarily publicly financed through taxes collected at the federal and provincial levels to provide coverage for hospital and physician services. Although often portrayed as "comprehensive coverage," Canadian health care is not truly comprehensive in that provinces are obligated to finance only "medically necessary" hospital and physician services. Since neither the federal government nor any of the provinces has defined "medically necessary," this term has often been inconsistently interpreted.

An outpatient pharmaceutical benefit is also not nationally mandated. All provinces do provide coverage for seniors and low-income residents and four provinces have instituted universal coverage for all age groups and utilize cost-sharing arrangements such as significant co-payments and/or deductibles.[1] The majority of provinces, including Ontario, provide drug coverage only for seniors and low-income residents. Therefore, 56 percent of Canadians live without universal prescription-drug coverage. These individuals often receive pharmaceutical coverage through employers, unions, or private insurers.

In order to control rising health-care costs, Canada over time has implemented a number of cost-containment measures. Unlike the U.S., which has a market-based system, the Canadian system has controlled costs by relying on government financing and price-control mechanisms.

In response to dwindling federal funds, provinces have cut spending on health-care services through de-listing or de-insuring ancillary services, like home health care, and increasing cost-sharing for pharmaceutical services. Although successful in reducing the rate of increase in health-care costs, the impact on patients has not been positive. For example, according to the Fraser Institute, a leading Canadian think tank, over 200,000 Canadians are waiting for surgical procedures.[2] In 1998, the average Canadian patient needing care waited:

- 13.3 weeks for treatment from a specialist (6 weeks to see a specialist, and nearly 7.3 more weeks to receive treatment);
- 11.4 weeks for an MRI scan;
- 25.4 weeks for orthopedic surgery, and
- About twice as long as is considered "clinically reasonable" for radiation for cancer and internal medicine.[3]

A December 1999 *Washington Post* article described the Canadian health system as "on the critical list, overwhelmed, and under attack." For example, "[In] Ontario, the waiting list for MRIs is so long that one Ontario resident booked himself into a private veterinary clinic that happened to have one of the machines, listing himself as 'Fido.' "[4] Wait times for prostate cancer patients became so long that a patient group actually formed the Society of those Awaiting Cancer Therapy, according to *The Wall Street Journal.*

Clearly, public dissatisfaction with health-care services in Canada is high and on the rise. Recent polls show that 78 percent of Canadians now say that their health care system is in crisis.[5] In a poll taken in December 1999 by Ekos Research Associates, 93 percent of the 3,000 Canadians interviewed reported that improving health care should be the federal government's top priority.

Drug Pricing in Canada

In sharp contrast to the U.S. where pharmaceutical prices are largely determined by market forces, drug pricing in Canada is regulated by two separate governmental bodies. Canada's Patented Medicine Prices Review Board (PMPRB) is a federal government board that sets the maximum prices for innovative, patented medicines in Canada.

Prior to product launch, a manufacturer can either have discussion with pricing-board officials and submit cost-benefit information used to assist the company in determining its price, or make a formal request for an Advanced Ruling Certificate (ARC) for pricing, which occurs only rarely.

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[1] The Canadian Pharmacists Association, Provincial Drug Benefit Programs, 1999, (21st Edition).

[2] Michael Walker and Martin Zelder, *Critical Issues Bulletin: Waiting Your Turn*, The Fraser Institute (Vancouver), 1999.

[3] Id.

[4] S. Pearlstein, "Health Care on the Critical List: Canada's Public System is Overwhelmed, and Under Attack," *The Washington Post,* December 18, 1999, p. A20.

[5] Angus Reid Group, Inc., February 2000.

If a manufacturer has not received pre-approval for a price for a new product from the PMPRB, the price charged by the manufacturer must be submitted to the Canadian government pricing board within 60 days after introduction so that it can rule whether the manufacturer price is excessive. If the price of the medicine is deemed excessive by the Canadian government pricing board, manufacturers have two options:

- *Make a Voluntary Compliance Undertaking (VCU)*. A VCU is an agreement by the manufacturer with the PMPRB to reimburse the government for the difference between the price it had been charging and the price set by the PMPRB, and to accept the maximum price set by the pricing board rather than take the dispute further. This, however, does not mean that a manufacturer agrees that the price it established was excessive.
- *Appeal for Consideration.* If no agreement on a maximum price is reached with an appeal, the manufacturer can either agree to reduce the price and reimburse the government for differential revenues or it can appeal in the courts.

Ultimately, if there is no agreement on the maximum price a manufacturer can charge for a product, the Canadian government can:

- Impose a fine on the manufacturer equal to twice the amount of difference between the price actually charged and the government-controlled price;
- Annul the manufacturer's patent, and
- License the product to another pharmaceutical manufacturer.

In addition, if the government believes that a manufacturer knowingly sets the price of a product in excess of the Canadian government pricing board's maximum price, the manufacturer can be charged with a *criminal* offense. Not only must the price differential be reimbursed, but monetary penalties and jail terms are possible.

Maximum prices are determined by the Canadian government pricing board. The PMPRB uses several "tests" in controlling the prices of innovative medicines:

- The Reasonable Relationship Test is designed to ensure that the prices of different dosages or formulations of the same medicine are reasonably related.
- The Therapeutic Class Comparison Test compares the new medicine to other medicines in the same therapeutic class and sold in the same markets to ensure that prices are reasonably related.
- The International Price Comparison Test compares the average transaction price in Canada with prices in other price-controlled countries.
- The CPI Adjusted Price measures changes in the price of a medicine over time. It is designed to ensure that the price does not rise more quickly than CPI.

The Canadian government pricing board also establishes classes of new patented medicines for which price reviews are conducted.

Once the maximum price has been set by the PMPRB, the second tier of price regulation occurs at the provincial level. Provincial governments have separate health-care systems and drug-benefit programs that further restrict access to both care and drugs.

For example, Ontario, the province with the largest number of beneficiaries in its health-care system, has historically had one of the most restrictive formularies in Canada. From 1990 to 1997, Ontario only gave 35 new, innovative medicines full listings. From December 1996 to November 1997, this low rate of listing continued—Ontario gave full formulary listings to only 13 of the 80 innovative medicines introduced in Canada.

This double layer of price controls, along with restrictive provincial formularies, makes it difficult for Canadians to have access to and coverage for new, innovative, life-saving medicines.

How Canada's Drug Pricing System Affects Public Health

Cost-containment mechanisms have had a negative effect on access to pharmaceuticals and overall public health. For example, 27 percent of the physicians in British Columbia reported that they had to admit patients to the emergency room or the hospital as a result of mandated medicine switching.[6] Confusion or uncertainty by cardiovascular or hypertension patients due to mandated medicine switching was reported by 68 percent of doctors, while 60 percent observed worsening or

[6] Dr. Bill McArthur, *Think Tank Warns Clintonization is Candianization of Health Care*, The Fraser Institute, January 27, 2000.

accelerating symptoms.[7] British Columbia doctors reported similar problems, with the end result being an increase in patients who stopped taking their medications, which led to increased emergency-room visits.[8]

As compared to the U.S., Canadians experience longer delays in both access to and reimbursement for new pharmaceuticals due to:

- Delays in market approval dates.
- Delays in coverage until formulary decisions are made.
- Restrictions in product reimbursement because of restrictive formularies, reference-pricing schemes, and patient cost-sharing.[9]

Delays in Market Approval Dates

Although regulatory review times for new products have decreased over the past several years, the Canadian regulatory process has consistently taken 1.5 times as long as the U.S. system for drug review and approval.[10] For example, in 1998 the FDA approved new drugs in an average of 365 days, while the Canadian Therapeutic Products Programme (TPP) took an average of 570 days.[11]

Postponing Coverage Until Formulary Decisions are Made

The delays continue at the provincial level where various government "gatekeepers" review the "therapeutic value" of prescription drugs before they are included in the formulary. In the U.S., most health plans will cover new products either with no restrictions or through prior authorization until a formulary decision is made. In Canada, new products are not publicly reimbursed until formulary listing has been completed. Formulary access rates at six months post-product approval in Canada ranged from 51 percent in Quebec to less than 10 percent in Alberta, British Columbia, and Ontario. Eighteen months following new product approval, formulary access rates in Ontario, the province containing almost 40 percent of Canada's population, were still only 23 percent.

Restriction in Product Reimbursement

Canadian provinces limit product reimbursement based on formulary restrictions, referenced-based pricing, and patient cost-sharing. Although these cost-containment mechanisms have lowered utilization of prescription drugs by seniors and low-income adults, emergency-room visits and the use of other medical services increased.

For example, in the first 10 months following increased patient cost sharing in Quebec, savings of $17 million (Canadian dollars) were achieved for income security recipients who regularly took drugs for chronic diseases. However, due to the new cost-sharing structure, recipients financed one-third of the savings. Drug savings were all offset by a $4.1 million increase in other health-care expenditures.[12] In another example, British Columbia will only reimburse for two arthritic drugs as first-line therapy. Three commonly-used anti-arthritic drugs in the U.S. are not covered under any circumstances.

U.S.-Canadian Price Differences

Many have asked why drug prices are sometimes higher in the U.S. than in Canada. The answer is based on many variables. However, the main reason is that in the U.S. each individual company is generally able to price its own medications based on normal market factors, such as supply, demand, quality, value, and cost-effectiveness.

The prices set for medicines reflect the cost of drug development, not only for drugs that make it to the market, but also for those that do not. In 2001 alone, the pharmaceutical industry is expected to invest $30.5 billion in drug research and development. Estimates by the Boston Consulting Group indicate that the pre-tax cost of developing a medicine introduced in 1990 was $500 million.[13] And just because a drug makes it to market does not mean it is a commercial success. A 1994 study conducted by economists at Duke University found that only three out of every 10

[7] Id.
[8] Id.
[9] The Lewin Group, *The Impact of the Canadian System on Access to New Medical Technology Including Prescription Drugs*, March 7, 2000.
[10] Id.
[11] Id.
[12] Id.
[13] The Boston Consulting Group analysis based on J.A. DiMasi et al. (1991) as quoted by the Office of Technology Assessment in *Pharmaceutical R&D: Costs, Risks, and Rewards,* February 1993.

drug products, or new chemical entities, introduced from 1980 to 1984 had returns higher than average after-tax R&D costs.[14]

The prices also need to generate revenues that meet investors' expectations to continue to attract private investment. Investors seek to be compensated for their investment commensurate with risk; drug discovery and development are high-risk and require substantial funds over many years before medicines may reach the market.

In Canada, each company is denied the freedom to set prices for its own innovative prescription medicines. Prices are controlled by the Canadian government. The only choice a manufacturer has is to sell at the price set by the Canadian government—or not to sell its product. If a manufacturer opts not to sell its product, the government is allowed to authorize a Canadian company to copy and sell the drug, even without the patent holder's permission. In other words, if a manufacturer does not sell at a price Canada allows, the government effectively expropriates the value of the patent; the patent holder receives only royalties, which historically have been only 4–5 percent.

Outside the United States, most countries choose to interfere in the market and set limits or controls on pharmaceutical prices, particularly for new, innovative products, to control health-care expenditures. Unfortunately, these practices have not worked. As a part of Canada's total health-care spending in 2000, total expenditures on drugs at the retail level, excluding drugs prescribed for use in hospital settings, have increased faster than other major components of health care, and reached a forecast level of 15.5 percent of total health-care expenditures.[15] In contrast, in the United States, outpatient prescription drugs as a percentage of U.S. National Health Expenditures was estimated to be 8.6 percent for 2000.[16]

In addition to the use by Canada of price controls on prescription drugs, there are other reasons why prices for prescription drugs differ in the U.S. and Canada. Prices vary from country to country for a host of reasons, including living standards, income differences, willingness to pay, differences in medical practice, product volume, exchange rates, the level of competitive medical service or product prices, patent term and expiration dates, the length of time and costs of drug-marketing approval, as well as government-imposed reimbursement and price controls.

Another common reason that price differences exist between the U.S. and Canada and the U.S. is product liability. Questions of whether to sue, the nature of the forum, the level of proof needed to prevail, the nature or size of the case, and the level of damages awarded often make product-liability cases in the U.S. more costly to pharmaceutical manufacturers than in other countries, particularly in Canada.

A study released in December 2000 by the U.S. International Trade Office (ITC) explored foreign markets and U.S. prices, pharmaceutical development and approval processes in various countries, and how prices are established within countries. The report also considered how to measure the differences in prices between countries and concluded, "A single, definitive, unbiased measure of comprehensive price differences does not exist."[17]

Most Cross-National Price Comparisons are Flawed

Recently, snapshot cross-border comparisons of pharmaceutical prices have gained great popularity as "demonstrating" that prices charged in the U.S. are higher than those charged abroad. Like any still frame out of a movie, these snapshots often mislead and fail to tell the whole story.

The ITC report examined several studies relating to pricing and determined that there are methodological flaws with each. Sample selection issues biased comparisons and "severely limit the generality of the conclusions of this research." The report also identifies the replacement cost benefit that pharmaceuticals can play in overall health care, stating, "At times, pharmaceutical products are used instead of costlier options such as hospitalizations."[18]

Virtually all of the cross-border "studies" comparing drug prices have been flawed by faulty methodology. Professor Patricia Danzon of the Wharton School, and Fredrik Andersson and colleagues at the Battelle Medical Technology and Policy Research Center, have published extensively on the shortcomings of different approaches for comparing drug prices internationally. They conclude that international

[14] Henry J. Grabowski and John M. Vernon, "Returns to R&D on New Drug Introductions in the 1980's," Journal of Health Economics 13 (1994) 338–406.

[15] See the *National Health Expenditure Trends,* 1975–2000, published by the Canadian Institute for Health Information (CIHI), 2000.

[16] Health Care Financing Administration, OACT, 2001.

[17] "Pricing of Prescription Drugs," United States International Trade Commission, Investigation No. 332–419, Publication 3333, December 2000.

[18] Id.

price comparisons are misleading and generally based on flawed methodologies, and suggest that public policy is all too often influenced by price studies without an understanding of their technical limitations.[19]

One of the most common flaws of many price comparisons is comparing manufacturers' list prices for drugs in the U.S. with list prices in other countries. This practice leads to erroneous conclusions because the actual transaction price in the U.S. is often significantly lower than the list price, unlike in many other countries.

Another common flaw is that price comparisons are also typically made on the basis of simple averages of the top-selling drugs in a given country for which matching products are available in other countries. This often results in the use of extremely small samples. The studies also typically make no attempt to include the most frequently used drugs in comparison countries, nor do they attempt to weigh the prices based on the consumption of drugs in countries examined.

Yet another flaw in many comparisons is that the sampled drugs are not always directly comparable. Differences in package size, dosage forms, strengths, indications, and dispensing methods need to be taken into account, but rarely are. In short, apples-to-apples comparisons are rare, so reported results must be viewed with care.

Converting foreign prices to local prices for comparison purposes produces another type of error, given that changes in exchange rates over time create considerable variability in price relationships.

This problem is further exacerbated by foreign government price setting. When faced with a devaluation, U.S. exporters of most products try to raise their price in local currency to keep constant in U.S. dollars. This is evident to anyone visiting a local bookstore. A $25 book in the U.S. is actually priced on the jacket at Canadian $33. Newspapers costing $1.50 in the U.S. are listed at Canadian $2. But with pharmaceuticals, the price ceiling imposed in Canada by the PMPRB—totally disconnected from exchange rates—has no mechanism that allows U.S. exporters of medicines to adjust their prices in Canada due to exchange-rate fluctuations.

Many studies have focused on the final prices to patients or third parties rather than revenue received by the manufacturers. However, in most countries, pharmaceutical wholesalers and retail pharmacies are reimbursed at fixed percentage mark-ups over the ex-manufacturer price. The margins are set by law and differ substantially from one country to another. Many countries also impose a value-added tax. Even if a manufacturer were to set a uniform wholesale price in all industrialized countries, the final retail price to consumers would vary by as much as 90 percent due to these mark-ups. If a manufacturer sold a product for $1.00 in North American and European markets, the final price to a consumer would range from a low of $1.14 in the UK to a high of $2.08 in Finland. The U.S. price would be $1.43. Only the UK and Sweden would have a consumer price lower than that available to U.S. consumers.

There are numerous ways in which "simple" cross-border comparisons result in inaccurate conclusions. While these problems may be well known in academia, they are often missing from the public debate. On top of all of the technical problems discussed above, it is also important to remember that for U.S., non-government purchases, market forces set the price. In other countries, like Canada, governments, directly or indirectly, set the price and no government bureaucracy has ever been able to mimic a market-based price for a large number of products on a sustainable basis.

Many Products, Not Just Prescription Drugs, Are Less Expensive in Canada

Many products, not just prescription medicines, are generally less expensive in Canada than in the United States. *This is because the Canadian government imposes price controls and unnecessary regulations on many industries*. The Canadian government runs marketing boards for most industries. The boards operate within a specific province or throughout the entire country. For example, one such board is the Wheat Board. As Chairman Dorgan is keenly aware, the Wheat Board in Canada monitors and sets prices on the sale of wheat in Canada. Therefore, the cost of wheat products, such as bread, *are* directly related to the price dictated by the Wheat Board.

Reimportation of Pharmaceutical Products into the U.S.

Although some seniors in the U.S. are traveling to countries like Canada or using foreign-based web sites in search of less expensive pharmaceuticals, they may be

[19] See e.g. Danzon, P., *Pharmaceutical Price Regulation: National Policies versus Global Interests*, (AEI Press: Washington, DC, 1997).

putting their health at risk by doing so. Government investigation into the reimportation of pharmaceuticals has shown that it opens our nation's borders to counterfeit medicines and places vulnerable populations at risk. Reimportation proposals are a distraction to the real solution—a Medicare prescription drug benefit.

Conclusion

In conclusion, although pharmaceutical prices in Canada are sometimes less than what they are in the U.S., it is important to remember why this is so. As discussed above, there are many reasons for price differences between countries. But the primary reason is government-mandated price controls. In Canada, this has meant limited choice and access to the newest and most innovative medicines. It has also meant lengthy delays for other health-care treatments and less access to medical technology. So although government-imposed price controls can appear as an attractive choice, they hurt the very people they are designed to help—patients.

We should learn from Canada's mistakes—not import them. Nor should we make the mistake of adopting a risky and dangerous reimportation scheme instead of addressing the underlying problem by reforming the Medicare program, including enacting a prescription-drug benefit.

That concludes my formal presentation. I will be pleased to answer any questions that the Chairman or Members of the Subcommittee may have.

Senator DORGAN. Ms. Powell, thank you very much.

Next we will hear from Stephen Giroux, Community Pharmacist, Middleport Family Health Center in Middleport, New York, and Member of the National Community Pharmacists Association. Mr. Giroux, thank you for being here.

STATEMENT OF STEPHEN L. GIROUX, COMMUNITY PHARMACIST, MIDDLEPORT FAMILY HEALTH CARE CENTER, AND MEMBER OF THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, ACCOMPANIED BY JOHN M. RECTOR, SENIOR VICE PRESIDENT FOR GOVERNMENT AFFAIRS AND GENERAL COUNSEL TO NCPA

Mr. GIROUX. Thank you, Senator, I am pleased to be here, and I might add that I come from western New York, Niagara County, home of Niagara Falls, and it is a small community not unlike those in North Dakota that you have described several times. When someone knows I am from New York, they have a little bit different picture than where I am actually from. I have heard you tell that story and I related very closely to it because my little village in Middleport has about 1,800 residents, so it's a similar size community.

Senator DORGAN. That is a big town.

Mr. GIROUX. Also, in addition to being an actively practicing community pharmacist and owning three community pharmacies as well as a home medical equipment business, I am the past president and current board member of the board of directors of the Rochester Drug Co-Op, which is a regional drug wholesaler that sells about $300 million worth of pharmaceuticals and we do business in New York and Pennsylvania. I am also a past president and board member of the Medina Memorial Health System, a nonprofit hospital which buys products far lower than I can as a retailer, even though I do a lot more business than the hospital does. And I am pleased to serve on the executive committee of the National Community Pharmacists Association, formerly known as the National Association of Retail Druggists. I am accompanied today by John Rector, Senior Vice President for Government Affairs and General Counsel to NCPA.

I thank you, Senator, for having this hearing today, and these are very very crucial issues, both to consumers and to small businesses.

NCPA, the National Community Pharmacists Association, represents more than 25,000 independent pharmacies where over 75,000 pharmacists dispense more than 50 percent of the nation's prescription drugs and related services. Independent pharmacists serve 18 million people daily. NCPA has long been acknowledged as the sole advocate for this vital component of the free enterprise system, and for decades has been the only national pharmacy association with universal state association membership, including those of the committee members.

Our members function in the market in a variety of forms. We do business as single stores ranging from small apothecaries to full line high volume pharmacies; as independent chains, sometimes ranging as large as a hundred locations; also as franchises, such as NCPA members involved with the Medicine Shop franchise. Whatever form of business entity, however, independent pharmacists are the decisionmakers for this wide variety of NCPA members companies. As owners and managers and employees of independent pharmacies, our members are committed to legislative and regulatory initiatives designed to protect the public and to provide them a level playing field with a fair chance to compete.

We appreciate the opportunity to assist the Committee in assessing the differences between American and Canadian pharmaceutical prices, and how these prices affect the American consumer, and means to bring American prices in line with Canadian prices.

In May 1999 we endorsed a bipartisan International Prescription Drug Parity Act by Representatives Marion Berry, Bernard Sanders and Jo Ann Emerson, and S. 1191, sponsored by you, as well as Senator Wellstone, Olympia Snowe, and Tim Johnson. We work closely with you, Senator, and Senator Jeffords, and House and Senate allies in this important and crucial legislation.

With the exception of the sunset provision, that legislation was nearly identical to the language that was overwhelmingly approved by the U.S. Senate, and we have examples of that in the packet.

Our business, my own business is located about 40 miles from the Canadian border. Never a day goes by that in the course of my practice of pharmacy that I don't have a conversation with a patient or a patient's family member that is concerned with the astronomically high costs of prescription drugs.

And, at the outset, I must say that we do need a Medicare prescription drug benefit for our nation's elderly, not some scam like President Bush's cash discount card that gives absolutely no benefit to our seniors by picking PBM's as market favorites, creating an anticompetitive environment that will severely harm the small businesses that we represent. In any case, we need to get some relief from the high cost of prescription drugs for the elderly and the uninsured.

This legislation provides an excellent free market safe approach to allow our patients access to safe and lower priced FDA-approved prescription drugs without bypassing established distribution channels or the important professional services of a pharmacist. After all, it is the pharmacist who has the well established trust relationship with patients.

As our President John Carson observed last May, we are deeply disappointed that President Bush reconsidered his announced support for this new law and the resulting delay by HHS Secretary Thompson and his failure to implement this bill.

Our house of delegates unanimously approved a resolution last year calling for the expeditious implementation of this new law. Today we reiterate our views.

The nation's retail pharmacists operate in an extremely competitive marketplace on razor thin margins averaging less than 3 percent. My drug wholesaler mark-ups are even slimmer. My wholesaler will use an alternative vendor supplier for pharmaceuticals for a savings of as little as 1 to 2 percent. We will move our market share to an alternate vendor supplier.

If we are afforded, through the implementation of this legislation, the opportunity to import or reimport safe FDA-approved drugs for a 40 to 60 percent savings, we will do that in a heart beat, and these savings will be shared with our members who will pass those savings along to the patients that we serve. The competitive nature of our marketplace demands that.

Importation can be achieved safely and cost effectively by our small regional wholesalers and our buying groups through existing distribution channels. The large wholesalers and chain pharmacy corporations are potentially opposed to this implementation, which would not require any authorized purchaser, not require, but it would be voluntarily to do this reimportation. Perhaps these companies that oppose that, already operate in an international marketplace and do not want to give up their competitive advantage.

This current law, we do not want to allow the bypassing of the valuable counsel that's available from the trusted relationship with the community pharmacist. We do want to give access to the benefits of lower global pricing to American consumers.

The Bush Administration is denying American consumers, especially the elderly and the uninsured, equal access to the benefit of global prescription drug pricing. This legislation takes this opportunity to do it in a—to allow these pharmacists and their consumers this access in a free market and nonbureaucratic way.

I have taken the opportunity to bring eight examples, not any duplicates of those that you brought, Senator, of Canadian products and their American counterparts. We have eight examples, they range anywhere from a discount of 6 percent less expensive to a maximum of 83 percent in the eight examples I brought. On average that represents a 40 percent lower Canadian dollar price difference between the American price and the Canadian price.

This is a significant difference. It does not take into consideration the Canadian exchange rate, which is additionally about 40 percent as we speak today.

I have an example here, a bottle of 100 tablets, that sells at the Canadian pharmacist for $33. That same bottle, same size to the U.S. market, nets down to the American pharmacist at $194. That is the 83 percent example.

The next one, this purple pill, which goes off patent, is available in Canada for $50.88, and available in the United States for

$100.48, same dose, a 41 percent lower price, not taking into consideration the 40 cents on the dollar when we take our American dollars over there.

A blood pressure medication, this is the 6 percent difference, blood pressure medication widely used, $73.94 cents for a bottle of 90 in the United States and $70.63 in Canada, not taking into account the exchange difference of 40 cents on a dollar, and it's a real bargain.

The next example is a lipid lowering medication, Lipitor, a cholesterol lowering drug I should say, and hormones, female hormones—47% lower in Canada. A bottle of a thousand Wyeth Ayerst, manufactured right up on the New York–Canadian border, and in Canada nets down to $121.50 for a bottle of a thousand, and in the United States the cheapest price I can get is $531.91 for that same thousand. That's a difference of 77 percent, again, before we take into consideration the American exchange on the dollar.

We think this is a dramatic impact, we think it's criminal in fact for our American consumers not to have access to these lower prices. We calculated that based on just the 40 percent savings not having anything to do with the exchange rate, but that's about $845 million a week or $120 million a day that our American consumers are paying in higher prices every day that this bill is not implemented. We think this is very serious money, we think that it's important that we have access to Canadian pharmaceuticals, FDA-approved, safe pharmaceuticals, through existing distribution channels, and we can accommodate that, as I say, in a heart beat through existing distribution channels.

Mr. Chairman, I thank you for the opportunity to present today, and I look forward to helping you in any way possible to get this legislation enacted and implemented.

[The prepared statement of Mr. Giroux follows:]

PREPARED STATEMENT OF STEPHEN L. GIROUX, COMMUNITY PHARMACIST, MIDDLEPORT FAMILY HEALTH CENTER, AND MEMBER OF THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, ACCOMPANIED BY JOHN M. RECTOR, SENIOR VICE PRESIDENT FOR GOVERNMENT AFFAIRS AND GENERAL COUNSEL TO NCPA

Mr. Chairman, Members of the Committee

I am Stephen L. Giroux. I am owner of 3 retail community pharmacies, a home medical equipment business and a Hallmark card/gift and old-fashioned soda fountain shop. Our company has about ten million dollars of annual revenue. We are located in upstate Western New York. Middleport Family Health Center, Transit Hill Pharmacy, Rosenkrans Pharmacy, Lockport Home Medical and Thee Barker Store. I am a past president and current member of the board of directors of the Rochester Drug Co-Op, a regional drug wholesaler with about 300 million dollars of annual revenue doing business in New York and Pennsylvania. I am a past president of and board member of the Medina Memorial Health System (hospital) and serve on the executive committee of the National Community Pharmacists Association (NCPA), formerly the National Association of Retail Druggists. [See Exhibit A].* I am accompanied today by John M. Rector, Sr. Vice President Government Affairs and General Counsel for NCPA.

I want to thank you for inviting us to testify on these critical consumer and small business issues.

The National Community Pharmacists Association (NCPA) represents more than 25,000 independent pharmacies, where over 75,000 pharmacists dispense more than 50% of the nation's prescription drugs and related services. Independent pharmacists serve 18 million persons daily. NCPA has long been acknowledged as the

* The information referred to has been retained in the Subcommittee files.

sole advocate for this vital component of the free enterprise system. For decades have been the only national pharmacy association with universal state association membership, including those of the Committee's members.

Our members function in the market in a variety of forms. They do business as single stores ranging from apothecaries to full line high volume pharmacies; as independent chains (e.g., 100 pharmacies) and as franchisees such as NCPA members involved with the Medicine Shoppes franchise. Whatever the form of business entity, however, independent pharmacists are the decision makers for this wide variety of NCPA member companies.

As owners, managers and employees of independent pharmacies, our members committed to legislative and regulatory initiatives designed to protect the public and provide to them a level playing field and a fair chance to compete. We appreciate the opportunity to assist the Committee in assessing the differences between American and Canadian pharmaceutical prices, how these prices effect the American consumer and means to bring American prices in line with Canadian prices.

In May of 1999, we endorsed the bipartisan International Prescription Drug Parity Act, H.R. 1885 by Representatives Marion Berry, Bernard Sanders, and Jo Ann Emerson and S. 1191 by Senators Byron Dorgan, Paul Wellstone, Olympia Snowe, and Tim Johnson. [Exhibit B].*

We worked closely with Senators Dorgan and Jeffords and their House and Senate allies in support of P.L. 106–387, which with the exception of the sunset provision was nearly identical to the language overwhelmingly approved by the U.S. Senate. [Exhibit C].*

Our businesses are located about 40 miles from the Canadian border. Never a day goes by that in the course of my practice of pharmacy that I don't have a conversation with a patient or a patients' family member that is concerned with the astronomically high cost of prescription drugs.

At the outset, I must say that we need a Medicare prescription drug benefit for our nations elderly. Not some scam like the Bush cash discount card that gives absolutely no benefit to our seniors by picking PBMs as market favorites creating anticompetitive environment that will severely harm the small businesses that we represent [Exhibit D].* In any case, we need to get some relief from the high cost of prescription drugs for the elderly and the uninsured.

The drug importation/re-importation law P.L. 106–387 provides an excellent free market, safe approach to allow our patients access to safe and lower priced, FDA-approved prescription drugs without bypassing established distribution channels or the professional services of the pharmacist. After all, it's the pharmacist who has a well-established trust relationship with patients. As NCPA's president John Carson observed last May, "We are deeply disappointed that President Bush reconsidered his announced support for the new law and resulting in HHS Secretary Thompson's failure to implement it." [Exhibit E].*

The NCPA House of Delegates unanimously approved a resolution on October 18, 2000, calling for the expeditous implementation of the new law. Today, we reiterate our views.

The nations retail pharmacies operate in an extremely competitive marketplace on razor thin margins averaging less than 3%. My drug wholesaler mark-ups are even slimmer. My wholesaler will use alternate vendor suppliers for as little as a 1–2% savings. If we are afforded through the implementation of P.L. 106–387 the opportunity to import/reimport safe FDA-approved drugs for a 40–60% savings, we will do it in a heartbeat. Those savings will be shared with our buying group members who will pass along any savings to the patients they serve.

Importation can be achieved safely and cost effectively by our small regional wholesalers and buying groups through existing distribution channels. The large wholesalers and large chains are opposing the implementation of the new law which would provide—not require—any authorized purchaser the opportunity to import FDA-approved Rx drugs. Perhaps many of these companies already operate in an international marketplace and do not want to give up their competitive advantage. Obviously the pharmaceutical manufacturers are opposed to any scenario that could alter their present monopolistic opportunity for profits.

We don't bemoan their financial success. As the most profitable industry in the world, we do need them to continue to bring innovative technologies and life improving and even life saving drug products to market—*just not at the highest prices in the industrialized world*. We are also concerned about encouraging patients to obtain their medications directly through mail order or by personal trips across the border generally neither are legal under current law and importantly bypass the valuable counsel, and services of their trusted pharmacist.

* The information referred to has been retained in the Subcommittee files.

The brand drug manufacturers are creative marketers. For example, the brand name manufacturers have disparaged generic drugs for several years and yet have purchased generic companies, formed generic divisions, and attempted to control that sector. When one brand name drug company executive was asked why they didn't pursue the generic market by lowering prices of a branded product once all of the patents had been exhausted, he said that they would not be able to make sufficient money. The brand name drug industry is unique in that it frequently raises prices when patents expire and their market share is reduced.

In a similar vein the brand drug manufacturers have creatively claimed that imported or reimported prescription drugs that they or their parent companies have made threatened the safety of the American consumers. For many years consumers, through mail order, border crossings, and more recently the Internet, have been obtaining FDA-approved prescription drugs from other countries, however, it was only when the U.S. House of Representatives and the U.S. Senate (74 to 21) [Exhibit F]* authorized imports by wholesalers and pharmacists that drug makers belatedly expressed serious concerns about the safety of imports. [Exhibit G].*

Interestingly, the drug manufacturers have been importing prescription drugs at record levels [Exhibit H].* The drug makers are not sharing the benefits of lower global pricing with American Consumers. They are even authorized to import non FDA-approved bulk products and export them as finished unapproved prescription drugs. By not implementing P.L. 106–387 the Bush Administration is denying American consumers especially the elderly and the un-insured equal access to the benefit of global prescription drug pricing.

It's important to recall that all of the drug makers' customers are not charged the high prices that even the largest retail pharmacies must pay. The drug makers have denied retail pharmacies equal access to economies of scale. The discriminatory pricing practices of the drug makers have been the subject of the extensive litigation and federal and state legislation. Implementation of P.L. 106–387 would provide long overdue relief for pharmacists and consumers in a free market and non-bureaucratic way. For the Committee's review, I have with me today several examples of Canadian prescription drugs obtained from a Canadian pharmacist to show the similarity in quality and price differences for these basically FDA-approved pharmaceuticals. [See Exhibit I.]

Exhibit I

Manufacturer	Drug	Package Size	Net US Price	Canadian Price Net Wholesale	Savings percentage calculated before Canadian Exchange rate of 42% on US dollar expanding the savings
TAP	Prevacid 30 mg	100's	$358.21/100	$200.00/100	44%
Glaxo Smith Kline	Paxil 10 mg	30's	$65.59/30	$46.04/30	30%
Searle Pfizer	Celebrex 200 mg	500's	$1109.40/500	$625.00/500	44%
Glaxo Smith Kline	Lamictal 25 mg	100's	$211.48/100	$33.15/100	84%
Pfizer	Zoloft 50 mg	100/250*	$202.67/100	$160.00/100 $400.00/250	21%
Wyeth	Premarin 0.3 mg	100/500*	$73.20/100	$10.58/100 $52.90/500	86%
Astra Zeneca	Nexium 40 mg	30/28*	$100.42/30	$58.80/28	37%
Pfizer	Lipitor 10 mg	90's	$167.11/90	$144.00/90	14%

*The information referred to has been retained in the Subcommittee files.

Exhibit I—Continued

Manufacturer	Drug	Package Size	Net US Price	Canadian Price Net Wholesale	Savings percentage calculated before Canadian Exchange rate of 42% on US dollar expanding the savings
Merck	Vioxx 25 mg	100's	$220.19/100	$125.00/100	43%
Merck	Zocor 10 mg	60/500 *	$181.96/60	$890.00/500	41%

Please note:
* Different dosage forms (i.e. tablets vs. caplets) or different package sizes (as noted).

On behalf of the members of the National Community Pharmacists Association, we thank the Committee for the opportunity to participate in the ongoing assessment of the need to provide pharmacists and their consumers equal access to global pricing of safe prescription drugs.

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

Finally, we will hear from Dr. Alan Sager, Professor of Health Services and Co-Director of the Health Reform Program at Boston University. Welcome, Dr. Sager.

STATEMENT OF ALAN SAGER, PH.D., PROFESSOR OF HEALTH SERVICES AND CO-DIRECTOR, HEALTH REFORM PROGRAM, BOSTON UNIVERSITY SCHOOL OF PUBLIC HEALTH

Dr. SAGER. Mr. Chairman, thank you, and good morning. My name is Alan Sager, I am a professor of Health Services at the Boston University School of Public Health, and I am honored to have the chance to appear before you today.

The average American will spend $575 this year for prescription drugs. Not seniors alone, that's the average for all Americans. This is the highest spending in the world. Yet 70 million of us have no insurance for prescription drugs and dozens of millions of others have insurance that is sadly lacking. As a result, we have to choose among greater suffering, paying more for medications or changing the way we do business.

If Americans paid average Canadian prices for brand name drugs, savings would total $38.4 billion this year alone. Savings would range from $56 million in Alaska to over one-half billion dollars in median states like Arizona and South Carolina. Eleven states could save over a billion dollars, and California would save over $3.2 billion. But the average state like South Carolina or Arizona would save between 500 and $600 million yearly.

All Americans could enjoy the benefits of Canadian prices. Today, as we've heard, individual citizens are able to import drugs from Canada and enjoy the price differences. The legislation that you have been advocating today is overall a good idea, but I fear that even if it were to pass, it wouldn't have the practical effect that many of us would hope. That's because I think the manufacturers would produce fewer medications in Canada or export fewer medications to Canada, drying up supplies in Canadian warehouses and simply making fewer pills available for importation back into the United States. In other words, they would dry up the reservoir.

There have also been concerns that other techniques might be employed by manufacturers.

Still, I think that the aim of the legislation is exactly what we are trying to achieve, should try to achieve. Americans could win the Canadian low prices by importing the regulatory techniques that Canadians employ, not the lower priced drugs themselves. We don't need to wash our medications through a Canadian laundry.

If U.S. drug prices stay high, insurers and employers will work ever harder to suppress drug use through higher copayments and formularies and other methods, but suppressing drugs just flies in the face of economic and medical realities.

Economically, the marginal cost of making more drugs is typically very low once you do the research and build the plant. Medically, restricting use denies many patients the medications they need, as we have heard, and the nation would directly gravitate toward a Rolls Royce drug market.

Lowering drug prices requires bringing all stakeholders to the table, including drug makers, which requires getting past drug makers' bluster about supposed free markets that supposedly legitimate the world's highest prices. And also getting past drug makers' threats that lower U.S. prices would destroy research.

Careful public action is much less likely to damage research than is the industry's commitment to run their business as usual. High drug prices frighten many Americans and that can translate into precipitous political action two or 4 years from now, and that would gut prices, and that will harm research. So I think if we care about research, we can't let the industry control prices.

That's like what Clemenceau said about the French generals. He couldn't trust them to control the war, because that led to 4 years of blood, machine guns, barbed wire and trench warfare. That's what we face with prescription drugs.

Our nation generates so great a share of drug makers' incomes that we have to cut prices carefully. Here are four elements of a package deal that might be called a prescription drug peace treaty.

First, the federal government enacts a law to lower brand name drug prices to Canadian levels. This alone cuts drug makers' revenues by $38 billion yearly.

Second, drug makers would replace most of the lost $38 billion through higher volume in the private market. They would be filling more prescriptions owing to lower prices.

Third, the federal government would guarantee the drug maker could recoup any amount of the $38 billion that they didn't make up in the private market, through publicly-subsidized purchase of medications for people who couldn't afford even the discounted prices. So you take away $38 billion but you give it back to drug makers as they fill more prescriptions. It's simple recycling. All dollars saved are recycled to buy more drugs.

The fourth element of the peace treaty makes drug makers financially whole. They would have to be paid the extra manufacturing costs of the additional pills. Retailers would have to be paid the extra dispensing costs.

As a result, all Americans of all ages can afford the drugs their doctors prescribe, drug makers' profits and capacity to finance research are unimpaired, but we avoid windfall profits to drug makers through the Medicare prescription drug benefit if the prices weren't contained.

If this were to happen, I estimate that up to 977 million additional prescriptions for brand name drugs might be filled if Americans could afford them. That's a high-side estimate. The added cost of manufacturing and dispensing almost one billion more prescriptions, which is a one-third increase above current levels, would be in the range of $6.4 to $11.8 billion, depending on dispensing fees and added costs of manufacture, to protect all Americans against the cost of medications.

That may seem like a low estimate, but I think it's warranted by the likely dispensing costs of these drugs and by the likely actual manufacturing costs.

To make this work for the long haul, though, we have to continue to promote breakthrough research, and that means rewarding breakthrough research very generously, but not rewarding copy cat research, on which up to 40 percent of research dollars today, in my opinion, are largely wasted.

The final job is to keep costs low and affordable so we can get medications to all Americans for the next 5, 10 or 20 years. No one tool will suffice, but there some obvious candidates.

First, cut marketing waste. Drug makers' marketing costs appear to be substantially greater than estimates from industry-related sources suggest. The second chart from the supplemental package shows how drug makers actually spend their money according to their own financial reports, and we see that in that pie chart, that 31 percent of drug maker revenue goes to marketing and administration, versus only 11 percent to R&D, and the lion's share of the marketing and administration, we believe, does go to marketing.

The next chart shows the increase in employment in marketing, employment in marketing and employment in research between 1990 and 2000. The blue chart trends up slightly for research, up about 10 percent. Marketing employment is up about 50 percent. That's money that we pay for when we buy our pills.

A couple of other approaches. Measure each drug's efficacy, and compare with the costs, and disseminate the real evidence on which drugs work for which patients, perhaps through NIH or FDA, or perhaps an independent agency that would have no financial stake.

The final step is to think harder about profits. For example, in 1999, Merck reported consolidated before-tax return on revenue of 26 percent, but Merck apparently garnered an actual 37 percent before-tax return on revenue, more than 40 percent greater after factoring out its MEDCO PBM-related costs.

In conclusion, we can learn a great deal from the evolution of state efforts to wrestle in the trenches with prescription drugs. Their first phase was throwing money at the problem by buying medications; that was vital to do.

Their second phase now is holding down prices. The federal government should marry these two approaches from the start, lower prices and higher volume. Winning affordable medications for all Americans is the easiest problem to solve in the United States of America.

Thank you very much, Mr. Chairman.

[The prepared statement of Dr. Sager follows:]

PREPARED STATEMENT OF ALAN SAGER, PHD., PROFESSOR OF HEALTH SERVICES AND CO-DIRECTOR, HEALTH REFORM PROGRAM, BOSTON UNIVERSITY SCHOOL OF PUBLIC HEALTH

AMERICANS WOULD SAVE $38 BILLION IN 2001 IF WE PAID CANADIAN PRICES FOR BRAND NAME PRESCRIPTION DRUGS

How to Win Those Savings and Use Them to Protect All Americans against High Drug Costs without Hurting Drug Makers or Drug Research

With State-by-State Savings Estimates

Disclaimer: As always, I write and speak only for myself, not on behalf of Boston University or any of its components.

Acknowledgment: This testimony rests heavily on analyses conducted with my colleague, Deborah Socolar.

Earlier reports and testimony on prescription drug costs and reform methods are posted on our web site, http://dcc2.bumc.bu.edu/hs/ushealthreform.htm

Mr. Chairman and members of the Committee—Good morning. My name is Alan Sager and I am a professor at the Boston University School of Public Health. I am honored by your invitation to testify today.

I. Introduction

Together, we face two challenges:

- making all needed medications available to all Americans at affordable prices, while
- building a durable financial foundation under drug research and delivery in the U.S.

I am convinced we can do both of these. One reason is that we already spend enough money to do so. But not if we continue business as usual.

II. What is the Nature of the Problem?

Many Americans can't afford needed prescription drugs because they lack insurance, suffer low incomes, and face excessive U.S. prices.

Today, 70 million Americans of all ages have no insurance for prescription drugs. Additional dozens of millions have skimpy coverage.

Yet American prescription drug spending per person this year is the world's highest. Total prescription drug spending will be about $165 billion this year,[1] or roughly 11.6 percent of overall U.S. health spending.[2] That is some $575 for the average American.[3]

The drug cost problem will probably worsen. Drug spending in the U.S. is doubling every five years and is rising about three times as fast as overall health care spending. Between 1994 and 2000, estimated retail prescription spending rose by 116.4 percent while total health spending rose by only 34.2 percent.

If we fail to make vital drugs available to all who need them, public fear and anger will grow. But reasonable action today will prevent reckless over-reaction tomorrow.

Our nation must choose among:

- *Suffering:* Many of us could suffer and die for lack of needed medications, but that is intolerable.
- *Paying:* We could spend much more public or private money—or both—to buy needed drugs, but that is both unaffordable and unnecessary.
- *Changing:* We could secure more drugs from manufacturers for the amount we already spend, plus small extra sums to cover drug makers' actual incremental costs.

Change is the only realistic choice. Buying drugs at lower price levels, such as those already prevailing in Canada—as a result of government action[4]—is an important first element of that change. Today's high U.S. prices make medications unaffordable for many patients. They induce private efforts to cut drug use, resulting in denial of needed drugs. And they handicap public actions to expand drug coverage for more citizens.

III. U.S. Payments for Brand Name Drugs at Canadian Prices

If Americans paid average Canadian prices for brand name drugs this year, savings across the United States would total $38.4 billion, I estimate.

Exhibit

Calculating U.S. Savings on Brand Name Drugs If We Paid Canadian Prices in 2001

($ billions)

1. 2001 brand name drug sales, USA, net of discounts and rebates	$113.7
2. Assume undisclosed discounts and PhRMA generics of 10%	– $11.4
3. Conservative estimate of sales, USA, brand name prescription drugs	= $102.3
4. If U.S. paid Canadian prices, which averaged 62.5 % as high in 2000	– $63.9
5. Savings if paid Canadian prices in 2001	= $38.4

Note: All dollars are those actually paid to brand name prescription drug manufacturers, net of discounts and rebates.

A. How the Savings Were Calculated

1. To calculate the $113.7 billion starting point, we began with PhRMA's figure on total projected 2001 U.S. sales net of discounts and rebates. We then factored out veterinary sales in line with their actual share of PhRMA's 1999 total. The result: $113.7 billion.

2. We then assumed undisclosed discounts and rebates plus generic sales by PhRMA members equal to 10 percent of PhRMA's reported sales. (The 10 percent figure may be generous, but we wish to be conservative in our estimate of U.S. spending and therefore in the estimate of savings gained by paying Canadian prices.) The aim is to address PhRMA's stated concern that some U.S. discounts and rebates are not publicly disclosed and are therefore not considered by the Canadian Patented Medicines Price Review Board in its international price comparisons.

3. This yields a conservative projection of human sales of brand name prescription drugs by manufacturers in the U.S. in 2001 of $102.3 billion.

4. The Canadian government's Patented Medicine Prices Review Board calculated that Canadian brand name drugs' factory prices averaged just 62.5 percent of those in the U.S.A. in 2000. We applied this to calculate how much would be spent in the U.S. in 2001 if we paid Canadian prices.[5]

5. The result: cutting U.S. payments to manufacturers by $38.4 billion this year.[6]

B. State-by-State Savings

We apportioned this year's $38.4 billion in estimated U.S. savings from paying Canadian prices among the states.[7] The results are shown in the next exhibit. Savings ranged from $3.2 billion this year in California to $56 million in Alaska.

Exhibit

State-by-State Projected Spending on Brand Name Drugs in 2001, and Savings if the U.S. Paid Canadian Prices

($ millions)

	Brand Name Drug Spending in 2001 at Factory Prices	Savings if Paid Canadian Prices		Brand Name Drug Spending in 2001 at Factory Prices	Savings if Paid Canadian Prices
Alabama	$1,751	$657	Montana	$264	$99
Alaska	$150	$56	Nebraska	$706	$265
Arizona	$1,577	$592	Nevada	$539	$202
Arkansas	$1,019	$383	New Hampshire	$441	$166
California	$8,506	$3,193	New Jersey	$4,001	$1,502

Exhibit
State-by-State Projected Spending on Brand Name Drugs in 2001,—Continued
and Savings if the U.S. Paid Canadian Prices
($ millions)

	Brand Name Drug Spending in 2001 at Factory Prices	Savings if Paid Canadian Prices		Brand Name Drug Spending in 2001 at Factory Prices	Savings if Paid Canadian Prices
Colorado	$1,095	$411	New Mexico	$454	$170
Connecticut	$1,528	$574	New York	$8,037	$3,017
Delaware	$339	$127	North Carolina	$2,896	$1,087
D.C.	$203	$76	North Dakota	$217	$81
Florida	$7,001	$2,628	Ohio	$4,399	$1,651
Georgia	$2,776	$1,042	Oklahoma	$1,192	$447
Hawaii	$351	$132	Oregon	$1,036	$389
Idaho	$377	$141	Pennsylvania	$5,682	$2,133
Illinois	$4,474	$1,679	Rhode Island	$451	$169
Indiana	$2,323	$872	South Carolina	$1,484	$557
Iowa	$1,066	$400	South Dakota	$227	$85
Kansas	$964	$362	Tennessee	$2,403	$902
Kentucky	$1,765	$663	Texas	$6,797	$2,551
Louisiana	$1,701	$638	Utah	$636	$239
Maine	$515	$193	Vermont	$207	$78
Maryland	$1,894	$711	Virginia	$2,404	$902
Massachusetts	$2,451	$920	Washington	$1,809	$679
Michigan	$4,384	$1,646	West Virginia	$876	$329
Minnesota	$1,683	$632	Wisconsin	$1,969	$739
Mississippi	$1,086	$408	Wyoming	$150	$56
Missouri	$2,047	$768	**USA**	**$102,300**	**$38,400**

IV. Americans Can Enjoy the Benefits of Canadian Prices

Importing drugs from Canada has the potential to provide a measure of relief from high prices to some or even many individuals, so it should be tried until more effective price relief can be obtained. I expect that individual citizens will be able to continue to pursue retail importing solutions that lower their costs, but drug makers will continue to block effective wholesale importing solutions. If, indeed, importing drugs probably cannot do enough to make all needed medications affordable, then more direct techniques will be necessary to give Americans the benefits of low brand name drug prices that Canadians now enjoy.

Americans could try to obtain Canadian prices in three ways. *First,* we could travel to Canada, as growing numbers of Americans are now doing. Several problems arise. They include inconvenience of obtaining a valid prescription and the loss of a single, local pharmacy and pharmacist coordinating all of the patient's medications. Worse, it becomes necessary to transport something relatively heavy, a person, instead of something relatively light, a pill. This defies all we know about transportation economics.

Second, Americans could import drugs from Canada, either individually or collectively.

Some pursue this approach idealistically because they reside in border states and are frustrated by visibly lower prices nearby. They justly bemoan the burden borne by older or chronically ill patients who are today forced to travel across the border to buy drugs at more affordable prices. The numbers of people who buy medications from Canada is impossible to quantify but appears substantial. One Massachusetts senior has received over 700 inquiries in the middle few months of 2001 regarding methods of ordering medications from Canada by fax through family physicians.[8]

One objection to this approach is that it creates new and duplicative channels of drug distribution, some legal and some possibly illegal. Some have raised questions about the safety of the imported medications themselves.

The other objection is that, were the law changed to allow wholesale importation of medications at foreign prices, and if the volume of imports were to swell, the drug makers would predictably adapt, as they have adapted to other types of reform in recent years. They probably would:

- export lower volumes of medications from U.S. factories to other nations in the first place, thereby drying up one source of lower-priced prescription drugs;
- hold down the volume of drugs produced at the foreign factories subject to FDA inspection, thereby drying up the other source of lower-priced drugs; and
- try to threaten foreign nations with higher prices if they allow medications to be exported to the U.S.[9] or simply negotiate or set terms of their sales to other nations that prohibit re-sale of drugs abroad.

Therefore, I do not expect importing to do enough to make medications affordable for all Americans.

Allowing easier importation of medications is an attractive idea. But it resembles other attractive ideas of recent years—many of them implemented through changes in legislation or medical practice—that have failed to make medications affordable to all Americans. These ideas include patenting of copy-cat drugs, developing formularies, promoting generic substitution, relying on PBMs, and relying on managed care generally. All of these have attempted either to boost competition or to reduce spending through care management or price negotiations by fragmented buyers.

All of these ideas for winning lower prices indirectly seemed appealing. None—individually or together—has apparently slowed the rate of increase in U.S. drug spending. Consider, for example, that generic drugs now account for about two-fifths of all U.S. prescriptions but less than one-tenth of drug makers' revenues [10]— indicating that today's soaring spending is driven by soaring payments for brand name drugs.

Third, Americans could act more directly to win Canadian prescription drug prices by importing the general methods that Canadians employ, not the lower-priced drugs themselves. Adopting Canadian methods in the United States does not require moving people to pills or laundering pills through the Canadian pricing structure. It does not hitchhike on foreign regulation. Rather, it would mean forthrightly regulating drug prices.

Simply legislating lower prices for brand name drugs in the U.S. could work but passing such a law is obviously difficult politically. As you know, the law that actually passed in October of 2000 provided for re-importing drugs, but it is unlikely that this law would actually lower prices even if it were ever implemented, for the reasons just mentioned. We again seem to face the dilemma of "what can work won't pass and what can pass won't work." This is demoralizing. It breeds cynicism. We can do better.

V. Reassuring the Drug Makers by Negotiating a Peace Treaty

By themselves, price cuts will hurt drug makers. On the other hand, price cuts alone will clearly aid three groups: a) many people who are now able to afford their medications; b) the private insurors/HMOs and public programs that help to finance medications for most of those people; and c) some people who will be able to afford medications (or more of their medications) after the price cuts take effect. But price cuts will not help those Americans unable to afford even the newly reduced prices.

Happily, price cuts can be combined with other approaches to protect both patients and drug makers. If prices are to be lowered to Canadian levels, we should at the same time devise methods of addressing all stakeholders' legitimate interests, including those of drug makers. And including those of all Americans who cannot afford prescribed medications today.

Doing this requires bringing all stakeholders, including drug makers, to the table to conduct serious negotiations. And that requires filtering out manufacturers' bluster about free markets and manufacturers' threats that government interventions to lower U.S. drug prices will destroy research.

No free market sets drug makers' prices. Free markets require many small buyers and sellers, so every actor is a price taker, not a price maker. Free markets require an absence of artificial restrictions on supply, demand, and price. Free markets require easy entry. And free markets require that all parties have good evidence about price and quality.

In the prescription drug market, patents, mergers among drug makers, entry barriers associated with high research and marketing costs, allegations of anti-competitive practices, patients' (and, often, physicians') lack of good information about price and quality, and patients' inability to act as sovereign consumers combine to mean that nothing close to a free market acts to set drug prices.[11]

Nor do drug makers set prices to cover costs of research (whatever those costs really are). Drug makers today are obligated to their stockholders to set prices to maximize profits.

If government acts to win lower prices, "The lights go out in the labs, and there is no R&D," according to Tracy Baroni, senior director of policy for PhRMA.[12] This is an example of what my colleague and I call PhRMA's fog of fear.

Reasonably careful, well-tested, and—if possible—negotiated government intervention is much less likely to damage research than is the drug industry's own insistence on more money for business as usual.

The drug industry is on a collision course with financial and political realities. The industry's insistence on high prices is frightening and angering many Americans. A few years from now, that anger could translate into precipitous political action to gut drug prices. And that would gravely threaten research (and profits). Worries that this might happen could make today's drug makers the most nervous very-well-dressed people in America.

Fortunately, government intervention to lower prices to Canadian levels can—in combination with other reasonable steps—be designed to protect and promote research, and even to protect drug makers' profits.

Careful U.S. action is vital to protecting and promoting research. Unlike other nations, and unlike some U.S. states, the United States government cannot simply cut drug prices without regard for the cuts' effects on research. Because we buy so great a share (and an increasing share) of the world's brand name drugs, the world's drug makers rely on the U.S. market for a disproportionate share of their profits and the dollars they require to finance research.

Four Elements of a Prescription Drug Peace Treaty

The challenge is to put together the right package of policies. Here is an interlocking four-part method.

First, the federal government could enact a law to lower brand name drug prices to Canadian levels. If nothing else changed, the price cuts would deprive drug makers of $38.4 billion in revenues from the U.S. market, as calculated earlier.

But *second,* drug makers would replace much or most of this $38.4 billion in lost revenue through the natural rise in the volume of prescriptions filled in the private market. Lower prices allow patients to fill more of their prescriptions and do so more often. The relation between price and volume for prescription drugs appears to be elastic, meaning that the volume of drugs bought by patients in a private market grows substantially when prices are cut.[13]

Third, the federal government could guarantee drug makers that they would recoup every penny of lost revenue that was not replaced through higher private market volume. The best vehicle for replacing that revenue would probably be public subsidies to assist drug purchases by patients of all ages who are unable to afford even the newly discounted prices. The subsidies would be set to ensure replacement of all the revenue lost by drug makers that was not recaptured through higher private market volume. This public spending would not result in an increase in total spending on prescription drugs. Rather, it replaces some of the drug maker revenue lost from the price cut.

Fourth, the public subsidies would also include dollars needed to cover the actual incremental costs of manufacturing the higher volumes of drugs. These are relatively low, compared with current total costs.[14] Public subsidies would also cover the added cost of dispensing the additional volumes of drugs in pharmacies and elsewhere. These two items would result in increased total spending on prescription drugs, but these are all that would be required to extend pharmaceutical security to all Americans. No additional costs would be incurred to pay higher profits to drug makers, because drug makers' profits as a percentage of equity would already be preserved and protected at the high levels antedating the peace treaty's provisions for price cuts, higher private volume, and higher public volume.

Such a peace treaty achieves three things:

1. All Americans—not Medicare beneficiaries alone—can now afford to obtain the prescription drugs they require.
2. Drug makers are kept financially whole. All lost revenue is replaced, and the added cost of producing more pills is covered. Drug makers' profits and capacity to finance research remain intact at today's levels. This guarantee could be maintained for perhaps five years. (It will be useful to consider whether profits should be assured as a percentage of equity or of revenue.)
3. The actual incremental costs of protecting all Americans are relatively low (as estimated in section VI), making the proposal affordable. Cutting prices to Canadian levels makes it much easier to expand coverage. Manufacturers make up for lower prices with higher volume. In other words, the $38.4 billion squeezed out of the drug makers (by cutting their prices) is returned to them (because many more prescriptions are filled)—when they serve patients who previously could not afford needed medications. Manufacturers do forego windfall profits that they would have garnered from higher volume in the absence of the price cuts.

This straightforward approach works most simply for the short run. It makes today's drugs affordable for all. The arrangement could be designed to run for perhaps five years. The main remaining questions concern how to reward drug makers that develop new medications and how to constrain the projected explosive growth in the cost of pharmaceuticals. These matters are taken up in section VII.

High drug prices constitute the main logjam blocking the flow of government reforms to win prescription drug security for all Americans. Once prices are lowered, it becomes possible to buy medications for all people who need them at a price that people and payors can afford.

VI. Estimating Short-Run Costs

Those who have sought to design a prescription drug benefit for Medicare have experienced great frustration during the past two years. Estimates of the cost of federal government subsidies rose from $118 billion for ten years in the first Clinton plan of June 1999 to $318 billion for ten years in the Senate Democrats' plan of June 2001.[15]

Some of this is attributable to changes in benefits and some to rising estimates of underlying drug spending and other factors. CBO projects that drug spending by or for Medicare beneficiaries during the decade from 2001 to 2010 will be $1.3 trillion under current law—without a prescription drug benefit. These projections have themselves been rising rapidly.[16]

Sadly, even at the $318 billion level, only about one-quarter of beneficiaries' expected baseline drug costs of the $1.3 trillion (that is, costs before the Medicare coverage is introduced—costs that would surely rise in the wake of new insurance protection) would be covered, requiring very substantial monthly Medicare premiums and out-of-pocket payments.[17] A plan with low premiums and low out-of-pocket payments could cost as much as $1 trillion over a decade.[18]

Some of this is attributable to most proposed legislation's inability to limit drug prices meaningfully, resulting in huge windfall profits for drug makers. Under most Medicare prescription drug plans, drug makers would sell substantially higher volumes of medications at only slightly lower prices. Even with 25 percent or 40 percent discounts, drug makers' incremental revenue would far exceed their incremental cost, generating the windfall profits.

Much of this is also attributable to drug spending projections that take as givens continued unrestricted growth in drug marketing, continued unrestricted introduction of expensive new drugs without careful evaluation of their incremental benefits to patients, and other costs, year after year.

Clearly, unrestricted increases in drug spending are unaffordable. Drug makers would like to imagine that they can marry today's high prices in combination with tomorrow's Medicare prescription drug benefit that boosts volume at those high prices. But that is a fantasy. Even without a Medicare drug benefit, restraint is inevitable—through either private or public action. In response to high drug prices, employers are establishing higher co-payments to try to suppress the volume of drug use. More can be expected in the future if high prices persist.

But that flies in the face of economic and medical realities. Economically, the marginal costs of making more medications are typically very low, once the research is performed and the factories are built. Medically, high prices lead to restrictions on use that can deny many patients the medications they need. The nation would gravitate toward a Rolls-Royce drug economy when it needs Fords and Chevy's.

To make all of today's medications available to the patients who need them at an affordable cost, and to promote research to develop new medications, The nation needs two coordinated approaches, one short-run (for perhaps the next five years) and the other longer-run.

Short-run Cost Estimates

Cutting drug prices to Canadian levels yields markedly lower estimates of the actual short-run incremental cost of financing full prescription drug coverage for all Americans—not only Medicare beneficiaries.

This added cost has two components, retail dispensing costs and actual incremental manufacturing costs.

I estimate that as many as 977 million additional prescriptions for brand name drugs would be filled if all Americans could afford the medications their physicians prescribed. This is a deliberately conservative (high-side) estimate.[19] It amounts to a one-third increase over the total number of retail prescriptions filled in 2001.[20] This estimate requires considerable refinement, but it will serve for now to permit a rough calculation of the short-run costs of pharmaceutical security for all.

I estimate that the added costs of manufacturing and dispensing these 977 million prescriptions would be in the range of $6.4 to $11.8 billion annually.

The lower of the two estimates assumes

- a dispensing fee per prescription of $3.00 and
- an average incremental manufacturing cost of $3.51 per prescription, or five percent of the projected average retail price for brand name drugs in 2001.[21]

The sum of the two costs is $6.51 per prescription. Multiplying that by 977 million additional brand name prescriptions yields an added total cost of $6.4 billion annually.

The higher of the two estimates assumes

- a dispensing fee per prescription of $5.00 and
- an average incremental manufacturing cost of $7.03 per prescription, or ten percent of the average retail price for brand name drugs in 2001.

The sum of these two costs is $12.03. Multiplying that by 977 million additional brand name prescriptions yields an added cost of $11.8 billion annually.

This $6.4–$11.8 billion range estimates the full, total incremental cost of filling almost one billion additional prescriptions, enough to protect all Americans in 2001. Some seven aspects of these estimates are worth noting:

1. These are total incremental costs above estimated 2001 spending on brand name prescription drugs. If they are paid publicly, no additional sums for copayments or premiums are needed.

2. These incremental costs are a small fraction (3.9 percent–7.2 percent) of the $165 billion projected to be spent on prescription drugs in the United States in 2001. That is less than six months' increase in total prescription drug spending—increases that have been running around 15 percent annually.

3. These incremental costs are a fraction of those estimated to be required to cover Medicare beneficiaries alone. Consider the $318 billion Medicare-only estimate for ten years that still leaves very substantial premium and out-of-pocket costs, or the $1 trillion Medicare-only estimate for ten years that eliminates premium and out-of-pocket costs that were mentioned earlier.

4. Because these are incremental prescription drug costs, they do not include the recycling of the $38.4 billion squeezed out of the drug makers by applying Canadian prices for brand name drugs to the U.S. market in 2001. That is because all of this money is returned to the drug makers through higher private market purchases and higher publicly subsidized purchases of medication in response to the lower prices.

5. As the $38.4 billion is recycled, the private share of payments for prescription drugs will fall somewhat and the public share will rise somewhat. That is because individuals, employers, and insurors/HMOs will enjoy most of the benefits of the $34.8 billion in price reductions, but these private parties will probably pay a smaller share of the costs of replacing the lost revenue. (I have not yet estimated the size of these offsetting changes.)

6. Additional costs of higher volumes of generic drugs are excluded from these calculations. That is because pricing methods for generics are different from those for brand name drugs. And discounts are substantially lower. International comparisons of prices typically employ brand name drugs only. As noted, generics today amount to only about 8.6 percent of total U.S. prescription drug spending, even though they are over forty percent of prescriptions. So higher spending on generics should not be substantial under this approach. Also, lower prices for brand name drugs would reduce the price differentials between generics and brand name drugs, probably reducing generics' share of total prescriptions over time.

7. The estimates do not reflect one-time costs of building pharmacies' capacity to substantially increase the number of prescriptions dispensed annually.

VII. Promoting Development of Breakthrough Drugs, and Containing Long-Term Costs So That All Medications Remain Affordable for All Patients

In the short run, the prescription drug peace treaty described in Section V of this testimony would make all of today's needed medications available to all Americans at a surprisingly low incremental cost.

Looking forward, a number of strategic interventions must be undertaken to keep medications affordable for all Americans and for all payors, to promote the development of new breakthrough drugs, and to generously reward drug makers that develop those drugs.

Clearly, today's pace of drug spending increases cannot continue; spending that doubles every five years is unaffordable. But even reversion to the rates of increase of earlier years could raise grave financing problems: five percent or ten percent annual increases in drug spending would be very costly because they build on 2001's $165 billion base.

A. Spurring Research to Develop Breakthrough Drugs

Several policy and financing approaches should be considered to encourage breakthrough research. The first is to reward breakthrough research generously. The reward for a new drug should be keyed to the magnitude of its clinical benefit (years of life gained, disability reduced, and pain and suffering for patient and family relieved) for the typical patient who uses it, the number of patients who use it, the actual risks and actual costs of research borne by the company that develops the drug, the drug's effects on other medical and non-medical costs (costs of physician and hospital services, costs of long-term care, and the like), and possibly other factors.

It should be recognized that drugs cannot be cleanly divided between breakthrough or non-breakthrough drugs. Rather, they should be arrayed on a continuum, with profits set in proportion to the benefits and costs just listed.

This activity is essential because nothing close to a genuine free market exists to reward research.

One clear step should be to cease to reward copy-cat research. According to DiMasi, some 40 percent of pharmaceutical research today is imitative.[22] PhRMA claims that its members will conduct $23.6 billion worth of research in 2001.[23] If that claim is accurate and if 40 percent goes to copy-cat research, some $9.4 billion is probably being spent sub-optimally from the perspective of society.

Some would claim that copy-cat research is essential to generating competition, and that that is essential to holding down prices. Perhaps that is true in today's world (conceptually though not practically, since prices have not been held down very effectively). But holding down prices by regulation is much simpler. And $9.4 billion is accordingly made available to finance breakthrough research this year alone.

Others would claim that some copy-cat drugs could have superior efficacy or fewer side-effects. In these cases, their developers should profit in proportion to the additional value provided by the copy-cat medication.

In sum, one good way to promote breakthrough research is to pay for it generously, and to refrain from generously rewarding copy-cat research.

Another good way to promote breakthrough research is to subsidize it publicly through the National Institutes of Health. Such subsidies have long been very important to new drug development, and NIH funding has been rising rapidly in recent years. Public dollars often finance the riskiest share of the research. Drug makers should not profit from costs and risks borne publicly, but rather from their own efforts. In that way, effort and results are rewarded, not ability to capitalize on the accomplishments of publicly-financed research.

B. Containing Costs in Order to Keep Medications Affordable for All

The peace treaty described in Section V will make today's medications affordable for all. The research promotion just described will continue to spur the development of new breakthrough medications. The remaining challenge is to make tomorrow's medications affordable for all.

This is probably the knottiest job. No one tool will suffice. Although other approaches will probably be necessary as well, I suggest starting with these three tools:

1. Cut marketing waste

PhRMA does not, apparently, estimate or report its members' marketing costs. Instead, the drug makers cite an estimate from IMS Health that drug makers' marketing costs were only $13.9 billion in 1999. (This estimate is unnaturally low, since about one-half of it is the retail value of samples, which grossly exceeds their cost to drug makers.) The drug makers did report that their own research spending that year was $20.4 billion.

A more skeptical estimate puts marketing spending at $24 billion and research at $10 billion. This rests on an analysis of the allocations of drug makers' revenue published in manufacturers' financial reports. As shown in the following exhibit, 31 percent of drug makers' revenue went to marketing and administration, while only 11 percent went to research and development.[24]

Exhibit
How Six Drug Makers Spent Their Money, 1999

Marketing and administration	31%
Research and development	11
Production	32
Taxes	6
Other	4
Profit	16

The truth may well be somewhere between the two sets of estimates. Clearly, more accurate information and analysis is required to resolve conflicts and inadequacies plaguing some of the currently available data.

But one piece of evidence is clear—the drug makers' marketing employment soared by 57 percent between 1990 and 2000, while its research employment rose by only 10 percent, as shown in the following exhibit.

Exhibit
PhRMA Members' Marketing and Research/Development Employment, 1990 and 2000

Type of employment	1990	2000	% change
Marketing	56,014	87,810	+56.8%
Research and Development	43,952	48,527	+10.4%

In today's world, drug marketing aims to maximize company profits. Drug makers rely on their current marketing techniques, despite their high cost, because these techniques pay off in higher sales. But it is far from clear that the nation's patients are getting their money's worth. Often, new medications are being widely marketed, advertised, and sold even though they are much costlier than older medications they replace—and without adequate evidence that they are markedly more effective.

This may be good for drug makers but it is not good or affordable for patients. At some point, it will probably be necessary for the federal government and the drug makers to negotiate simple and enforceable limits on marketing and advertising expenditures.

2. Carefully evaluate the efficacy of each medication and compare efficacy with cost, and disseminate the results to physicians and patients.

If marketing becomes much less important, how will physicians and patients learn about which drugs might be helpful, and whether they are worth the money?

This function should probably be performed by a research office in the National Institutes of Health or the Food and Drug Administration, or possibly by a separate non-governmental non-profit research corporation. Objective evidence on efficacy should be compiled, along with the information needed to calculate a fair return on a drug maker's investment in a new medication. The objective evidence should be disseminated to all physicians, along with recommendations from expert panels of physicians and scientists regarding which medications are effective and efficient in treating various ailments.

We can marshal the huge sums now badly spent on marketing, and recycle them to finance the job of collecting and disseminating this objective evidence.

Any public agency charged with this work must be insulated politically. It cannot be influenced by pressure from cost-cutters to downgrade its assessment of the value of a new drug in order to reduce public spending. That would undermine citizens' trust. We should not substitute information from a public agency motivated to hold down spending for information from drug makers motivated to increase spending. This consideration might argue for relying on an independent non-profit corporation.

3. Give more careful thought to what constitutes fair profits for drug makers

As my colleague and I have noted,[25] drug makers' reported profits have been extraordinarily high since at least the 1970s. The data in the following exhibit indicate that the prescription drug industry's return on equity in 1999 of 35.6 percent was 2.21 times as great as the 41-industry median of 16.1 percent. And the prescription drug industry's return on revenue of 18.6 percent was 3.58 times as great as the 41-industry median of 5.2 percent.[26]

Exhibit
Prescription Drug Industry Returns on
Equity and Revenue Compared with 41-Industry Median, 1999

	prescription drugs	41-industry median	Rx/41-industry ratio
return on equity	35.6%	16.1%	2.21
return on revenue	18.6%	5.2%	3.58

The profits that drug makers actually garner by manufacturing and selling prescription drugs may be substantially higher than those they report overall. It is important to be clear that, in making this statement, I am not in any way suggesting that any drug maker has done anything remotely improper. Corporations report corporation-wide financial results.

For example, my colleague and I examined Merck's profits as a percentage of revenue (the only measure that could be calculated) after factoring out the relatively low returns on revenue of its Medco PBM subsidiary.[27]

Merck reports a consolidated 1999 income before taxes of $8,619.5 million on revenue of $32,714.0 million, for a before-tax return on revenue of 26.3 percent. This includes revenue and profit on Merck's large Merck-Medco segment. But how much did Merck make on its prescription drug business alone?[28]

The answer is that Merck garnered a 37.4 percent before-tax return on revenue on its prescription drug business. A brief glance through Merck's annual report did not reveal this number, though it may be there, somewhere. The 37.4 percent return on revenue is more than two-fifths greater (42.2 percent greater) a return on revenue than the consolidated 26.3 percent of revenue that Merck reports overall. The calculations are shown in the exhibit that follows.

Exhibit
Merck Pharmaceutical Segment's Revenues and Profits, CY 1997–1999
($ millions)

	1997	1998	1999
1. Segment revenue	$12,122.20	$12,839.90	$14,418.70
2. Segment profit	$7,396.20	$7,367.30	$8,495.40
3. Less *all* unallocated costs	$3,162.90	$2,370.20	$3,109.10
4. Segment profit after unallocated costs	$4,233.30	$4,997.10	$5,386.30
5. Segment profit as % of segment revenue	34.9%	38.9%	37.4%

Source, Merck & Co., Inc. 1999 Financial Report, p. 55.[29]

Drug makers say they need high profits to finance research. But profits do not finance research. The profits that they report—and that are so far above those of other industries—are the sums left over *after* they pay for research, manufacturing, marketing, advertising, administration, taxes, and other costs.

Finally, the drug makers are not willing to identify a ceiling on their profits or revenues—the level of profit or revenue beyond which no more money is needed to finance useful research. Similarly, the drug makers are unwilling to identify any floor on their profits or revenues—the level below which vital research would suffer. Their position is simple: more money (for themselves) is better. That would make sense only if the drug makers operated in a competitive free market. They do not, as discussed earlier.

For all these reasons, it will be necessary to investigate, debate, and negotiate the level of profit required to induce drug makers to retain their motivation to innovate and produce breakthrough drugs.

VIII. LEARNING FROM THE EVOLUTION OF STATE PRESCRIPTION DRUG POLICY

Examining the evolution of states' prescription drug policy in recent decades may enlighten future federal action. States' first phase was paying for drugs. Their second phase is holding down prices.

All state governments began paying for prescription drugs on a large scale through their Medicaid programs. Many others followed with special pharmacy programs to subsidize drug purchases for citizens who did not qualify for Medicaid, usually for seniors.

In the past few years, many states have realized that soaring drug costs were raising the costs of both of these activities to troubling levels.

States therefore moved from financing to price controls Maine legislated an innovative price control law. Vermont sought to cover more citizens under the umbrella of its Medicaid rebate. The drug industry has challenged these efforts in the courts. If the drug industry prevails, states will try other techniques, such as establishing themselves as sole buyers or wholesalers of drugs within their borders, thereby perhaps avoiding a possible Commerce Clause pre-emption of state action.

Thus far, some states have been motivated, politically, to respond to the crisis of high drug prices because state governments feel those prices directly and because, it appears, ordinary citizens who suffer from high drug prices have been able to make themselves heard by some state governments.

States can act to cut drug prices without worrying about the consequences for research. The federal government cannot do so.

The federal government has, in one way, already acted to protect itself against high drug prices by legislating low prices for the Veterans Administration and the military. Unlike other nations, however, the federal government has thus far protected mainly itself—not all citizens—against high drug costs.

High prescription drug prices are one of the main reasons many Americans cannot afford needed medications. High prices have spurred a number of complicated, sometimes well-intentioned, and usually ineffective responses, ranging from PBMs to formularies to higher co-payments to obtaining drugs from abroad.

High prices spur efforts to reduce use. But this can harm patients who would benefit from those drugs, and it flies in the face of the low incremental or marginal cost of those drugs.

Instead of cutting use in response to high prices, federal action should cut prices to Canadian levels, in order to facilitate higher use, as medically appropriate. This is best done as part of a comprehensive prescription drug peace treaty that protects the legitimate needs of patients, payors, and drug makers.

NOTES

1. PhRMA projects $121.7 billion in U.S. domestic sales in 2001 for ethical prescription drugs. Sold in the U.S. by U.S. and foreign members of PhRMA, these are overwhelmingly brand-name drugs for human use. Based on 1999 breakdowns, we calculate that 93.4 percent of this is for humans. Applying the 93.4 percent share to the $121.7 billion yields $113.7 billion. See Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile, 2001*, Appendix tables 11 and 12, *http://www.phrma.org/publications/publications/profile01/app__a2.phtml#table__11.* It is estimated that some 74 percent of the overall retail dollar goes to manufacturers. (See National Association of Chain Drug Stores, "The Facts about Prescription Drug Pricing," Alexandria, Virginia: NACDS, 1999 (unpublished draft), 3rd quarter 1998, chain drug stores only.) Applying this 74 percent share to the $113.7 billion yields $153.6 billion in retail sales of prescription drugs for humans. We round up to $165 billion to account for generics manufactured by non-PhRMA members. In 1998, spending on generics was 8.6 percent of the U.S. total. That figure was reported by the Generic Pharmaceutical Industry Association, "Generic Share of U.S. Market," Facts and Figures, *www.gpia.org/edu__facts.html,* but it appears that this site is no longer in operation.

2. This rests on the Health Care Financing Administration/CMS projection of 2001 total health spending of $1,424.2 billion. See Health Care Financing Administration, National Health Projections, Table 1, March 2001, *http://www.hcfa.gov/stats/NHE-Proj/proj2000/tables/t1.htm.*

3. This reflects our projection of U.S. population for 1 July 2001. The population estimate is built on the U.S. population reported in the 2000 Census and increases it by the average annual population rise from 1990 to 2000, and adds one-quarter of a year to move the estimate from 1 April to 1 July.

4. David J. Cantor, "Prescription Drug Price Comparisons: The United States, Canada, and Mexico," Washington: Congressional Research Service, Library of Congress, 23 January 1998; see also U.S. General Accounting Office, *Prescription Drugs: Companies Typically Charge More in the United States than in Canada,* Washington: The Office, 1992 (GAO/HRD–92–110).

5. Patented Medicine Prices Review Board, *Annual Report 2000,* Ottawa: The Board, 11 June 2001, Figure 8. The report expressed U.S. and other non-Canadian prices as percentages of Canadian prices; we calculated Canadian prices as a percentage of U.S. prices.

6. The low Canadian prices for brand name drugs are no aberration. Consider these nations' brand name drug prices as a percentage of U.S. prices in the year 2000:

Italy	52.9 %
France	55.2
Canada	62.5
Sweden	63.6
Germany	65.3
U.K.	68.6
Switzerland	69.2

Source: Patented Medicine Prices Review Board, *Annual Report 2000,* Ottawa: The Board, 11 June 2001, Figure 8.

7. Actual savings in a given state would vary slightly from those calculated here. That is because these calculations make three simplifying assumptions:

a) That prescription drug spending in 2001 is distributed among the states in the same proportions as reported by the Health Care Financing Administration's Office of the Actuary for 1998. (See United States Health Care Financing Administration, 1980–1998 State Health Care Expenditures Estimates, 29 September 2000, posted on-line at *http://www.hcfa.gov/stats/nhe-oact/stateestimates/*.)

b) That private insurance, Medicaid, and self-pay shares of the market are similar from state to state. These actually varying somewhat from state to state.

c) That discounts and rebates are shared evenly among the states; in reality, these also vary somewhat from state to state.

8. Personal communication from Hilda BenEzra (regarding Isaac Ben Ezra) to Deborah Socolar, 30 August 2001.

9. The last tactic would be useful only when drug prices are negotiated rather than regulated. I am indebted to John McDonough for mentioning this tactic, one that drug makers apparently employed when a U.S. state was considering obtaining medications from a Canadian province.

10. Generic Pharmaceutical Industry Association, *Facts & Figures.* See *www.gpia.org/edu.*

11. The United States government emphatically rejects PhRMA's claims that a free market legitimizes drug makers' prices, or that cutting prices is dangerous, by taking a 42 percent (or so) price discount for medications for the Veterans Administration and the military, and by taking an 18 percent (or so) rebate for the Medicaid program. This is the sort of thing foreign governments have long done for all their citizens.

We point to these six specific indicators of the absence of a free and competitive market:

1. Prevailing price disparities are themselves evidence of the lack of a free market for prescription drugs. While different payors today pay very different prices for the same drug, prices would tend to converge if there were a free market. In a free market, price competition would result in the same price throughout the market.

2. The drug industry's high U.S. prices—prices many times marginal cost of production—also suggest that nothing close to a freely competitive market is at work here. In a free market, prices tend to track marginal costs.

3. The industry's monopolistic (or oligopolistic) character in many sectors gives drug manufacturers tremendous power to set prices. Recent reports have documented that there is only limited competition within many major categories of medication. For example, in four important categories of drugs, the top-selling three drugs accounted for 71–90 percent of 1998 U.S. retail sales. (National Institute for Health Care Management, *Prescription Drugs and Intellectual Property Protection*, Washington: NICHM Research and Educational Foundation, 24 July 2000, p. 2, and p. 6, Figure 4, *http://www.nihcm.org/prescription.pdf.* Similarly, see Henry J. Kaiser Family Foundation, *Prescription Drug Trends: A Chartbook*, Menlo Park, CA: The Foundation, July 2000, p. 65, and p. 69, Exhibit 4.4, *http://www.kff.org/content/2000/3019/PharmFinal.pdf.*)

4. This power will grow as drug makers merge into fewer and larger corporations. ("Mergers Could Kill Competition for Drugs, Spur Price Hikes," Associated Press, 28 January 2000.)

5. Vertical integration—including Merck's control of a major PBM—is also a concern.

6. And allegations of such anti-competitive practices as suppression of generic competitors are further signs of continued monopoly and oligopoly. (See, for example, U.S. Federal Trade Commission, "FTC Charges Drug Manufacturers with Stifling Competition in Two Prescription Drug Markets," Press Release, 16 March 2000, *http://www.ftc.gov/opa/2000/03/hoechst.htm;* John Martin, "Conspiracy to Fix Drug Prices: Drug Makers Keep Generic Drugs Off the Market," 16 March 2000, *http://abcnews.go.com/onair/CloserLook/wnt_000315_CL_genericdrugs_feature.html;* Ronald Rosenberg, "Drug Makers Seeks Curb on Sale of Generic Cyclosporin," *The Boston Globe*, 7 April 2000; Michael F. Cannon, "Suppressing Generic Drugs Fleeces Consumers," Citizens for a Sound Economy Foundation *Issue Analysis*, No. 86, 25 February 1999; "The High Price of Drugs," ABC News, *20/20*, 23 July 1999, *www.abcnews.go.com/onair/2020/transcripts/2020_990723_drugs_trans.html;* and Sheryl Gay Stolberg and Jeff Gerth, "How Companies Stall Generics and Keep Themselves Healthy," *The New York Times*, 23 July 2000, *http://www.nytimes.com/library/national/science/health/072300hth-generic-drugs.html.)*

12. Cited in Deborah Baker (Associated Press), "Many in Southwest Lack Drug Benefits," *Albuquerque Journal,* 7 September 2000. Ms. Baroni was testifying before the New Mexico legislature's Health and Human Services Committee.

13. First, some market responses to predictions of lower drug prices suggest that high sales volumes would offset threatened price discounts. Three British drug companies' stock prices rose 3.4 percent (Glaxo), 2.3 percent (SmithKline Beecham), and 1.9 percent (AstraZeneca) following President Clinton's January 2000 State of the Union speech calling for a Medicare prescription drug program. " (Glaxo Leads UK Drugs up after Clinton Speech," *Dow Jones Newswires,* 28 January 2000.)

Second, we have seen earlier estimates of the price elasticity of demand for prescription drugs ranging from –0.10 to –0.64. (A price elasticity of demand of –0.10, for example, would mean that a 1 percent price cut for drugs would result in an offsetting 0.1 percent rise in volume of drugs purchased. The increase in volume, multiplied by the prices of the drugs purchased, would equal the replacement revenues garnered by the manufacturers in response to the lower prices.) Much of the empirical work on price elasticity of demand for medications rests on introduction of, or increases in, co-payments for prescription drugs. It is not clear how easily these findings can be generalized to price cuts, especially to substantial price cuts.

Third, a June 1999 Merrill Lynch analysis estimated that a 40 percent price cut for Medicare recipients lacking prescription drug coverage would result in a 45 percent volume increase for these individuals. (Merrill Lynch, "Pharmaceuticals: A Medicare Drug Benefit: May Not Be So Bad," Merrill Lynch, 23 June 1999.) That translates into a price elasticity of demand of –1.125. (A similar price elasticity of demand might also apply to the remainder of the 69 million or more Americans lacking prescription drug coverage.)

Merrill Lynch also estimated that the same 40 percent price cut would net out to a 25 percent price cut for Medicare recipients who have prescription drug coverage (because they already enjoy discounts estimated to average 15 percent), and that the 25 percent price cut would raise the volume of drugs purchased by 10 percent. We suggest that is a very conservative estimate of the increase in volume for Medicare recipients who have prescription drug coverage. Many recipients have very shallow coverage, such as a benefit through an HMO with a cap of $500 annually.

Even with that conservative estimate, the Merrill Lynch report concluded that, taking increased sales volume into account, a 40 percent price cut for Medicare beneficiaries would yield only a 3.3 revenue loss—or even a slight revenue gain.

Fourteen months later, Merrill Lynch continues to strongly espouse this general position. In August of 2000, Merrill Lynch's health care manager, Jordan Schreiber, has asserted that "Even with drug price cuts I think there's a good chance the pharmaceutical group will actually come out as a net beneficiary as the presently uninsured become customers, albeit less profitable customers." (Ian McDonald, "10 Questions With Merrill Lynch Healthcare Manager Jordan Schreiber," *TheStreet.com,* Fund Watch I, 14 August 2000, *http://biz.yahoo.com/ts/000814/fund1__000814.html.*

See also Beth M. Mantz, "Merrill's Tighe Sees $207.08B in '00 Global Drug Revs," Dow Jones Newswires, 25 September 2000.) Other Wall Street observers have recently concurred. (See Derrick Jackson, "Drug price cuts won't kill industry," *The Boston Globe,* op-ed, 22 September 2000.)

14. Once research is conducted and factories are built, it should not be very great. We estimate the marginal cost of additional volumes of medications at 5 percent of the retail dollar, or about 6.8 percent of the manufacturer's cost. (Taking the manufacturer's share of the retail dollar at 74 percent.) How can this be so low?

First, because producing the medications consumes a relatively small share of the average manufacturer's total revenues. In 1999, for example, only 32 percent of six large drug makers' revenues, on average, was devoted to acquiring raw materials and to manufacturing drugs. As this is the average cost, which includes substantial fixed costs for engineering, equipment, and workers, then the marginal cost of producing additional volumes will be substantially lower. Costs of raw materials are typically very low. One report noted that "the cost of the raw materials runs only a few cents in pills that often sell for up to $15 apiece." (Elyse Tanouye, "Drug Dependency: U.S. Has Developed an Expensive Habit: Now, How to Pay for It?" *The Wall Street Journal,* 16 November 1998.) A revealing example was reported recently. The vital ingredient for Xalatan, a successful medication to prevent glaucoma, costs only about one percent of annual sales. (Jeff Gerth and Sheryl Gay Stolberg, "Medicine Merchants: Birth of a Blockbuster; Drug Makers Reap Profits on Tax-backed Research," *The New York Times,* 23 April 2000.)

Second, private conversations with managers of drug factories have supported the 5 percent figure.

Third, the prices set by manufacturers of generic drugs are very much lower than those set by manufacturers of brand name drugs. A Mylan executive has asserted that her company sells two-fifths of its 104 products at prices equal to 10 percent (or less) of the prices charged by brand name manufacturers. (Patricia Sunseri, "FTC Antitrust Complaint vs. Mylan," 23 December 1998, *www.genericaccess.com/info.html.*)

15. See, for example,

First Clinton Plan: Associated Press, "Drug Stocks Soar in Light of Medicare Proposal," *The Boston Globe,* 30 June 1999;

CBO's estimates of cost of first Clinton plan: Robert Pear, "Budget Office Says Clinton Underestimated Cost of Drug Plan," *The New York Times,* 23 July 1999. Underestimates were attributed by CBO to faster growth in underlying drug costs, including drugs for nursing home residents (which should be a transfer from Medicaid to Medicare, thus result in no real increase in total federal plus state government costs), more low-income people expected to apply for federal aid in paying premiums and co-payments, and lower expected discounts won by PBMs in a federal program than in a private program.

Senate Democrats' Plan: Robert Pear, "Rival Medicare Drug Plans Are Both Ruled Affordable," *The New York Times,* 9 June 2001.

16. In only eight months from March 2000 to January 2001, CBO's projections for drug spending by or for Medicare beneficiaries during the decade from 2001 to 2010 rose from $1.1 trillion to $1.3 trillion under current law—without a prescription drug benefit. See Dan L. Crippen, "Laying the Groundwork for a Medicare Prescription Drug Benefit," Statement before the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, 27 March 2001, Table 2.

17. $318 billion divided by $1.3 trillion equals 24.5 percent.

18. Anjetta McQueen, "More Money Needed for Prescriptions," Associated Press, 16 May 2001.

19. It assumes the following:

Group of people	number in group	added brand name prescriptions/ person	total increase in brand name prescriptions annually
number of Non-Medicare uninsured	57,000,000	5	285,000,000
number of Non-Medicare underinsured	75,000,000	3	225,000,000
Non-Medicare subtotal			510,000,000
number of Medicare uninsured	13,843,148	15	207,647,225
number of Medicare underinsured	25,936,014	10	259,360,135
Medicare subtotal			467,007,360
Grand Total			977,007,360

20. Some 2.84 billion retail prescriptions were filled in 2000, a five percent rise from 1999. Another five percent rise in 2001 would mean 2.98 billion prescriptions in 2001. (National Association of Chain Drug Stores, "Facts at a Glance," *www.nacds.org/wmspage* provided 1999 and 2000 data.) And the 977 million increase divided by 2.98 billion equals 33.4 percent.

21. The average price of a brand name retail drug in 2001 is estimated at $70.27, making for an estimated incremental cost of $3.51, with the increment estimated at five percent of retail. The $70.27 average price was calculated by applying the 1999 to 2000 rate of increase in price to the average price in 2000. National Association of Chain Drug Stores, "Facts at a Glance," *www.nacds.org/wmspage* provided 1999 and 2000 data.

22. Cited in Merrill Goozner, "The Price Isn't Right," *The American Prospect,* Vol. 11, No. 20, 11 September 2000, *http://www.americanprospect.com/archives/V11-20/goozner-m.html.* Goozner also reports that "FDA statistics for the 1990s suggest that about half of the industry research is aimed at developing me-too drugs."

23. Pharmaceutical Research and Manufacturers of America, Pharmaceutical Industry Profile, 2001, Appendix Table 1, *http://www.phrma.org/publications/publications/profile01/app__a1.phtml#table__1.*

24. The data were compiled from an opportunity sample of seven large drug companies (now merged into six) whose financial reports were readily on-hand. The drug makers are Merck, Pfizer plus Warner-Lambert (which have merged), Bristol-Meyers-Squibb, American Home Products, Lilly, and Schering-Plough. We are grateful to Robert DeNoble for his careful work in compiling and reducing the financial data. The firms' combined 1999 revenue was $114.8 billion. The firms are generally representative of the industry.

25. Alan Sager and Deborah Socolar, *A Prescription Drug Peace Treaty: Cutting Prices to Make Prescription Drugs Affordable for All and to Protect Research:* Boston: Health Reform Program, Boston University School of Public Health, 5 October 2000.
26. The prescription drug industry and other industries' data are presented in *http://www.fortune.com/fortune/fortune500/medians.html.* We calculated the 41-industry median at the mid-point between the 20th- and 21st-ranked industries on each list of 41 industries.
27. Alan Sager and Deborah Socolar, "Prescription Drug Spending Is Already Enough to Buy All the Drugs All Americans Need," Session on Cutting Drug Prices and Expanding Coverage—Federal and State Efforts, Health Equity and Public Hospitals Caucus, American Public Health Association, Monday 13 November 2000.
28. *Merck & Co., Inc. 1999 Financial Report,* p. 42.
29. Note: Unallocated costs are "indirect production costs, research and development expenses and general and administrative expenses, all predominantly related to the Merck pharmaceutical business, as well as the cost of financing these activities."
We calculated these unallocated costs by starting with before-tax profits reported for all segments (which do not reflect those costs not allocated to any segment) from p. 55 of the Financial Report, and subtracting before-tax profits reported on the consolidated income statement (which reflect all costs). See *Merck & Co., Inc. 1999 Financial Report,* pp. 42 and 55.

Senator DORGAN. Dr. Sager, thank you very much.

I regret that we are running out of time due to other commitments this morning, but I want to ask just a couple of brief questions. First of all, I think the testimony of this panel has been excellent and provides some interesting perspective about this issue from a range of different points on the compass.

Let me ask you, Ms. Powell, you have heard the testimony that preceded yours by the FDA. The question that was left hanging was, do the Canadians, and speaking specifically now about Canada, do the Canadians have a regime of safety and quality assurance and chain of custody that should make consumers feel comfortable? So let me ask you that question because your industry sells a substantial amount of products into Canada and markets a substantial amount of prescription drugs in Canada.

Do the Canadians, in your judgment, give us reasons to worry about the safety of their prescription drug supply?

Ms. POWELL. Senator Dorgan, I know that the equivalent of FDA, the agency of that reviews and approves or denies marketing for prescription drugs in Canada, uses fairly similar processes for determining safety and effectiveness. I, however, do not know what the distribution system is within Canada. I would be happy to do some research and get back to you, but I don't know how the Canadian system insures that the product sold by the manufacturer in fact gets to the pharmacy through a chain of custody, I don't know what their chain of custody system is. I would be happy to get back to you on that.

Senator DORGAN. We will ask a number of groups to determine that. Mr. Giroux, you run a pharmacy south of the border, so I assume you know what is happening north of the border. Do Canadians have reasons to worry about the safety of their drug supply?

Mr. GIROUX. In my judgment, clearly not. I think there is no difference between the Canadian system and the U.S. system. If you look at any one of these products, they are clearly sealed from the manufacturing plant and in all likelihood the bottles are identical, as you have already pointed out. They are coming from the same plants, from the same machines, and they are sealed in these packages with a slightly different label for the Canadian identifier when shipped to Canada.

And as all pharmacists do with any product that comes into our doors, when we open the package, it has to be sealed. If it isn't, it goes back.

Senator DORGAN. Are there common distributors between, for example, a Canadian drugstore north of the New York line and your drugstores, are you buying from common distributors?

Mr. GIROUX. There are several of the larger wholesalers who do have facilities in Canada and as I mentioned, probably they are already potentially taking advantage of this. I don't know.

Senator DORGAN. So is it likely the chain of custody is probably almost identical from a manufacturing plant to the same distributor to the drugstore in Canada as to your drugstore? So it would be an identical chain of custody?

Mr. GIROUX. Absolutely. And I think the example that the gentleman from FDA used in terms of the counterfeit, which I think is a somewhat unrelated issue, but he used an example of a product that was actually adulterated in Long Island, New York and shipped to Chicago. It had nothing to do with the Canadian drug distribution system. That can happen in any chain of distribution, not necessarily from Canada to the U.S. I would be totally confident and comfortable buying these products from a Canadian supplier. They are sealed, they are intact, if they weren't, we wouldn't buy it, plain and simple.

Senator DORGAN. Dr. Sager, your testimony was interesting because it mentioned some new and interesting approaches, some of which may be unable to be dealt with by this Congress, but several of you have talked about the need to put a prescription drug package in Medicare. I certainly agree with that and feel strongly that we should do it. However, if we do that, and we are oblivious to the issue of cost, and we see cost increases of 16, 18, 19 percent a year, which includes both utilization and price inflation, we are just going to break the bank.

I think what we have to do is address both issues. We need to put a prescription drug program in the Medicare program, but we need to find ways to put dominant pressure on prices to the extent that we can. That is the reason this reimportation issue is important. Let me reemphasize that my end goal is not to ask people to leave this country to go elsewhere to purchase prescription drugs. My end goal is that if the distributors and pharmacists can do that, the pharmaceutical manufacturers will understand and will reprice their product in this country. That is the end stage of this whole thing.

Mr. Marvin?

Mr. MARVIN. Senator, our people in Maine clearly understand that the U.S. Government is involved in the Medicare program negotiating with the prices for hospitals, they're involved in the Medicare program negotiating prices with doctors, they are involved in the Medicare program negotiating with virtually every aspect of medicine except prescription drugs. And our people in Maine are wondering what's so sacrosanct about the drug industry that it should be exempted from dealing with the U.S. Government as a negotiator on behalf of citizens as opposed to all the other aspects of the Medicare program.

Senator DORGAN. Ms. Powell, do you want to answer that?

Ms. POWELL. We support a federal Medicare drug benefit. However, we believe it can most effectively be administered through the private sector and there are a variety of models for that kind of program, where the federal government is not the sole purchaser of the medicines, but the federal government provides support for seniors having access to prescription medicines.

For example, within the Federal Employee Health Benefit program, the federal government pays for Federal employees' drugs but it does not negotiate a price for drugs, it contracts with healthcare providers and we think that Congress should look at a variety of those kinds of approaches to providing the drug benefit. But I certainly would echo that a Medicare drug benefit is needed.

Ms. WENNAR. A couple points I would like to make here. First, the private side, let's not forget, they to are having some difficulty with prescription drug supplies. Even the largest of payers, Wellpoint in California, have told us that it's breaking the bank, and they are fairly large in terms of negotiating power, and so I think, don't be fooled into a false sense of security that by going to the private sector that you are going to see this problem resolved.

And I do agree that prescription drugs do need to be covered under Medicare because they are critical, as I pointed out, on the provider side, the technology is now here to stay in the form of a pill and it is going to continue to grow that way.

I think our concern is that you have to figure out how to have access to affordable prescription drugs before you cover it under Medicare because if you go out there and you cover it, and you can't control the cost, you very well, as you pointed out, might have a major issue.

The other thing is, I would like to just pose a question. I mean, I have heard a lot discussed around quality. You know, just consider it this way on this side. The FDA does not monitor samples in physicians' offices last I checked. They don't check the temperatures, they don't check the storage. They don't take any consideration in terms of looking at things. I don't know whether they have the authority to or not, but a lot of medication is being dispensed in the form of samples, and nobody monitors that.

Why would you be any more concerned about the prescription drugs coming in the manufacturer's bottle from Canada than you would be concerned about physicians giving samples out?

Ms. POWELL. I'm going to disagree with you, because there is legislation. FDA, because of the 1998 statute, has extensive regulations that control the entire process of sample distribution, so I think it's not correct to say that those are not controlled. Let me point out——

Senator DORGAN. We were not talking about control, we are talking about whether in practice and whether as a matter of fact you have FDA inspectors going out and inspecting samples.

Ms. POWELL. My understanding is that FDA is authorized to monitor the process of samples throughout the distribution system.

Senator DORGAN. But I am wondering if they do or not.

Ms. POWELL. That I don't know, but I know that they are authorized to.

And I would also like to point out that samples constitute more than 50 percent of the administration and marketing costs that Mr. Sager refers to, and samples are one of the mechanisms that manufacturers have used, along with their voluntary patient assistance programs, to address the problems of people who do not have insurance for prescription drugs, and they are one of the ways that I know doctors deal with seniors who do not have access to insurance.

But we think a more efficient way is through a Medicare drug benefit.

Senator DORGAN. Dr. Sager, from an academic standpoint—first of all, I appreciate the work you have done, your testimony is very interesting as is all the testimony here—from an academic standpoint you heard me suggest that if we cannot do it the way we want to do it, then we will legislate the first step by dealing with Canada only. Does that make sense to you?

Dr. SAGER. Well, I think it addresses some of the issues that people have been complaining about, yes, but I'm still worried about what I think is the likely response of drug manufacturers, which will be to limit the supply available to Canada for reimportation.

Senator DORGAN. That was my next point. You assume, and I assume, that pharmaceutical manufacturers are making a profit with those drugs they sell in Canada, do you not agree?

Dr. SAGER. Right.

Senator DORGAN. If they are making a profit and limiting supply, it seems to me they would be shooting themselves in the foot. But having said that, having observed that, can I ask again from your standpoint, would you submit for the Subcommittee your analysis of methods by which the industry could thwart what we do?

Let us assume that we can pass a piece of legislation and get past the point of having HHS and FDA decide they are going to implement it. We have always understood that there are devices by which the industry can try to undermine the law. We have never gotten to that point because we have not been able to get through HHS at this point, but I think we are going to, and it would be helpful if you would, because you mentioned one approach, if you would give us from your standpoint as an academician, your thoughts about what approaches might be used by the industry that could undermine or thwart the intent of legislation like this.

Now having said that, I must adjourn this hearing because of other obligations, but let me make one additional point. I think this has been an interesting exchange of views. I think the testimony that all of you have brought today has given us a record that a number of us will use in various ways, and perhaps those who oppose what I am trying to do will use it as well.

I did not mention, and I should have, Senator Wellstone and Senator Johnson of South Dakota have been very active here in the Senate on this legislation, and I should have mentioned them.

It has been bipartisan, Republicans and Democrats, who are interested in doing something in this area.

Again, thank you for participating. I know some of you have come long distances today, but this is a very important issue, and we appreciate your attendance.

This hearing is adjourned.

[Whereupon, the hearing adjourned at 11:10 a.m.]

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