party can make and sell the drug while it is under patent protection.

It takes an average of 15 years and a half a billion dollars to create one of the blockbuster drugs. So we have to be careful. We must be able to continue to attract the private sector investment into committing to the research and development that has made the American drug development pipeline so successful. We jeopardize this with reimportation of drugs.

We can't just do what appears on the surface to be good but, in essence, could kill people and undermine our fundamental system of encouraging innovation and rewarding hard work.

How successful is pharmaceutical innovation in Canada? They have price controls, and nobody is going to invest the money into developing these lifesaving and cost-saving drugs over the long run in those countries with price controls.

This is another step toward price controls that will weaken one of the most important industries in America at a time when we just mapped the human genome, and we are at the point where we can actually create more lifesaving medicines.

When the value of American inventions is stolen, it is American inventors and American consumers who suffer. The United States cannot and should not allow free riders around the world essentially to force the American public to underwrite a disproportionate amount of the research and development that results in the next breakthrough product. On the surface it seems there's no harm if drugs obtained from outside the United States at prices lower than U.S. prices can be resold in the U.S.; presumably this could lower prevailing U.S. prices. But great harm can come from this. I can say that where nations impose price controls, the research and development we count on to bring us miracle cures is jeopardized.

How can we guarantee that foreign government price controllers will not set an artificially low price on some new badly-needed Alzheimer's or Parkinson's or Lupus drug? We can be sure that this will have the unintended, but real, effect of convincing company officials to forgo research on this new class of drugs for fear that, in conjunction with the new liberal re-import policy, they will not be able to recoup their investment?

Let's stop the free riders and cheap riders overseas while American citizens are paying the full freight of R&D. Look, I understand the appeal of bringing goods sold cheaper abroad back to the United States at presumable savings to U.S. citizens. Yet, the amendment provides no guarantee that those wholesalers and pharmacists importing the products would pass their savings on to the consumer. And so, at best, with this bill we could be trading public safety for middleman profits.

We would also incur far more costs policing this endeavor. The cost of implementing the Dorgan bill would require very substantial resources at a time when we are stretching our funding to HHS and other federal departments to prevent future terrorist incidents.

We have to find a way around this drug access problem in this country without creating a public health hazard and ''gray market''.

We will be importing not just drugs but some other government's questionable safety standards and price controls into U.S. market dynamics.

In our valid and justified quest to help make drugs more affordable to the American public, we would be mindful not to unwittingly impede innovation.

Even the Dean of the House, Representative JOHN DINGELL of Michigan did not support similar legislation in the past when the House Energy and Commerce Committee issued a report that concluded that ''the very existence of a market for reimported goods provides the perfect cover for foreign counterfeits.''

The concerns are relevant to the Dorgan bill that we are considering today.

In our haste to bring cheaper drugs to seniors and other needy Americans—an important and laudable goal—we risk making changes to key health and safety laws and changes in our innovative pharmaceutical industry that no one can afford. We must bring safe, effective drugs to Americans, and particularly seniors, through avenues such as the Tripartisan Medicare Bill.

We need to focus our efforts on passing a Medicare prescription drug benefit bill. We should not pass another feel-good drug reimportation bill before the election that we already know today will not and cannot be implemented after the election.

UNANIMOUS-CONSENT AGREEMENT

Mr. REID. Mr. President, I ask unanimous consent that at a time to be determined by the majority leader, following consultation with the Republican leader, the Senate may proceed to the consideration of Calendar No. 486, H.R. 5011, the Military Construction Appropriations bill; and that it be considered under the following limitations; that immediately after the bill is reported all after the enacting clause be stricken and the text of Calendar No. 479, S. 2709, the Senate committee-reported bill be inserted in lieu thereof; that debate time on the bill and substitute amendment be limited to a total of 45 minutes; with an additional 20 minutes under the control of Senator MCCAIN; that the only other amendment in order be an amendment offered by Senators FEINSTEIN-HUTCHISON, which is at the desk; with debate limited to 10 minutes on the Feinstein-Hutchison amendment; that upon the use or yielding back of time on the amendment, without further intervening action or debate, the Senate proceed to vote on adoption of the amendment; that all debate time, not already identified in this agreement, be equally divided and controlled between the chair and ranking member of the subcommittee or their designee; that upon disposition of the Feinstein-Hutchison amendment, and the use or yielding back of all time, the substitute amendment, as amended, be agreed to; the bill, as amended, be read three times, that Section 303 of the Congressional Budget Act be considered waived; and the Senate then vote on passage of the bill; that upon passage of the bill; the Senate insist on its amendment, request a conference with the House on the disagreeing votes of the two Houses; and that the chair be authorized to appoint conferees on the part of the Senate, without further intervening action or debate.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2001—Continued

The PRESIDING OFFICER (Mr. CARPER). The Senator from Mississippi.

Mr. COCHRAN. Mr. President, under the designation of the Senator from New Hampshire, I yield to the distinguished Senator from Louisiana, Mr. BREAUX.

The PRESIDING OFFICER. The Senator from Louisiana is recognized.

Mr. BREAUX. Thank you very much.

I thank the distinguished Senator from Mississippi who I think is preparing an amendment which will be offered later on in the debate on the whole question of importation of drugs, which in essence is the same amendment that 97 Senators voted for the last time we addressed this issue on the question of importation of drugs.

Let me mention, to start with, that I think the topic of the debate on how we can provide prescription drugs for all of our Nation's seniors is really the challenge that is before the Senate. We can get waylaid, or delayed, or sidetracked by saying we are going to fix the problem by opening our borders to imported drugs coming from foreign countries or from Canada. That is something we need to discuss. But it is certainly not, by any stretch of the imagination, going to solve the problem of prescription drugs for seniors until we come up with a comprehensive, across-the-board Medicare package that can guarantee insurance coverage for prescription drugs just as every Member of the Senate has when we buy prescription drugs. That is the type of plan we have. People compete for the right to sell us those drugs. We have a choice between the plans that best can serve our families' needs at the best possible price.

That is the type of system on which I think we should be working and, in fact, on which we are spending a great deal of time.

With regard to the specific issue before this body at the current time—the

question of importation of prescription drugs from our neighbors to the north in the country of Canada—the concern I have with that is guaranteeing, before you allow these drugs to come into this country, that they are going to be just as safe and just as real as the drugs we buy in this country which are certified by the FDA and tracked from the manufacturer all the way to the pharmacist and to the customer.

We had hearings just a week ago in the Senate Aging Committee where we discussed the issue of counterfeit drugs. We had U.S. Customs come in, we had the FDA Administrator come in, and give us information from their perspective about imported drugs coming from Canada or from other foreign countries. Here are some statements from the FDA about the issue of imported drugs.

It is not just a question of whether they are cheaper. Of course, they could be cheaper. I can get open heart surgery in Juarez, Mexico, a lot cheaper than I can get it at the Houston Medical Center. The question is, Is that the type of open heart surgery I want? The answer, from my perspective—and I think most Americans—is that it is not. I want it to be not just the cheapest price, I also want the best service.

The issue is not where you can get the cheapest drugs but where you can get drugs that are also affordable and are also the real thing.

It is estimated that about 8 percent of the drugs coming into the United States right now are counterfeit, and the projection is, if you open up the borders, that amount will increase greatly.

Here is what the FDA said when testifying before the Senate Aging Committee:

> For those who buy drugs overseas, we have been consistently saying that you are really taking a great risk. You certainly risk your pocketbook, but you may be risking your health, and you may even be risking your life.

FDA also said:

> Unapproved drugs and reimported approved medications may be contaminated, subpotent, superpotent, or counterfeit.

The final thing they said, which I think is significant because the argument is this is from Canada, and they are our friend, they are a democracy and not a third-world country, and it is all right to do it from Canada; we are not going to let you do it from Bangladesh, they said in our hearing:

> Throwing the door open to drugs purchased by individuals directly from Canadian sellers will encourage unscrupulous individuals to devise schemes using Canada as a transshipment point for dangerous products from all points around the globe.

It is not just going to be drugs manufactured in Canada that can penetrate our border under an importation policy but drugs manufactured in Colombia, manufactured in Bangladesh, and manufactured in some very unsettled parts of the world that can be transshipped through Canada and come into the United States.

Here is an example. I have a lot of examples. Some of our colleagues have held up two bottles and said: This bottle cost $350 in America, and this bottle of the same stuff cost $20 in Canada. That is fine, if it is the same stuff. The problem is when it is not the same stuff.

Here is an example of a product that is supposed to be an anti-inflammatory drug. This is great. This is a prescription drug. In this particular case, they took a white powder. They stamped the name of the product into the little bitty pills. You can't tell the difference in the pills. They put it in a blister pack and sold it as the drug Ponstan. The only problem is that it sure looks like Ponstan. The package looks like Ponstan. It has every word on it that the real thing has, and the dosage is the same in fine print. The pill is exactly the same. It has the name Ponstan stamped into it.

Here is what is really in it. When you analyze it, the yellow powder which they put in it, instead of being the real thing, ended up being stuff that could do grave damage. This happens to be boric acid, floor wax, and yellow, leaded highway paint. That is a heck of a thing to be able to do. Is this cheaper than the real stuff? Oh, yes, it is a lot cheaper. But I don't want to take a pill that says it is the real thing but is yellow, leaded highway paint which they pressed into these packages and sold.

Can they sell it a lot cheaper? Yes. I can sell it for 2 cents a pill. I don't care what I sell it for because it does not cost much to make yellow, leaded highway paint and sell it as a pill and take it across the border.

It is my understanding, in reading the legislation and amendment before this body, that you can immediately suspend importation, but after the fact, after they have exhibited a pattern of importation of drugs ''that is counterfeit or in violation of [these] requirement[s] . . . or poses an additional risk to the public health.'' After we determine that it is being done, then you can stop it from being done.

Isn't it better to have to have that certification up front before we allow them to start bringing things over the border that may be real or may not be real; may be half real and half not real? Shouldn't we establish what the rules are before we let them in?

The Senate has discussed and debated that issue. And by a unanimous vote, every single one of us who voted on this issue before supported the Cochran amendment, 97 to 0, that said, before we can allow it to start coming in, we have to have a system in place that is guaranteed by our Food and Drug Administration that it is coming in and it is not counterfeited; it is safe; we have tracked the manufacturer and we know how they make it, what they are doing, and what is in the little packets of pills.

The legislation before the committee, I fear, now says that only after our Government determines that there is a pattern of counterfeiting or a pattern of bringing in drugs that pose a risk to the human health—then, and only then, can we suspend their operations.

Don't do it after the horse is already out of the barn. You have to stop it before it starts. How many people are going to have to take yellow, leaded highway paint before they can show there is a pattern of doing this in order to come in with a suspension of these importations? Do we have to have five people—to create a pattern—get sick from taking yellow, leaded highway paint? Do we have to have 100? I would not want to be 1 of the 100, if that is the establishment of what we have to do before we can suspend their operations.

It is far superior to take the approach: Yes, we will let you bring in imported drugs from Canada, but only if there is established, prior to the time it starts, a guarantee that these drugs can be brought in and are not counterfeit and are not harmful to your human health and are, in fact, not yellow, leaded highway paint.

Mr. DURBIN. Will the Senator yield for a question?

Mr. BREAUX. I am happy to.

Mr. DURBIN. Can the Senator tell me, in this particular instance, was this drug imported from Canada?

Mr. BREAUX. I am not sure where it was from.

The point I make is, Canada is our good friend, a civilized society, with high-quality manufacturers. But what Food and Drug says about Canada is the following:

Throwing the door open to drugs purchased by individuals directly from Canadian sellers will encourage unscrupulous individuals to devise schemes using Canada as a transshipment point for dangerous products from all points around the globe.

The PRESIDING OFFICER. The time of the Senator from Mississippi has expired.

Ms. COLLINS. Mr. President, I rise in support of the amendment offered by my colleague from North Dakota, Senator DORGAN, to allow for the reimportation of prescription drugs from Canada by pharmacists and wholesalers.

The United States leads the world in the discovery, development and manufacture of cutting-edge pharmaceuticals. Yet too many citizens who live in Maine and elsewhere must travel over the broader to Canada to buy the prescription drugs that they need to stay healthy for much lower prices than they would pay at their neighborhood drug store.

It is well documented that the average price of prescription drugs is much lower in Canada than in the United States, with the price of some drugs in Maine being twice that of the same drugs that are available only a few miles away in a Canadian drug store.

It simply does not seem fair that American consumers are footing the

bill for the remarkable, yet costly, advancements in pharmaceutical research and development, while our neighbors across the border receive these medications at substantially lower prices.

That is why I cosponsored legislation in the last Congress, the Medicine Equity and Drug Safety Act, to allow American consumers to benefit from international price competition on prescription drugs by permitting FDA-approved medicines made in FDA-approved facilities to be re-imported into this country. A modified version of that bill was signed into law last October, and I am extremely disappointed that the Department of Health and Human Services continues to refuse to implement the law.

I am therefore pleased to cosponsor this amendment, which will allow American consumers to benefit from international price competition in two ways:

First, it allows U.S. licensed pharmacists and drug wholesalers to import FDA-approved medications from Canada, which has a drug approval and distribution system comparable to ours.

Second, the amendment codifies existing U.S. Customs' practices that allow Americans to bring limited supplies of prescription drugs into this country from Canada for their personal use. That way, consumers who follow the rules won't have to worry that their medicines will be confiscated at the border.

While this amendment is a step in the right direction, it is not the solution to the prescription drug problem in the United States. I believe that our top priority should be to strengthen Medicare and include a prescription drug benefit, and I look forward to working on a bipartisan basis with my colleagues to give all Americans better access to affordable prescription drugs.

Mr. DORGAN. Mr. President, how much time remains for both sides.

The PRESIDING OFFICER. The Senator from North Dakota controls 7½ minutes.

Mr. DORGAN. Is that total time?

The PRESIDING OFFICER. Total time.

Mr. DORGAN. I yield 3 minutes to the Senator from Vermont.

The PRESIDING OFFICER. The Senator is recognized for 3 minutes.

Mr. JEFFORDS. Mr. President, it is not often I disagree with my good friend from Louisiana, but when you come from a northern State such as Vermont, and when you see what is happening, and you are buying a drug from a drugstore, which is certified under Canadian law, which is just as strong as ours, and you can pay half the price for it—to say you cannot go across the border to do that just does not make any common sense.

The real threat as far as drugs coming into this country, because of the disproportionate pricing, is the utilization of the Internet. That is where the problems are. On the Internet there is no checking, and you can order your drugs over the Internet. That is where you ought to look to try to prevent sales coming into this country. And that is wide open now.

When I was chairman of the committee that put together the pharmaceutical bill, we worked carefully with the FDA to make sure that when this bill passed, it gave them authority for sales across the border, and that they would have full authority to make sure that any sales are stopped that should not be allowed under the law. So I think the statements that are being made now just do not fit the reality of the situation.

To deny our people the ability to purchase these drugs, under a safely designed plan, which the FDA has the authority to approve, to make sure there is no counterfeiting or unlawful sales—it is just without merit to say that we need the protection there. It is there. We did that before. We passed it by a large vote, I believe, and put it into law. But the Secretary had authority not to let it go forward. And under the previous administration, that happened.

So what we should do now is pass this bill to allow our people the opportunity to get good pharmaceuticals that are not overpriced, which are safe and available. I think all the comments to the contrary are missing the point and missing the bill.

This amendment will allow pharmacists and wholesalers to import safe, U.S.-made, FDA-approved lower-cost prescription drugs from our neighbor to the north—Canada. This amendment will do nothing to undermine the gold standard of safety in this country because our northern friends have virtually the same standards. What this amendment will do is rein in the platinum standard we have for prices we pay for our medicines.

Prescription drugs have revolutionized the treatment of certain diseases, but they are only effective if patients have access to the medicines that their doctors prescribe. The best medicines in the world will not help a person who cannot afford them.

Americans pay by far the highest prices in the world for prescription drugs, and for many the prices is just too high. What's worse is that those Americans who can least afford it are the ones paying the highest prices. Americans who don't have health insurance that covers drugs are forced to pay the ''sticker price'' off the pharmacist's shelf.

It is sad that during a time when the United States is experiencing economic problems and higher unemployment it is becoming more common to hear of patients who cut pills in half, or skip dosages in order to make prescriptions last longer, because they can't afford the refill.

This is not about the Medicare benefit that we will also have an opportunity to debate later. But this too is a tripartisan effort. And, it is equally important because this will effect all Americans—not just our Medicare seniors. The question that we must ask is, can we put politics aside and work in a nonpartisan manner to deal with this national crisis? I say we must. And I am hopeful that today we can.

This amendment is based on legislation I introduced in the last Congress, the Medicine Equity and Drug Safety Act. Then, as now, we were joined by my friends Senators DORGAN, SNOWE, WELLSTONE, and COLLINS. I am also glad to see that this year our group has been joined by Senator STABENOW and Senator LEVIN. That measure passed on an overwhelming vote of 74 yeas to 21 nays. It is time for us to take that vote again, and again pass this legislation.

This amendment has been substantially revised to address the concerns over safety that have been raised.

Two key elements. First, the FDA approved drugs can only be brought in from Canada. These are the same drugs that are currently being brought in under existing FDA policy. There have been no reports of adverse events, poisonings or counterfeit by the senior citizens taking buses to Canada. In addition, it gives the Secretary the authority to suspend this program should these safety issues arise.

I would also point out to my colleagues that this amendment specifically authorizes FDA to incorporate any other safeguard that it believes is necessary to ensure the protection of the public health of patients in the United States.

It is important to remember—these are exactly the same drugs that have been approved by the FDA except they are sold for far less.

Why is it that Canada and the rest of the developed world pays less for drugs than the U.S. It is because drugs are somehow exempt from the laws of the open market and free trade. And for that reason we have been subsidizing the rest of the world, in spite of the fact that we have U.S. citizens going without health care and without the medicines they need.

Why should Americans pay the highest prices in the world for prescription drugs? All this amendment does is allow international competition to bring rational pricing practices to the prescription drug industry. It introduces competition which is the hallmark of our success in this Nation.

I want the record to clearly reflect that I still feel strongly that Vermonters should not be in violation of Federal law if they go a few miles across the border into Canada to get deep discounts on prescriptions. We do nothing in here to indicate they should not be allowed to do so.

This amendment will provide equitable treatment of Americans, particularly those who do not have insurance, or access to big discounts for large purchases like HMOs. This is not the only solution. I strongly believe we need a good competitive prescription drug benefit in the Medicare program. And I

look forward to working with all of my colleagues to develop a balanced, generous prescription drug benefit that can be supported by Members from both sides of the aisle.

But right now, this is a commonsense measure that we can enact now to ease the burden of expensive prescription drugs on our people, for those on the borders, and all Americans.

I yield the remainder of my time.

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. DORGAN. Mr. President it is unusual we have a real debate on the floor of the Senate. I think it is interesting to do so. It is also interesting to listen to the debate and see the tactics we have heard about terrorists, terrorism, heart surgery in Tijuana, everything but poppy seeds from Afghanistan—yellow highway paint from somewhere around the world. He is not sure where it comes from.

Well, he just won a debate no one is having. It is the easiest debate in the world to win. Congratulations.

The real subject, however, is vastly different than the presentation you just heard. This is about FDA-approved drugs, only FDA-approved drugs produced in FDA-approved manufacturing plants, moved across the border by licensed pharmacists and licensed distributors, and only those.

Apparently—obviously—the pharmaceutical industry does not like what we are doing here. I understand that. And I understand why people stand up and say the pharmaceutical industry does not want this to happen.

But what they are saying is, it is OK for the manufacturers to move prescription drugs back and forth across the border—and they do; they do a lot of it every day—but it is not appropriate for licensed pharmacists or distributors to do so.

Why is it we trust the manufacturers so much more than the Main Street pharmacists? Tell me about that, if you will. Why is one trustworthy and the other untrustworthy. And is it not the case that there might be a price differential, I say to my colleague from Louisiana, between the United States and Canada?

It is a fact that there is a very substantial price differential, and that the American consumer is charged the highest prices in the world for the identical prescription drug.

There is a lot of fog in this debate and very little light. We are talking about something very simple. We are not talking about counterfeit drugs or adulterated drugs. We are not talking about terrorism. We are talking about very careful circumstances under which a licensed pharmacist or distributor goes to Canada, which has a chain of custody that is similar to ours, accesses the identical prescription drugs that are FDA approved, brings them back across the border, and passes the savings along to the American consumer.

Why don't the pharmaceutical companies like that? Because it will force them to reprice their drugs in this country. It will force down drug prices to the U.S. consumer. That is why they do not like that.

I renew the question I have asked time and time again, for which no one in this Chamber has an answer—no one. Why should American citizens have to go to Canada to get a fair price on a prescription drug that was manufactured in the United States?

There is no answer to that in this Chamber. No one has attempted an answer. What we have seen is a discussion about——

Mr. SANTORUM Will the Senator from North Dakota yield for an answer?

Mr. DORGAN. I have very limited time. I am sorry.

Mr. SANTORUM. I would be happy to answer at some point.

Mr. DORGAN. The Senator will have ample time to answer the question. I will inquire when he does so.

In the minute or so I have remaining, let me say this: This is life or death for a lot of people, this issue of prescription drug pricing. Yes, we need to put a prescription drug benefit in the Medicare Program. I support that strongly. But if we do not do something to put downward pressure on prescription drug prices, we will simply break the bank, in my judgment.

That is why we need reimportation. And we need the generic amendment—the base bill. We need to do both of these things. I am not interested in compromising safety under any condition or any circumstance. This amendment is very simple. It says, in part, that the Secretary of Health and Human Services can suspend and will suspend and shall suspend the implementation of this reimportation if, in fact, there is a counterfeiting problem, or other problems such as terrorism.

The issue of counterfeit drugs that had been raised, the issue of terrorism, has nothing at all to do with this amendment. We are talking about licensed pharmacists, licensed distributors, FDA-approved drugs, FDA-approved plants—a system in which those from the U.S. who are licensed to do so can get the exact same prescription drug safely from Canada at much cheaper prices and pass those savings along to customers.

I understand we will have another amendment following the vote on this amendment. That amendment will have the effect of essentially making this provision unworkable. We will have to debate that at that time.

How much time remains?

The PRESIDING OFFICER. Twenty seconds.

Mr. DORGAN. I yield back my time.

The PRESIDING OFFICER. All time has expired. The question is on agreeing to amendment No. 4300 offered by the Senator from Nevada for the Senator from North Dakota.

Mr. DORGAN. Mr. President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second. The clerk will call the roll.

The senior assistant bill clerk called the roll.

Mr. NICKLES. I announce that the Senator from North Carolina (Mr. HELMS) is necessarily absent.

I further announce that if present and voting the Senator from North Carolina (Mr. HELMS) would vote ''no.''

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 69, nays 30, as follows:

[Rollcall Vote No. 179 Leg.]

YEAS—69

Akaka	Dorgan	Lugar
Allard	Durbin	McCain
Baucus	Edwards	McConnell
Biden	Feingold	Mikulski
Bingaman	Feinstein	Miller
Bond	Fitzgerald	Murkowski
Boxer	Graham	Murray
Brownback	Grassley	Nelson (FL)
Burns	Gregg	Nelson (NE)
Byrd	Harkin	Reed
Cantwell	Hollings	Reid
Carnahan	Inouye	Rockefeller
Chafee	Jeffords	Sarbanes
Cleland	Johnson	Schumer
Clinton	Kennedy	Sessions
Cochran	Kerry	Smith (NH)
Collins	Kohl	Smith (OR)
Conrad	Landrieu	Snowe
Craig	Leahy	Specter
Crapo	Levin	Stabenow
Daschle	Lieberman	Stevens
Dayton	Lincoln	Wellstone
Dodd	Lott	Wyden

NAYS—30

Allen	Ensign	Nickles
Bayh	Enzi	Roberts
Bennett	Frist	Santorum
Breaux	Gramm	Shelby
Bunning	Hagel	Thomas
Campbell	Hatch	Thompson
Carper	Hutchinson	Thurmond
Corzine	Hutchison	Torricelli
DeWine	Inhofe	Voinovich
Domenici	Kyl	Warner

NOT VOTING—1

Helms

The amendment (No. 4300) was agreed to.

The PRESIDING OFFICER. Under the previous order the Senator from Mississippi is to be recognized to offer an amendment.

The Senator from Mississippi.

AMENDMENT NO. 4301 TO AMENDMENT NO. 4299

(Purpose: To protect the health and safety of Americans)

Mr. COCHRAN. Mr. President, I send an amendment to the desk and ask that it be stated.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Mississippi [Mr. COCHRAN], for himself and Mr. BREAUX, proposes an amendment numbered 4301 to amendment No. 4299.

On page 15, line 17, strike ''section.''. and insert ''section,'' and insert the following new subsection:

''(2) CONDITIONS.—This section shall become effective only if the Secretary of Health and Human Services certifies to the Congress that the implementation of this section will—

''(A) pose no additional risk to the public's health and safety, and

''(B) result in a significant reduction in the cost of covered products to the American consumer.''.''

The PRESIDING OFFICER. The Senator from Mississippi.

Mr. COCHRAN. Mr. President, I support the effort to make prescription drugs more affordable for all Americans. However, I am concerned that creating new opportunities to bring counterfeit or dangerous drugs into the United States from foreign countries is not the way to do it.

The amendment I have sent to the desk on behalf of myself and the Senator from Louisiana, Mr. BREAUX, will provide an opportunity for the Secretary of Health and Human Services to make a certification that the reimportation of drugs from Canada will not jeopardize human safety, the consuming public who buys these drugs, and it will, in fact, lower the cost of prescription drugs for Americans.

I have also been asked to state that other Senators who want to be added as cosponsors to this bill are Senator ROBERTS of Kansas and Senator SANTORUM of Pennsylvania. I make that request.

The PRESIDING OFFICER (Mr. WELLSTONE). Without objection, it is so ordered.

Mr. COCHRAN. Mr. President, the amendment of the Senator from North Dakota could very well make it easier to avoid U.S. standards and inspections at a time when we are increasing border surveillance and trying to prevent acts of terrorism.

Two years ago, a similar amendment was added to the Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Act for Fiscal Year 2001. However, the Senate-approved language that I offered at that time required the Secretary of Health and Human Services to certify that implementation of the amendment would pose no additional risk to the public's health and safety and would result in a significant reduction in prescription drug costs for U.S. consumers.

Secretary of HHS Donna Shalala was not able to make such a demonstration as required by that law.

I ask unanimous consent that a copy of her letter to President Clinton dated December 26, 2000, be printed in the RECORD.

There being no objection, the letter was ordered to be printed in the RECORD, as follows:

THE SECRETARY OF HEALTH
AND HUMAN SERVICES,
Washington, DC, December 6, 2000.

Hon. WILLIAM J. CLINTON,
The White House,
Washington, DC.

DEAR MR. PRESIDENT: The annual appropriations bill for the Food and Drug Administration (FDA) (P.L. 106–387), signed into law earlier this year, included a provision to allow prescription drugs to be reimported from certain countries for sale in the United States. The law requires that, prior to implementation, the Secretary of Health and Human Services demonstrate that this reimportation poses no additional risk to the public's health and safety and that it will result in a significant reduction in the cost of covered products to the American consumer.

I am writing to advise you that I cannot make the demonstration called for in the statute because of serious flaws and loopholes in the design of the new drug reimportation system. As such, I will not request the $23 million that was conditionally appropriated for FDA implementation costs for the drug reimportation system included in the FY 2001 appropriations bill.

As you know, Administration officials worked for months with members of Congress and staff to help them design safe and workable drug reimportation legislation. Unfortunately, our most significant concerns about this proposal were not addressed. These flaws, outlined below, undermine the potential for cost savings associated with prescription drug reimportation and could pose unnecessary public health risks.

First, the provision allows drug manufacturers to deny U.S. importers legal access to the FDA approved labeling that is required for reimportation. In fact, the provision explicitly states that any labeling information provided by manufacturers may be used only for testing product authenticity. This is a major loophole that Administration officials discussed with congressional staff but was not closed in the final legislation.

Second, the drug reimportation provision fails to prevent drug manufacturers from discriminating against foreign distributors that import drugs to the U.S. While the law prevents contracts or agreements that explicitly prohibit drug importation, it does not prohibit drug manufacturers from requiring distributors to charge higher prices, limit supply, or otherwise treat U.S. importers less favorably than foreign purchasers.

Third, the reimportation system has both authorization and funding limitations. The law requires that the system end five years after it goes into effect. This ''sunset'' provision will likely have a chilling effect on private-sector investment in the required testing and distribution systems because of the uncertainty of long-term financial returns. In addition, the public benefits of the new system are diminished since the significant investment of taxpayer funds to establish the new safety monitoring and enforcement functions will not be offset by long-term savings to consumers from lower priced drugs. Finally, Congress appropriated the $23 million necessary for first year implementation costs of the program but did so without funding core and priority activities in FDA, such as enforcement of standards for internet drug purchase and post-market surveillance activities. In addition, while FDA's responsibilities last five years, its funding authorization is only for one year. Without a stable funding base, FDA will not be able implement the new program in a way that protects the public health.

As you and I have discussed, we in the Administration and the Congress have a strong obligation to communicate clearly to the American people the shortcomings in policies that purport to offer relief from the high cost of prescription drugs. For this reason, I feel compelled to inform you that the flaws and loopholes contained in the reimportation provision make it impossible for me to demonstrate that it is safe and cost effective. As such, I cannot sanction the allocation of taxpayer dollars to implement such a system.

Mr. President, the changes to the reimportation legislation that we have proposed can and should be enacted by the Congress next year. At the same time, I know you share my view that an importation provision—no matter how well crafted—cannot be a substitute for a voluntary prescription drug benefit provided through the Medicare program. Nor is the solution a low-income, state-based prescription drug program that would exclude millions of beneficiaries and takes years to implement in all states. What is needed is a real Medicare prescription drug option that is affordable and accessible to all beneficiaries regardless of where they live. It is my strong hope that, when Congress and the next Administration evaluate the policy options before them, they will come together on this approach and, at long last, make prescription drug coverage an integral part of Medicare.

Sincerely,

DONNA E. SHALALA.

Mr. COCHRAN. More recently, on July 9, 2001, a letter from the current Secretary of Health and Human Services, Tommy Thompson, indicated that based on an analysis by the Food and Drug Administration on the safety issues and analysis by his planning office on the cost issues, he could not make the required determinations, and he stated his view that we should not sacrifice public safety for uncertain speculative cost savings.

Secretary Thompson also indicated that prescription drug safety could not be adequately guaranteed if drug reimportation were allowed and that costs associated with documentation, sampling, and testing of imported drugs would make it difficult for consumers to get any significant price savings.

I ask unanimous consent that Secretary Thompson's letter be printed in the RECORD at this point.

There being no objection, the letter was ordered to be printed in the RECORD, as follows:

THE SECRETARY OF HEALTH
AND HUMAN SERVICES,
Washington, DC July 9, 2001.

Hon. JAMES JEFFORDS,
U.S. Senate,
Washington, DC.

DEAR SENATOR JEFFORDS: I am writing to follow up on my earlier response to your letter of January 31, 2001, co-signed by fifteen of your colleagues, regarding the Medicine Equity and Drug Safety Act of 2000 (MEDS Act).

You and other Senators and Representatives asked that I reconsider former Secretary Shalala's decision and make the determination necessary to implement the MEDS Act. As I mentioned in my prior communication, I asked the Food and Drug Administration (FDA) to carefully reexamine the law to evaluate whether this new system poses additional health risks to U.S. consumers, and the Office of the Assistant Secretary for Planning and Evaluation (OASPE) to examine whether the new law will result in a significant cost savings to the American public.

I believe very strongly that seniors should have access to affordable prescription drugs. I applaud your leadership in this area, and agree that helping seniors obtain affordable medicines should be a priority. However, as my earlier response stated, I do not believe we should sacrifice public safety for uncertain and speculative cost savings.

SAFETY CONCERNS

After a thorough review of the law, FDA has concluded that it would be impossible to ensure that the MEDS Act would result in no loss of protection for the drugs supplied to the American people. As you know, the drug system as it exists today is a closed system. Most retail stores, hospitals, and other outlets obtain drugs either directly from the drug manufacturer or from a small number

of large wholesalers. FDA and the states exercise oversight of every step within the chain of commercial distribution, generating a high degree of product potency, purity, and quality. In order to ensure safety and compliance with current law, only the original drug manufacturer is allowed to reimport FDA-approved drugs.

Under the MEDS Act, this system of distribution would be opened to allow any pharmacist or wholesaler to reimport drugs from abroad; this could result in significant growth in imported commercial drug shipments. As you know, the FDA and the states do not have oversight of the drug distribution chain outside the U.S. Yet, opening our borders as required under this program would increase the likelihood that the shelves of pharmacies in towns and communities across the nation would include counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired drugs, contaminated drugs, and drugs stored under inappropriate and unsafe conditions.

While the MEDS Act requires chain of custody documentation and sampling and testing of imported drugs, these requirements cannot substitute for the strong protections of the current distribution system. Counterfeit or adulterated and misbranded drugs will be difficult to detect, and the sampling and testing proposed under this program can not possibly identify these unsafe products entering our country in large commercial shipments.

I can only conclude that the provisions in the MEDS Act will pose a greater public health risk than we face today and a loss of confidence by Americans in the safety of our drug supply. Although I support the goal of reducing the cost of prescription drugs in this country, no one in this country should be exposed to the potential public health threat identified by the FDA in their analysis. Further, the expenditure of time and resources in maintaining such a complex regulatory system as proposed by the MEDS Act would be of questionable public health value and could drain resources from other beneficial public health program.

COST SAVINGS

The clear intent of the MEDS Act is to reduce the price differentials between the U.S. and foreign countries. The review of the Office of the Assistant Secretary for Planning and Evaluation (OASPE) concludes there are significant disincentives for reimportation under the MEDS Act, including the costs associated with documenting, sampling and testing, the potential relabeling requirements and related costs and risk associated with such requirements, the overall risk of increased legal liability, the costs associated with the management of inventories by wholesalers and pharmacists, and the risk to existing and future contractual relationships between all parties involved. Moreover, there are a number of reasons (including potential responses by foreign governments) why lower foreign prices may not translate into lower prices for U.S. consumers. Insufficient information exists for me to demonstrate that implementation of the law will result in significant reduction in the cost of drug products to the American consumer.

CONCLUSION

Since I am unable to make the determination on the safety and cost savings in the affirmative, as required under the law, I cannot implement the MEDS Act. Please find attached to this letter a more detailed analysis of the factors influencing the public-safety and cost-savings questions. If you need further clarification of my position on these issues, please do not hesitate to contact me.

Thank you for your leadership in health care. I look forward to working with you on new initiatives for making medicine more affordable to our citizens, and on other health issues of importance to our Nation.

Sincerely,

TOMMY G. THOMPSON.

Mr. COCHRAN. Even though the amendment being offered by the Senator from North Dakota, Mr. DORGAN, would apply under its terms only to drugs exported to and reimported from Canada, it would seem prudent that the safeguards we adopted 2 years ago by a vote of 96 to 0 should also be applied to this reimportation proposal. That is why I am offering this amendment.

We should be certain that any change we make results in no less protection in terms of the safety of the drugs supplied to the American people and will indeed make prescription drugs more affordable. Liberalization of protections that are designed to keep unsafe drugs out of this country, especially following the terrorist threats we face now, should occur only if the necessary safeguards are in place. This amendment will ensure that the concerns of the last two administrations regarding the safety and cost-effectiveness are addressed prior to the implementation of this proposal.

Currently, under the Federal Food, Drug, and Cosmetic Act, it is unlawful for anyone to introduce into interstate commerce a new drug that is not covered by an approved new drug application or an abbreviated new drug application. Approval must be sought on a manufacturer and product-by-product basis. A product that does not comply with an approved application, including an imported drug not approved by FDA for marketing in the United States, may not be imported, even if approved for sale by that country.

A product introduced into interstate commerce that does not comply with an approved application is considered an unapproved new drug in violation of the Food, Drug, and Cosmetic Act, as well as ''misbranded'' under the section of that act.

Under section 801 of the act, a drug that is manufactured in the United States pursuant to an approved new drug application and shipped to another country may not be reimported into the United States by anyone other than the original manufacturer. This prohibition on reimportation of products previously manufactured in the United States and then exported was added in 1988 to prevent the entry into this country of counterfeit and adulterated products.

Section 801 was enacted not to protect the corporate interests of pharmaceutical companies but to protect the safety of American consumers. Counterfeit drugs are a very real threat and can be deadly. Any liberalization of drug reimportation laws must assure safety from this threat. Limiting reimportation of drugs from Canada does not necessarily solve that problem.

During testimony before the Senate Finance Committee on March 7 of this year, the administrator of the Centers for Medicare and Medicaid Services, Tom Scully, was asked whether the administration opposes or supports the importation of prescription drugs into the United States. He said, and I quote:

> We have opposed it . . . there is no way for FDA to monitor and regulate drugs coming in from Canada, Mexico or other countries.

Others have told us there is no effective way to prevent transshipment of drugs from other countries into Canada and then into the United States. Limiting reimportation to Canada will only make Canada a port of entry for counterfeit and substandard drugs into the United States.

William Hubbard, who is FDA's Senior Associate Commissioner for Policy Planning and Legislation, told us at a September 5, 2001, hearing, before the Senate Consumer Affairs Foreign Commerce and Tourism Subcommittee, the following:

> Even if the Canadian system is every bit as good as ours, the Canadian system is open to vulnerabilities by people who will try to enter the U.S. market because, again, that is where the money is.

Last year, U.S. Customs and Drug Enforcement Administration officials testified before the House Energy and Commerce Committee that thousands of counterfeit and illegal drugs are already coming across our borders and through the mail from other countries. Far from supporting the reimportation proposals before Congress, these agencies recommended tightening our current regulations on reimportation of pharmaceuticals.

In a July 11, 2001, letter to the Energy and Commerce chairman and ranking member, William Simpkins, Acting Administrator of the Department of Justice Drug Enforcement Administration, who was referring to reimportation amendments, said the following:

> (W)e oppose . . . these amendments because they would hinder the ability of law enforcement officials to ensure that drugs are imported into the United States in compliance with long-standing Federal laws designed to protect the public health and safety.

On March 5 of this year, the New York Times in some articles explained that the illegal production in the United States of popular stimulants such as methamphetamine reflects lax regulation in Canada for the chemical ingredients. As a result, Canada has become the leading supply route for the raw ingredient into the United States where the substances are more tightly controlled. In the last 11 months, the U.S. Customs Service has seized more than 110 million tablets of decongestants that contain the primary ingredient for making methamphetamines, or speed, as smugglers attempt to bring shipments across the border in everything from furniture to glassware.

The article notes:

> An alliance of diverse organized crime groups, stretching from Mexico to Iraq to Jordan, have found Canada an easy entry point into a growing American market for synthetic drugs.

The Canadian Government concedes that they have relatively loose control on the powder used to make methamphetamine, which criminal elements have easily circumvented. According to an intelligence report by DEA and the Royal Canadian Mounted Police in January:

The diversion of pseudoephedrine from Canadian suppliers to the illicit market is reaching a critical level.

The FBI and DEA officials have tracked the profit trail to the Middle East where they are probing to see if it is being used to fund terrorist networks.

This amendment would also permit personal importation of drugs from any country. It is illegal to import unapproved drugs into the United States, but the FDA has for years, in the exercise of its enforcement discretion, allowed U.S. citizens to bring a 90-day supply of prescription drugs for their personal use. The reason for this policy is one of compassionate use. It was to allow patients with life-threatening or serious diseases to have access to non-FDA-approved therapies that are available in other countries. Under this policy, the patient affirms it is for his or her own use and provides the name and address of the U.S.-licensed doctor responsible for treatment.

The FDA has not officially permitted the importation of foreign versions of U.S.-approved medications because it has been unable to assure these products are safe or effective. In testimony before the Subcommittee on Oversight and Investigation in the House Committee on Energy and Commerce, in June 2001, William Hubbard of FDA indicated:

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 web site offer to prescribe medicines without a physical examination, bypassing the traditional doctor-patient relationship. As a result, patients may receive inappropriate medications because of misdiagnosis, or fail or 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.

The importation of personal use amounts by mail continues to increase according to FDA. A 5-week survey of mail in Carson City, California, conducted by Customs and the FDA in 2001 found serious public health risks associated with drugs intercepted. These included drugs that could not be identified because they had no labeling, drugs once approved by the FDA but withdrawn from the market due to safety concerns, and drugs that should only be used under the supervision of a doctor licensed to administer the drug.

In a letter to Congress last July, Mr. Hubbard indicated that the personal importation policy ''is difficult to implement'' partly ''due to the enormous volume of drugs being imported for personal use and the difficulty faced by FDA inspectors, or even health care practitioners, in identifying a medicine by its appearance.''

When I was discussing the amendment of the Senator from North Dakota, Mr. DORGAN, which we just approved, I told the story of how Senator KOHL and I had a meeting in Senator KOHL's office. We were anticipating a second amendment to the appropriations bill last year to find out more about the dangers and the difficulties our inspectors have at the border when dealing with imported prescription drugs. The Internet and mail resources, buying drugs here and there by mail, were another example of bypassing the inspections and bypassing the enforcement of a lot of U.S. regulations.

It is amazing the number of drugs that are now on the shelves in drugstores in America that are counterfeit and no one knows about it. These are difficulties that we now face. The proposal of this amendment by the Senator from North Dakota will further relax our capability to find illegal drugs, to find those drugs that are dangerous that are being brought into this country. It will create a new opportunity for transshipping drugs all over the world into our country which will be a great danger to the citizens of our country.

The conditions contained in my amendment, which would be added to the legislative proposal before the body, are the same as those previously adopted by this Senate and included in the 2001 Agriculture appropriations bill. They were adopted at that time by a unanimous vote of the Senate during our consideration of that appropriations bill. I ask my colleagues to again support this amendment.

The PRESIDING OFFICER. The Senator from Oklahoma.

Mr. NICKLES. I compliment Senator COCHRAN for his amendment. I ask unanimous consent to be added as a cosponsor of the amendment.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. NICKLES. Senator COCHRAN alluded to 2 years ago when we passed this amendment unanimously. He said if we are going to do it, let's make sure it does not impose significant additional risk on consumers, thereby saving money. I don't know why anyone would vote against that amendment. I hope no one will vote against this amendment. It is a very important amendment.

Let me make a couple of comments. Someone will ask, didn't we already do that in the Dorgan amendment which passed by a nice vote? The Dorgan amendment is full of loopholes. It says it would be suspended upon the discovery of a pattern of importation of prescriptions by the importer that is counterfeit or in violation of any requirement in this section. If this is the case, how many people will have to die before we realize there is a pattern? How many will realize those yellow tablets that Senator BREAUX was holding up are actually paint instead of maybe a lifesaving drug? How many patterns have to exist before we realize this really didn't work?

We have the FDA where we spend millions and millions of dollars inspecting, trying to make sure we have quality drugs for our citizens. We are just going to open up a gigantic loophole for unscrupulous manufacturers. I wish that were not the case, but if anyone travels anywhere in the world, they know it happens often. When you talk with our State Department about counterfeit drugs or copyright violations on software, they will tell you that it happens lots of time. Unfortunately, it should not happen. But we have a pretty closed system right now where FDA goes to great lengths to ensure the drugs coming into the United States are safe.

Last year, Senator DORGAN said, let's have it basically open ended coming from Canada and Mexico. Now we are just saying Canada. How safe is that?

My staff did some homework. Canada has a provision under the Canadian Food and Drug Act, section 37. It reads:

This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, If the package is marked in distinct overprinting with the word ''Export'' or ''Exportation'' and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner.

In other words, the Canadian Food and Drug Act does not apply to drugs brought in strictly for export. Canada can import drugs from Sudan and export them to the United States and they are not covered by Canadian Food and Drug regulations.

Yet Senator DORGAN's amendment says: Bring them on, bring them on. Our FDA people, our leaders, both past administrations as well as present administration, say we cannot do that safely.

Here is a letter that was addressed to Senator COCHRAN. It is an extensive letter that is critical of Senator DORGAN's approach. I will just read one paragraph:

The bill would actually create an incentive for unscrupulous individuals to find ways to sell unsafe or counterfeit drugs that, while

purporting to be from Canada, may actually originate from any part of the world. Canada could become a transshipment point for legitimate or nonlegitimate manufacturing concerns throughout the world, and in many cases we would not be able to determine the true country of origin. For all these reasons we find this provision would greatly erode the ability of the FDA to ensure the safety and efficacy of the drug supply and protect public health.

I could go on.

If Canada says we are not going to regulate drugs that are brought into Canada for export only, and we are saying wait a minute, Canada, we want to be able to import your drugs.

I listened to a lot of the debate. Almost every example that was given was of United States-manufactured drugs sent to Canada that are a lot cheaper in Canada than they are in the United States. There is nothing in Senator DORGAN's amendment that says these drugs have to be manufactured in Canada or the United States. These drugs could come from Sudan.

There was a pharmaceutical plant in Sudan that was bombed a few years ago. There are pharmaceutical plants all around the world. Some of them may have great quality controls, some of them may not. Some of them may be in terrorist states. Yet we are leaving ourselves wide open.

So I urge my colleagues——

Mr. SANTORUM. Will the Senator yield for a question?

Mr. NICKLES. I will be happy to, but I tell my colleagues I hope and pray the Cochran amendment will pass. If it does not pass, I will have an amendment that says the drugs that are covered should be of American or Canadian origin, manufacture, or control. American drugs are controlled. Even the drugs that we import, if they have FDA approval, we send FDA inspectors over to those plants to certify them. We have what is called a pedigree requirement to follow those drugs, to know where they are manufactured, know where they are distributed, before FDA puts their approval on them.

So we try to and do protect safety. We do not have that for all drugs that would be coming from Canada.

I would just mention there is a fatal flaw, in my opinion, in the Dorgan amendment we just adopted. One of those is that there has to be a pattern. If you look at the language of the amendment we just adopted, there has to be a pattern of importation from each importer.

That is too late when there are people who have already died, are already sick, when there are people who did not get cured because we waited for a pattern, we waited for evidence, we waited for unfortunate results—not to mention, there is no telling how many people would have been cheated out of money, and so on.

So I think the amendment we just adopted is probably not worth the paper it was written on.

I also find it kind of clever to think we had the original Dorgan amendment, then they had a second degree. They left out one paragraph, and then the second-degree was reinstating that one paragraph. I am guessing it was saying we will use this as a substitute for the Cochran amendment. That is a false and faulty substitute. It is not a satisfactory substitute.

The Cochran amendment—and I urge my colleagues to read it, and I cannot imagine anyone would oppose it—says:

> This section shall become effective only if the Secretary of Health and Human Services certifies to Congress that the implementation of this section (A) will pose no additional risk to public health and safety.

How could anybody oppose that?

And, second:

> . . . result in a significant reduction of cost of covered products to the American consumer.

We are all in favor of that. I compliment the Senator from Mississippi for his leadership on it this year and 2 years ago. As a result of the amendment of the Senator from Mississippi, we have saved lives and eliminated a lot of fraud and counterfeiting and abuse that would have transpired had he not been so vigilant for the last couple of years. I compliment him and urge all my colleagues to support the Cochran amendment, and I am happy to yield.

The PRESIDING OFFICER. Is the Senator yielding the floor?

Mr. NICKLES. I yield to the Senator for a question.

Mr. SANTORUM. I have a question. Listening to your comments, are you suggesting that a product made in Iraq or Yemen or Iran or some other country that may have terrorists in their country, they could actually send a drug through Canada into the United States, without anybody inspecting it, and have it show up here not marked as from what country it came, and be sold here in America, under the Dorgan amendment?

Mr. NICKLES. Under Canadian law, which I just read—this is section 37 of the Canadian Food and Drug Act—it said any item, whether it be packaged food, drug, cosmetic, or other devices—and if that item is imported and exported, not to be consumed or utilized in Canada, then it is not under their regulatory scheme.

Mr. SANTORUM. So it would come in here under the Dorgan amendment, reimportation, not being reviewed by the FDA before it came here? Only if we found out the terrorist attack was successful through this scheme would we then find out that we have a problem?

Mr. NICKLES. That would be too late.

Mr. SANTORUM. That would be far too late.

Mr. NICKLES. That would be under the category of the pattern of action.

Mr. DORGAN. Will the Senator yield for a question?

Mr. NICKLES. I am happy to yield for a question.

Mr. DORGAN. I appreciate the courtesy. The amendment deals with FDA drugs, so the condition under which that drug from Canada would come into this country would be it was purchased at a Canadian-licensed pharmacy or distributer by a licensed facility or distributor in this country, and therefore it must be FDA approved and produced in an FDA-approved plant. Is that not the case?

Mr. NICKLES. I am reading a letter from the FDA, and they said absolutely. I ask unanimous consent to have printed in the RECORD a letter dated July 17, from the Department of Health and Human Services addressed to Senator COCHRAN.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

DEPARTMENT OF
HEALTH & HUMAN SERVICES,
Rockville, MD, July 17, 2002.

Hon. THAD COCHRAN,
U.S. Senate, Washington, DC.

DEAR SENATOR COCHRAN. We take this opportunity to provide the views of the Food and Drug Administration (FDA) on S. 2244, the Prescription Drug Price Parity for Americans Act, introduced by Senator Byron Dorgan on April 24, 2002.

The Administration is sympathetic to the goal of making prescription drugs more affordable for American citizens, including senior citizens. However, FDA is concerned about the negative impact on public health of a proposal such as S. 2244 that aims to open the nation's drug regulation system and allow drugs from outside that system into U.S. commerce and our citizens' medicine cabinets. We therefore must oppose enactment of this legislation.

S. 2244 would allow wholesales, pharmacists and individuals to import drugs from Canada under certain specified conditions. The bill would create a new section 804 of the Food, Drug, and Cosmetic Act (the Act), replacing the current provisions of section 804, which are the drug re-importation provisions enacted in 1999 (the MEDS Act).

Currently, drugs marketed in the United States must be approved by FDA based on demonstrated safety and efficacy; they must be produced in manufacturing plants inspected and approved by FDA; and their shipment and storage must be properly documented. This ''closed'' regulatory system has been very successful in preventing unapproved, adulterated or misbranded drug products from entering the U.S. stream of commerce. Legislation that would establish other distribution routes for drug products, particularly where those routes routinely transverse a U.S. border, creates a wide inlet for counterfeit drugs and other dangerous products that are potentially injurious to the public health and a threat to the security of our nation's drug supply.

S. 2444 would establish two new routes for introducing drugs from Canada into U.S. commerce. First, new section 804(b) would require the Secretary of Health and Human Services (the Secretary) to promulgate regulations to permit pharmacists and wholesalers to import prescription drugs from Canada into the U.S. The bill purports to safeguard the domestic drug supply by requiring, in new section 804(c), that these drugs comply with sections 505, 501 and 502 of the Act, and that importers comply with detailed recordkeeping and testing requirements.

As a practical matter, meeting these requirements would be an enormous undertaking, and the testing required under the bill would be costly and time consuming,

both for the government and importers. Moreover, some of the testing requirements cannot even be met, as there is no testing that can ensure that a shipment of drugs does not contain counterfeits. Since counterfeits can easily be commingled with authentic product, either by the case, by the bottle, or by the pill, there is no sampling or testing protocol sufficient to protect against the grave public harm they pose. No random sampling plan will be able to detect and protect such criminal conduct since the threat does not depend upon the nature of the reimported product, but upon the integrity of those handling it. Furthermore, the legislation fails to require reporting of any counterfeits that may be found by testing, so even if counterfeits are discovered, FDA may never learn of them.

It is unlikely that Canadian sellers and U.S. importers would be willing to endure these new requirements, but even if they were, it is likely that the intended cost savings for consumers would be absorbed by fees charged by exporters, pharmacists, wholesalers, and testing labs. Because the bill requires that the drugs comply with sections 501, 502 and 505 of the Act, it may be found, in practice, that for the bill to have its intended effect U.S. manufacturers would have to sell drug products manufactured, labeled and intended for the U.S. market to Canadian distributors specifically for re-sale to the U.S. Even if they were willing to do so, these sales may represent illegal shipments to the Canadian market under Canadian law. All of these concerns make the proposed program for importation by pharmacies and wholeasalers both impractical and unworkable.

The second route proposed by S. 2244 for importing drugs into the United States is by allowing individual consumers to import drugs on their own from Canadian pharmacies. New section 804(k)(2) would compel the Secretary to promulgate guidance to allow consumers to directly import drugs and medical devices from Canada. This represents an enormous intrusion on the Department's enforcement discretion, and it would over-ride existing statutory provisions that allow FDA to refuse personal importation of prescription drugs from Canada if they are believed to be unsafe, ineffective, adulterated, radioactive, or contaminated.

In surveys conducted by FDA over the past several years, we have found that a wide variety of dangerous drug products have been imported by individuals from outside the United States, both by mail and by traveling to other countries. The bill would actually create an incentive for unscrupulous individuals to find ways to sell unsafe or counterfeit drugs that, while purported to be from Canada, may actually originate in any part of the world. Canada could become a transshipment point for legitimate or non-legitimate manufacturing concerns throughout the world, and in many cases we would not be able to determine the true country of origin. For all of these reasons, we find that this provision would greatly erode the ability of FDA to ensure the safety and efficacy of the drug supply, and protect the public health.

FDA has numerous other specific concerns that S. 2244 may undermine current law regarding drug labeling, record keeping, testing, and enforcement, and we have laid out these concerns in an attachment to this letter.

The Office of Management and Budget has advised that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

LESTER M. CRAWFORD, D.V.M., PH.D.
Deputy Commissioner.

Mr. NICKLES. This is the quote from FDA. I might say this is the position that is consistent, not only with this administration but the previous administration. They state:

The bill would actually create an incentive for unscrupulous individuals to find ways to sell unsafe or counterfeit drugs that, while purporting to be from Canada, may actually originate in any part of the world. Canada could become the transshipment point for legitimate or nonlegitimate manufacturing concerns throughout the world, and in many cases we would not be able to determine the true country of origin. For all these reasons we find this provision would greatly erode the ability of FDA to ensure the safety and efficacy of the drug supply and protect the public health.

Mr. DORGAN. If the Senator will yield for one additional question, the Senator is aware, I am sure, that today pharmaceutical manufacturers reimport a substantial amount of prescription drugs from Canada. What is to prevent the circumstance you just described from occurring now, with respect to current law?

Mr. NICKLES. Current law requires FDA, for their certification—for FDA to give their certification, you have a pedigree requirement. The pedigree requirement means we have FDA inspectors go visit the plants in Canada to certify that yes, these are FDA-approved drugs. They do the sampling. They make sure the packages are safe. Inspections are done at great expense. That is already done for FDA, for drugs that are manufactured in the United States or reimported into the United States. It would not be done under any drug in Canada or under the Canadian law, which basically says if these drugs are purchased strictly for export purposes, they do not fall under Canadian regulation.

Mr. DORGAN. But is it not then the case that they are not FDA-approved drugs and therefore our amendment deals with that?

Mr. NICKLES. Mr. President, I will reclaim the floor. That is not correct.

Mr. DORGAN. It is correct.

Mr. NICKLES. Again, I am reading to my colleague. I have a statement from the past FDA Administrator as well that says they can't guarantee the safety of these drugs. They do not have the regulators. The Senator's amendment did not have the pedigree requirement for drugs that would be imported into the country. That is a possible amendment that I am considering offering.

If the Cochran amendment doesn't pass, we are going to be on this bill for a while because I am going to offer an amendment—I will tell my colleague, and maybe you will accept it—I am going to offer amendment that says all the drugs covered by this act shall be manufactured in the United States or Canada, because that has been implied but it is not factual under the bill.

Ms. STABENOW. Will my friend from Oklahoma yield for a question?

Mr. NICKLES. Let me finish. I am also going to offer an amendment that will replace language under the Dorgan amendment that says there is a pattern of importation of drugs, counterfeit and so on. That would be replaced by ''any instance.'' So we are not going to wait for a pattern if this amendment is adopted. Again, I hope my colleague from North Dakota would agree, with this amendment, that it could be suspended if there were an instance of counterfeit drugs, if there is an intent of abuse of the system. Then they can be suspended and not wait for a pattern.

I think both of those amendments are very acceptable. I hope my colleagues will agree to consider them favorably.

I yield the floor.

The PRESIDING OFFICER. The Senator from Pennsylvania.

Mr. SANTORUM. Mr. President, I think the Senator from Oklahoma has made a vitally important point. We have gone through I can't tell you the number of steps to try to stop terrorism.

The Senator from Kansas has just come to the floor. He has been a leader in the area of bioterrorism and agriterrorism.

Under this provision that we are debating right now—the underlying Dorgan bill—you are creating an incredible loophole for terrorist attacks and bioterrorist attacks in this country. We are creating a loophole that allows any foreign country to go through Canada to import drugs into the United States. And the Canadian Government doesn't even inspect it and does not even open it. It can come right in here.

Ms. STABENOW. Mr. President, will the Senator yield for a question?

Mr. SANTORUM. Yes. I am happy to yield for a question.

Ms. STABENOW. The trading of drugs is probably more highly regulated than any kind of trade. I am wondering if my friend would also object to all the food that comes into the United States from Canada and other countries. We have foods and vegetables coming in every day. We have bottled water and alcoholic beverages coming in. We have all kinds of things that go back and forth across the border from a lot of countries that are not regulated nearly as much as prescription drugs. I am wondering if the Senator is also concerned about or would object to that kind of trade as well.

Mr. SANTORUM. That is why we have Customs inspectors and FDA inspectors, who do, in fact, monitor things coming into this country for purposes that are fundamentally different. When you are talking about pharmaceutical products, that is a fundamentally different area.

All I am suggesting is that what is being created in the Dorgan amendment is an opportunity. As the amendment says, you have to have a pattern of problems with these drugs before you can do anything.

I think that creates a loophole that is in today's world of terrorism, one

that would be certainly filled by any number of terrorist organizations that want to hit the United States with some sort of bioterrorism.

I want to get back to what the Senator from North Dakota said prior to the vote on the last amendment. He said he would like to have someone come here and explain to him why drugs in Canada are so much less expensive than they are here in the United States, why we pay such premiums for those drugs here in the United States, and why Canada can sell them so much less expensively than they do here. There are a lot of reasons. Let me give you a few.

No. 1, the Canadian health care system is a single-payer system. It is a government-run health care system. It is run through the provinces and the territories.

This government-run health care system negotiates prices. Not all drugs that are made available in the United States are available in Canada. Why? Because the Canadian Government has a formulary. There may be four arthritis drugs that may be very effective in dealing with different forms of arthritis. The Canadian Government basically negotiates with companies, plays one against the other, and gets the cheapest price. They make one available. That one available may be the right particular drug for this group of arthritis sufferers. But it may not be the best drug for the whole class. That is why there is probably four of them. They have different little initiatives that make their drug more effective on certain people in certain circumstances. But in Canada, you get one. Maybe you get two in a general class. They negotiate it based on the best price they can get.

That is one thing.

In Canada, people don't get access to the variety of different drugs that may be the best therapy available. They negotiate a price because they are a big purchaser. They purchase for the entire 35 million people in Canada. They purchase drugs, and they compete it so they get one company getting the entire market, in many cases. So they can get a much reduced price as a result of the volume discount which they give.

Again, they limit the access to a variety of different drugs to the people of Canada. It is a balancing act for the drug company that wants to compete in Canada to get access to that market.

I am sure the Senator from North Dakota and the Senator from Michigan are familiar with this.

The second thing is there is a provision in the Canadian law called ''compulsory licensing.'' Most Senators on the other side of the aisle know what compulsory licensing is. But just in case they don't, let me explain to Members what the impact of compulsory licensing has on drug prices.

Compulsory licensing is the ability for the Canadian Government, if they do not get a satisfactory negotiation for a drug they believe is necessary to be offered in Canada, and if they aren't happy with the price the pharmaceutical company is willing to sell that drug at, they can basically, in a word, steal the patent.

Let me repeat that.

If Merck, which happens to be a big pharmaceutical company in my State, wants to sell a particular drug that is effective for arthritis—maybe it is a very new drug, an important drug, one on which they have spent a lot of money, and it has tremendous results and they want to sell it in Canada—said: We will sell it for $2 a pill here in the United States. Canadian says: That is nice. We are not going to pay $2. We want a volume discount. Merck says: OK. We will negotiate some sort of volume discount. We will sell it to you for $1.50 a pill. Canada says: That is nice. We will pay you 50 cents. Merck says: That is not a fair price. So they negotiate back and forth.

OK. Fine. We believe this is an important drug for our people. If you want to sell it to us for 50 cents, you lose your patent. We will license it to someone here in Canada. They will make the drug, and you get nothing.

Most people would say that doesn't seem particularly fair. No. It is not fair. But under Canadian law, I would suggest to you that not just Canada but in most countries around the world, unfortunately, that is a fact of life for many drug companies. If you point to Brazil, to South Africa, or to France, or to some other country, and ask, How can they get these drugs? It is because if they do not sell the drug at the price the national government wants the drug sold at, they steal the patent, they compulsory license it.

You are now looking at a drug company that says: Wait a minute. We want to sell this drug for $2. It cost us 25 cents extra to make the pill. They say: Wait a minute. Why do you want to sell if for $2? It took us $800 million to bring this thing to market. We have a few research costs involved in getting this drug formulated, approved, and all the things that are necessary to make sure it is safe and effective. It cost us a lot of money. Yes, but making the pill doesn't cost a lot. But to get to where we can make the pill, it costs an enormous amount of money. We would like to recoup that. Because they are in business, they would like to make a profit. The Canadian Government says: Look, it only cost you a quarter to make this pill, but we are giving you 50 cents. You are making money. It is better than making no money. If you don't sell it to us for 50 cents, you make no money.

So the drug company has to make this decision. Do I sell the drug at 50 cents and make some money, or do I choose not to sell the drug?

They may have it be made somewhere else. Even if they don't compulsory license it—even if they say, no, they are not going to compulsory license it, they are not going to sell it, put aside compulsory licensing. They say: We want to sell the drug. It is 50 cents. You don't have access to our market.

So the drug company has to make a decision. Do I sell the drug at 50 cents and make a small profit to help underwrite the cost of the research that was done on this drug, or do I choose not to sell?

You can make the argument that they shouldn't sell. You can make the argument that they should try to negotiate a better deal. But there is one negotiator, the Government of Canada, and they set the price. If you do not like the price, you either don't sell, and no drug is made available in Canada, which is no skin off the back of Canadian Government because in most cases, most drugs are not available in Canada. It is just another drug that is not available.

If they really want your drug, and if they really believe it is important to get your drug, they simply license it to someone in Canada, and they make the drug, which they buy. They can make the drug in such sufficient quantities that they can actually import that drug into the United States. So they can steal your patent. And under this bill, a stolen patent can be imported.

I understand it is very, very popular to be beat up on pharmaceutical companies. They make money. We do not like anybody that makes money around here. So they make some money. They do some things that are cutting edge. For some reason this is a problem.

It is very popular to go out and beat up on pharmaceutical companies for charging all this money for products that people need. But let me remind you, the Senator from Massachusetts said this bill will save $60 billion. If I am wrong on that, that is what I thought I heard yesterday. The Senator from Massachusetts said this will save $60 billion for the American consumer.

My question is, save it from whom? Who is it going to cost? It comes from somewhere. The obvious answer is, it is going to save it from the pharmaceutical industry.

Let's look at the pharmaceutical industry in this country, the much maligned pharmaceutical industry. What did this pharmaceutical industry do to deserve this treatment? What it did to deserve this treatment is invest more as an industry in research and development than any other industry in America.

Let me repeat that. What have they done to incur the wrath of the U.S. Senate today? What they have done is invest more money in research and development than any other industry in America. As a result, they have come up with breakthrough drugs, which cost a lot of money but, by the way, save lives and improve the quality of life for millions in America.

So what are we doing to thank them, to congratulate them, for being one of

the leading exporters in this country, for improving our balance of payments in this country, for employing people in high-priced jobs in this country, for moving scientific research in this country, for curing diseases in this country, for improving the quality of life in this country, for extending lives in this country?

We say we are going to whack off $60 billion out of your bottom line, which means, of course, the research will stop or be dramatically reduced.

So understand what we are doing. We are all beating our chests saying: We are going to get the big, bad pharmaceutical companies that are pillaging the American public with outrageous drug prices, and we are going to cut those prices by 30 to 50 percent.

Understand the consequences. Less money in research. Less money in research means fewer new drugs. Fewer new drugs mean people will die who would otherwise be saved by those innovations. That is what the consequences are.

All I am suggesting is, if that is the tradeoff, if 30 percent less on your pharmaceutical price is a good tradeoff for not having the next generation of lifesaving drugs or quality-improving drugs, that is fine. That is a worthy debate in the Senate. It is one that we should have, but it is not one that we are having.

The debate we are having is, corporate greed versus poor senior citizen. That is the debate here: These horrible pharmaceutical companies that are raping and pillaging the people of America while making these enormous profits.

Look at their profit lines, look at the prices for their stock, and I will assure you, they are not showing those enormous profits.

What is going to happen—if this were successful and we did take $60 billion out of this industry—and that is where it is coming from. It is not coming from anywhere else. It is not being drawn out of whole cloth. It is coming out this industry, which means $60 billion less of research.

We run around this country, and we are very proud in the Senate talking about how we are increasing the budget for the National Institutes of Health and how we care deeply about improving the quality of health in this country and how we are going to put more and more taxpayers' dollars into solving diseases, into fighting problems that perplex us, into finding out more about how our bodies work. Wonderful. Wonderful. That is great basic research. It is important to do. It is great scientific discovery. But where does all this stuff lead? Where does this lead?

In many, many cases it leads to research then being handed off to a private-sector organization that goes ahead and develops that lifesaving cure, that pharmaceutical product that, in the end, saves lives.

Mr. FRIST. Mr. President, will the Senator yield for a question?

Mr. SANTORUM. I am happy to yield for a question.

Mr. FRIST. Mr. President, I will be very brief. The Senator from Pennsylvania addresses a very important point, which forces us to look to the future in terms of future cures, whether it is for HIV/AIDS, emphysema or heart disease.

He hit the point very directly, in a way that I have not heard on this floor, in response to one of the main reasons why drug prices are higher in the United States than in Canada.

I would like to ask the Senator the following question. Typically, in the United States an individual company will set prices in such a way to cover research. They will look at supply, demand, and the efficacy and efficiency with which the goal of cure or prevention is carried out.

In order for the prices of medicine to be sustained over time, you must allow some recoupment of that investment in research. We all know that, on average, only 3 out of 10 medicines that are eventually approved in this country actually generate enough revenue to pay for that investment over time in the United States.

Mr. SANTORUM. Not to mention all the hundreds or thousands of compounds that were even tried to be researched, and they ended up where they decided: No, we are not even producing a drug that could be sought for approval.

Mr. FRIST. That is correct. That is the United States.

The real question goes to the following: In Canada they have a very different system. Everybody looks to Canada's system as if it is similar to or in some ways better than ours. In Canada, not the United States—this is what you essentially said—is it not correct that each company is denied the freedom to set prices for its own innovative medicines?

Mr. SANTORUM. Let me explain to you exactly how that process works. It is not a free market. They cannot set their prices. They have to negotiate with a board, and it is called the Patented Medicines Price Review Board. That board sets the prices in Canada.

They do so in the following way. The statute mandates that the price of most new patented medicines may not exceed the price of the most expensive drug marketed in Canada that treats the same disease.

So let's take HIV/AIDS. You have a regiment of drugs that are out there to treat it. Someone comes on the market with a brand new AIDS drug that may cure AIDS or may substantially improve the quality of life for someone with AIDS.

In Canada, they cannot, under the statute, charge more than what the highest priced drug already in the market is, which may have an improving effect on the quality of AIDS but may not be one of those transformational drugs.

So, No. 1, statutorily they are limited. No. 2, the price in Canada of a drug constituting a breakthrough drug, in therapy, may not exceed the median of its price in seven countries.

Let me tell you, all of those specified countries, with the exception of the U.S.—that is one of the seven—the other six, interestingly enough, are all price-controlled countries where the government sets the prices.

So it is a spiraling-down effect. One refers to the other country as a way to set the price, and so they each keep setting lower and lower prices, and they rachet the price down by having all these price control countries as the reference point for Canada.

Ms. STABENOW. Will my friend from Pennsylvania yield?

Mr. SANTORUM. I will as soon as I finish the question from the Senator from Tennessee.

Mr. FRIST. Just a quick followup question.

Based on what you have said, the only choice a manufacturer has is to set it at the price that Canada allows or to not sell it.

If a manufacturer decided not to sell a medicine at a price the government allowed, then is it correct that the government would authorize a Canadian company to copy and sell the drug, even without the patent holder's permission, which, it would seem to me, throws out the meaning of patents?

If we throw out the meaning of patents when it comes to pharmaceuticals and drugs, what are the implications for us in this country or the person listening today who has heart disease or HIV/AIDS, as they look with hope for that cure?

Mr. SANTORUM. There are enormous implications if we allow the Canadian Government to deny and basically say to the company: Either take it at this price or we will go ahead and manufacture it ourselves.

By the way, once they license it in Canada, the Canadian manufacturer can appeal to the government and say: Look, yes, we are manufacturing it here, but for us to make a profit, we have to export some because we have to make it in sufficient quantities. And if that is approved, they can send the drug back here to the United States.

Our companies could do all the research, expend all the money, and then be forced not to be able to sell the drug. In that case, the Canadian Government will say, it is not important enough. If you don't give it to us at the price we want, you lose the competition between three other drugs that may be similarly situated. You just don't sell the drug in Canada. Or, if we think it is important enough, if we think it is vital to our national health and you don't want to sell it to us at a price we believe is reasonable, we will have compulsory licensing. They simply license it to another.

That is not some far off concept. Right after the anthrax scare in the Senate, the Canadian health minister said that if they cannot get enough quantities of Cipro, they were going to

revoke the patent of Bayer and produce it in Canada.

So just understand, this is not a theoretical concept. This is a real concept. Even if it is not done routinely, which it is not, it is certainly a hammer that the government uses to get prices at a level that they want, not that the manufacturer believes is fair for their product.

Ms. STABENOW. Will my friend yield?

Mr. SANTORUM. I yield for a question.

Ms. STABENOW. I appreciate the ability for us to debate this important issue. I am wondering, as a result of what you have described, and I appreciate the sympathies for drug companies, if you then support the fact that the average pharmaceutical drug for Americans is going up three times the rate of inflation?

Mr. SANTORUM. That is important because another provision of the Canadian system is that the price may not increase more than the consumer price index. They fix prices even after they have set them in place.

The prices of drugs are going up. The research involved in discovering new drugs and the complications of doing so is driving up drug prices. That is a problem. I think we do need to do something.

But the issue is not price control. It is access to insurance. That is the key. What we need to do is to provide, for the private-sector American, the Medicare-eligible American, an opportunity to get insurance to reduce the cost of drugs to them. That is vitally important.

Ms. STABENOW. I am wondering if my friend might also respond then to the well-known practice now that the companies are spending 2½ times more on advertising than they are on research and development, and how you might feel about that.

Mr. SANTORUM. I must respectfully disagree with my colleague's assertion on that point, for it is factually incorrect, although a commonly cited myth. According to recent findings by NDC Health, a health care information company, the pharmaceutical industry spends significantly more on research and development than it does on advertising. For 2001, $2.8 billion was spent on direct-to-consumer advertising. This is less than one-tenth of the $30.3 billion America's pharmaceutical industry spent on research and development. Moreover, I am someone who believes that a company is entitled to advertise and sell their product. Certainly, I don't know of any business that makes a product that doesn't tell anybody what their product is. If you look at the research and development cost of every other industry compared to their advertising cost, the pharmaceutical industry would probably stack up better than any other industry. You could say they are spending a lot on advertising. I would hope they are spending money to try to tell people what their products are about.

Are you telling me they shouldn't be able to spend money to tell American consumers or physicians or hospitals what their product is and how it can be used? Of course, they should. They have an obligation to.

Mr. FRIST. Would the Senator yield for another brief question?

Mr. SANTORUM. Yes.

Mr. FRIST. Mr. President, clearly the United States does subsidize the world in terms of research and development. For better or worse, many other countries do have strict price controls. Those price controls ultimately translate pretty uniformly across the world into less investment in terms of research and development and investigation and experimentation for future cures of a broad range of diseases that we globally suffer with today.

The hope out there—whether it is Parkinson's disease, emphysema, heart disease, or lung disease—comes in the development of new drugs.

My question to the Senator is to verify the data that at least has been made available to me. In the United States our pharmaceutical industry—and I will phrase this as a question—spends about how much? The answer is the United States spends around $30 billion for research and development in the private sector coming from private investment in this country. In Canada, the cost for all research and development in pharmaceutical agents is not $30 billion; it is $1 billion.

I mention that because people glorify the Canadian system and how inexpensive it is. We need to be very sensitive to the fact that the United States is doing the world's research and development in the pharmaceutical arena which gives us the hope. Canada does not. The system described does not.

Would the Senator agree with that?

Mr. SANTORUM. That is absolutely right. The initial comment the Senator made is right. This is the fundamental issue we need to debate. Should the American public, through its pricing system, free market pricing system of drugs, continue to subsidize the rest of the world in pharmaceutical research? If the answer is no, we need to state that. If the answer is, no, we don't want that to continue, we should come out in front and say: We are not going to let the United States consumer bear the brunt of researching new drugs. If that is what we want to do, we need to be very upfront about that.

That may be a very legitimate position to take. I don't share that view. I don't believe that is the right thing for us to do. I don't think that moves this country forward. I don't think that keeps us on the cutting edge of an industry that is a world leader.

If that is what this body wants, then we are going to make the short-term trade, and the underlying bill on generics is exactly in this direction. We are going to make the short-term trade. We will have to charge our consumers less, allow more generic drugs, allow reimportation of drugs, all of which will undermine and cut into the revenues and intellectual property of the pharmaceutical industry, which will subsequently reduce their ability to do research on drugs for the short-term gain of having cheaper prices on the drugs available today.

The exchange is, lower prices on the existing pot of drugs available today versus a cure for heart disease or cancer or emphysema or Parkinson's or you name it down the road. That is the tradeoff.

Let's be honest. Of the drugs available today, many of them are very good, but some of them are not as accessible. You could make the argument, it is more important to get those drugs to people today than it is to get that next generation of cures tomorrow. Maybe we will have to wait. Instead of getting them next year or 2 years from now, we will have to make it 5 or 10 years. That is a tradeoff.

Let's have a debate about that. But let's understand that all this other talk is just glossing over the broader issue. That is the fundamental issue.

I haven't seen any polls on this issue. There may be Americans who believe that is the way to go. There may be others who feel strongly the other way. We have to understand that is the debate.

With that, understand the bottom line: Lower prices, either on generic drugs or reimported drugs, versus cures tomorrow and the next. That is the debate. We must make a choice.

The PRESIDING OFFICER. The Senator from Nevada has sought the floor.

In my capacity as Chair, I might say to colleagues, I will try to switch back and forth on positions so I will recognize the Senator from North Dakota next.

Mr. REID. I say to my friend, you should recognize who asks, not back and forth. Unless there is some agreement, I respectfully suggest that the Chair should not do that.

The PRESIDING OFFICER. The Chair apologizes.

Mr. REID. Mr. President, if I could have the attention of the minority, I have talked to Senator COCHRAN, and he tentatively agreed to this schedule. We would have a vote at approximately 5:40 today; that the time between now and then would be equally divided, even though that perhaps is unfair. The Senator from Pennsylvania has spoken for such an extensive time, but I don't think we need to worry much about that.

So I would like to propound a unanimous consent agreement that we would have a vote on the Cochran amendment at 5:40; that following the vote, we would proceed to the Stabenow amendment, which would be in the form of a second-degree amendment to the underlying amendment; then following that, tonight, as soon as that amendment is laid down, we would go to the MILCON bill—which we got consent on earlier today, and I appreciate that—and we would complete that debate tonight and vote on that in the morning.

In the morning, we will start off with the Stabenow amendment, which will be debatable.

Mr. GREGG. Mr. President, if the Senator will yield, at this time we cannot agree to such an understanding. As the Senator has noted, this amendment has generated a very significant interest. Debate has been, obviously, substantive and there is still a fair amount of debate that has to flow under the bridge before we can close the game, if I can mix metaphors.

Mr. REID. I understand the statement of the Senator from New Hampshire, even though I do not agree. We have agreed to accept the amendment tentatively—unless something has changed in the interim. I think there would be an agreement that we could accept this amendment.

All I say to my friend is, if that is the case—and I think it is—again, we are legislating by virtue of slow-walking. As I say, we have tried—and if they would like to tango, we will play music; if they want to rumba, we will do that. But we need to move this legislation. We have a lot of things to do. We are constantly told by the President there are things he would like done. We do our best to meet what the administration wants. For example, if we are going to be able to get to the bill where he is talking about consolidating different agencies, we are going to have to do that. We have to finish this first. Here it is Wednesday at 4 o'clock at night. We have had one vote today—that is all I remember—and we are not able to go ahead with anything else. As I indicated, the homeland security issue is something the President believes we should do. The majority leader wants to do it. We cannot do it like this. Now we want to get to the military construction bill tonight.

I don't understand what we can do to be more cooperative and move things along. It is not as if we are asking the impossible. I am going to propound this request. I will yield to the Senator from Oklahoma for a question.

(Mr. DAYTON assumed the Chair.)

Mr. NICKLES. Will the Senator withhold propounding the request for a few moments until we have a little more time to look at it?

Mr. REID. I will be happy to do that. I say this respectfully, and I know the Senator from Pennsylvania has been talking and has not had an opportunity to look at this. We have been floating this for an hour or 2. Another few minutes will not matter.

I yield the floor.

The PRESIDING OFFICER. The Senator from North Dakota is recognized.

Mr. DORGAN. The Senator from Pennsylvania was speaking about advertising costs and so on. Toward the end of his speech, I know the Senator from Michigan wanted to be yielded to. I yield to her for a question at this point.

Ms. STABENOW. Mr. President, if I might share this for the RECORD for my colleagues and ask my friend from North Dakota to respond, I did want to put into the RECORD, as we were talking about advertising versus research and so on, that, in fact, today two and a half times more is spent on advertising and marketing of a product than is spent on research and development. What is more startling is the fact that according to a report released today by Family USA, we have companies that are having two or three times more in profits than they spend on research and development. This is no longer a research and development driven industry—which it needs to be. It has become much more about sales, marketing, and ''me too'' drugs rather than new breakthrough drugs.

Today, Family USA showed us in a report that, for instance, America, last year—in 2001—had a profit, a net income, that was three times more than what they spent on R&D. Pfizerpen's was one and a half times more. Bristol-Myers was two times more in profit.

What is also disturbing is that, while I appreciate the sympathies for the drug companies, it is really quite shocking when we look at where the money goes as opposed to R&D. This chart shows the five highest-paid drug company executives. I won't say them by name, but the CEO of Bristol-Myers gets $74 million, not counting unexercised stock options. Wyeth's gets $40 million, not counting stock options. If you include the stock options, you are looking at another $93 million for one company, $76 million for another, $60 million, and so on.

So I appreciate the concern about the drug companies and the different system in Canada. But if our concern is about research and development—which we should be concerned about because not enough is being done now—we have a lot of money going in a lot of other places that I think would be of concern to the average senior who is trying to figure out tonight at supper time whether they eat or get their medication. I appreciate the time.

The PRESIDING OFFICER. The Senator from North Dakota has the floor.

Mr. DORGAN. Mr. President, I have heard a generous and interesting presentation for 45 minutes or so—in fact, I think it was the most effective discourse I have heard for some while on behalf of the pharmaceutical industry and their pricing policies. Of course, I disagree with it very strongly. Nonetheless, I think it was a good representation of what the pharmaceutical industry believes about pricing strategies.

As I listened to the back and forth, it reminded me of a small grease fire in a small restaurant; a lot is going on, but nothing real urgent. Let me react to some of the statements made recently.

Statement: ''Some people in the Senate don't like anybody who makes any money.'' That is absurd, but obviously in the Senate we can say those things, I guess. I would like to see one Member stand up and say: All right, here is what I stand for. I stand for a pricing strategy by which the American consumer is charged the highest prices for prescription drugs of anybody in the world. I want to see one Senator stand and say that I stand with the pharmaceutical industry and the pricing strategy, and I want the American consumer to pay the highest prices in the world.

Nobody will stand and say that. Instead, they will use metaphors that mean something different. We are told, for example, the problem is that, if we don't pay those high prices, we don't get the R&D. The information that was used was, of course, incorrect. Actually, more money is spent in Europe on R&D than in the United States 37% versus 36%—not a lot more, but more—and in every country in Europe their consumers pay far lower prices for prescription drugs. How does that figure add up?

We just heard our colleague say to us that if you don't pay the highest prices for prescription drugs, you don't get the R&D. Tell us about the Europeans.

Mr. SANTORUM. Will the Senator yield for a question?

Mr. DORGAN. If the Senator will let me finish my statement first—I listened for 45 minutes to the great case the Senator made on behalf of the pharmaceutical industry—I will be happy to yield when I finish.

The point is this: We are told that the pricing strategy by which Americans are charged the highest prices is fair and is necessary—fair because it is the only way we will get the R&D, and it is necessary because nobody else will pay those prices. So we need to accumulate that cash from the American consumer in order to pay for the R&D.

There are a couple things wrong with that. One, we spend a substantial amount of taxpayers' money at the National Institutes of Health. We have gone from $12 billion to $24 billion. I supported that. It was bipartisan in the Senate. We doubled the amount of money for the National Institutes of Health for health and research, and the pharmaceutical industry benefits from that as well because they take that accumulated research and use it to create new and miracle medicine. Yes, they do research as well, and I commend them for that.

My point is, we do a lot in public policy, such as research at the NIH. We passed a tax credit—I assume my colleague from Pennsylvania supports that, as I do—to say we will give you a tax credit for research and development. This country gives a very substantial tax credit for research and development, and I support that. I voted for it for two dozen years. I bet my colleague did as well.

This is not about research and development, it is about a pricing policy, that says that we will do more research in Europe and charge them lower prices then the American consumer, and, oh, by the way, when someone wants to raise questions about that, we will say: No, you cannot raise questions about

that; this is a pricing strategy that is fair to the American people.

Not where I come from, and I come from a much smaller town, I am sure, than some others here, a town of 400 people. We had a drugstore. We had a fellow who came to my town when he was just out of medical school. His name was Doc Hill. He was the doctor and ran the drugstore in town. He knew everything about everything. There was not anything he could not treat or any diagnosis he could not make. He was just a wonderful guy.

I grew up with that kind of medicine in a small town. In my small town, if someone said: We have a little deal here in the county—we have three towns—Mott, Regent, and New England. Regent is mine, by the way. We have a policy. What we would like to do is charge you folks in Regent 10 times as much for tamoxifen. If you women have breast cancer and are using tamoxifen, we are going to charge you 10 times as much as we are going to charge the people in New England and Mott.

Do you know what the people in Regent would say about that? Are you nuts? Are you stark raving mad? For God's sake, what kind of a pricing policy is that? It is fundamentally unfair, they would say.

Let's take that globally. We are told this is a global economy, after all, and just as it would be for my county, we are told by the pharmaceutical manufacturers that with tamoxifen, Premarin, Zocor, Lipitor, or dozens of other medicines, we should ask the American consumer to pay much more than others.

I understood there are people here who represent the interests of those who want higher prices. That is not the President's position, by the way. This is the President's position. The third Presidential debate in St. Louis, from George W. Bush, now President Bush:

> Allowing the new bill passed in Congress, you know, for drugs that were sold overseas to come back into the United States, that makes sense.

That is President George W. Bush. That is called reimportation. That is President George W. Bush in 2000 saying it makes sense. Sure, it makes sense. It does not make sense to the pharmaceutical industry, and I understand why. They have price controls. They control the price. People say we do not have price controls in America. Yes, we do; of course, we have price controls. The pharmaceutical industry controls the price. With respect to this global economy, it is interesting, my colleague said: In effect, you are going to import price controls from Canada. Canada has price controls on prescription drugs. Yes, that is true. Canada has price controls on prescription drugs. So do many other countries. We reimport a lot of products from other countries. That is one of the factors that makes the global economy interesting. If my friend the Senator from Pennsylvania has a necktie that is made in China today—and I do not know if he does or not, but there is a pretty good likelihood many of us are wearing neckties made in China—then one might make the case that the price of that necktie supports the salary of the leader of a Communist government.

Does that make it tighter around our necks? I do not think so. It is the global economy. Do I like to buy something from a country that perhaps supports a Communist government? No, no, no, but a global economy means we move products back and forth, and sometimes we inherit policies we may not like. But inheriting the capability through reimportation to allow the American consumer to pay less for prescription drugs than they would otherwise pay is good public policy and makes good sense for our citizens.

The Capitol is full of people who care a lot about drug prices, and they are very concerned about this—they are lobbying this issue on behalf of the pharmaceutical industry. They have every right to do that. I talked about a woman named Elizabeth earlier. I know there was some chiding about that, the teary stories about individuals. But I am wondering if Elizabeth has anyone who is going to grab somebody by the arm before they vote and say: You know, it is very important that you cast your vote the right way.

Remember, Elizabeth is a farm wife who is 74 years old who drove a tractor until 2 years ago when she lost her husband and her lungs got worse.

She has scleroderma and was diagnosed at Mayo. She talks about how she has been on oxygen for 2 years. She talks about the one new pill that would cost $3,600 or more a year. She cannot afford it. But I ask: If there is anybody in the Capitol Building today who is representing Elizabeth today? There are plenty who represent those who want to keep the current pricing strategy.

Or Velma:

> I am 86 years old. I can't work.

That is pretty reasonable. She is 86 years old and says: I can't work.

> I get $303 in Social Security each month, and I pay $400 a month for medicines.

She has had heart surgery and osteoporosis.

Sylvia Miller, 70 years old, diabetes, heart problems, emphysema. She went with me to Emerson, Canada, to buy prescription drugs. In recent years, she has spent $4,900 on her medicines. It was up $1,000 from the previous year.

The point is, this is a very important issue. This is a tripartisan bill that is supported by Senator JEFFORDS and many on both sides of the aisle. There is no one advocating reimportation who wants in any way ever to diminish the safety standards that exist that allow the American people to access a safe supply of prescription drugs.

An important point is this: Prescription drugs are lifesaving and miracle drugs only to those who can afford them when they need them. They save no lives when those who need drugs cannot have access to them. These prices are unfair, and reimportation will help put downward pressure on prices.

I say to those who oppose reimportation, what approach do you have to put downward pressure on prescription drugs prices, or is it simply Katie bar the door? Is there another approach? I am willing to embrace almost any approach that attempts to put downward pressure on drug prices.

The Cochran amendment is offered, I know, to try to effectively scuttle the issue of reimportation because it was effective in doing so to the bill we passed 2 years ago. At the time we did not know it would scuttle that legislation, but it did, with two Secretaries.

I think those who bank on the Cochran amendment effectively killing this legislation this time are wrong. We have changed the reimportation amendment this year. Our legislation now does not permit reimportation of medicines from Mexico. It does not allow for the reimportation of medicine from Bangladesh. It does not allow for the reimportation of medicines from China or Taiwan or South Korea. It allows for the reimportation of medicines from one country, Canada, a country that has a nearly identical chain of supply to this country.

It will be, in my judgment, nearly impossible for a secretary to assert that there is additional risk by allowing the reimportation of prescription drugs from a country that has a nearly identical chain of supply, a country that is our nearest neighbor, a country that is our largest trading partner.

I do not believe the Cochran amendment is effectively going to kill reimportation. I know some believe this is a great way on behalf of the pharmaceutical industry to do that, but I do not think so. As a matter of fact, I think the Cochran amendment will not have the impact it had 2 years ago because the bill 2 years ago was not country specific. This bill is limited and deals only with the country of Canada.

The Senator from Pennsylvania answered a question I did not ask, so let me ask the real question and then answer that. I was asked a question: Why are prices higher here than in Canada? That is not the question I asked. I asked the question I have asked a dozen times, which is: Who here believes that an American citizen ought to have to go to Canada to get a fair price on prescription drugs made in the United States? That is the question I asked. That still has not been answered, and I do not believe it will be answered.

If I were to try to answer the question the Senator has asked—why are prescription drugs higher priced in the United States than in Canada?—the answer is fairly simple on two fronts. One, it is true that Canada does have price controls and we do not. Second, I have held a couple of hearing on this subject, and the answer as to why drug

costs in the U.S. are so high for prescription drugs is because the charges are set in this country at whatever the consumer will bear. That was essentially what the pharmaceutical manufacturers told us.

My feeling is that it is not a fair pricing system, and on behalf of a lot of Americans, not just senior citizens who have to find a way to access these prescription drugs to deal with their serious medical problems, I think we need to find ways to put downward pressure on prescription drug prices.

I do not want people going to Canada to access prescription drugs. That is not the goal of this amendment. Our goal is to allow pharmacists and distributors to bring them back, pass the savings along, and that will force the pharmaceutical industry to reprice those prescription drugs in this country. That is our goal.

I finish with this point. It is interesting to me that some on the other side say those of us who want reimportation are saying the pharmaceutical industry is a big, bad industry; shame on them for making profits. I have heard none of that rhetoric today. I certainly have not taken part in that myself. I have said repeatedly, the pharmaceutical industry is a big industry, a profitable industry. It has done some terrific things. I commend it. I want them to do well. I wish them well. Their pricing strategy is wrong, and I want them to change it.

They will not change it voluntarily, and I fully understand that. If that is the industry I worked for, I would not change it voluntarily, I suppose, because their responsibility to the stockholders is to maximize profits. Since they have the ability to control prices in this country and maximize profits for their stockholders, that is exactly what they do. But if we are going to put a prescription drug benefit in the Medicare program and if we are going to care about the needs of all Americans, not just senior citizens, who can't afford prescription drugs, then we have to do more.

We have to employ ways to put downward pressure on prescription drug prices. We have to do that. Failing to do so means we will break the bank, and I am not prepared to allow that to happen.

So that is why we offer this, not to tarnish the prescription drug industry and the pharmaceutical manufacturers. I trust the Main Street pharmacists. I trust those distributors. I trust the Canadian system which is nearly identical to ours.

I have heard this bizarre argument about counterterrorism and counterfeit drugs. In fact, one of my colleagues brought some yellow paint, I guess yellow cement paint, and some other devices, none of which came from Canada. Isn't that interesting? Maybe I could have brought some kangaroos to the floor of the Senate and watched them jump. Wouldn't that be interesting? Sure, it is all interesting, but it has no relevance to the discussion. So we can be interesting but maybe what we should do is care a little more about pricing of pharmaceuticals in this country in a manner that is fair to the American people. That is all we are trying to do with this amendment.

We are not trying to tarnish anybody. We are saying, give the American people a fair break. If 10 cents is going to be charged for a breast cancer drug in Canada, then do not charge a dollar for it to a woman with breast cancer in the United States. Do not do that. It is not fair to the American consumer. That is all we are saying.

I yield the floor.

The PRESIDING OFFICER. The Senator from Kansas.

Mr. ROBERTS. Mr. President, I rise today in support of the Breaux-Cochran amendment to the Dorgan amendment on this subject of reimportation of prescription drugs from Canada. It is not my intent to stand here as an expert in regards to how much money the pharmaceutical companies of the United States should spend on advertising, how much money they should spend on R&D or to talk about the global imports where we have price controls in various countries, or even as to where my tie came from.

I think the Senator from North Dakota indicated that we have a lot of imports. My tie is from Italy, by the way. It is a gift from my daughter. But the thing I want to talk about is safety, and this tie which came from Italy is safe, at least to the best of my knowledge it is, unless somebody gets ahold of me and yanks on the tie.

It is not my desire to talk about the hometown druggist whether it be in North Dakota or in Kansas, where I grew up, or whether you trust the druggist. I do want to talk about safety, and I do want to talk about the fact that Senator SANTORUM was kind enough to mention that I serve on the Intelligence Committee, used to be chairman of the Subcommittee on Emerging Threats on the Armed Services Committee. I am now the ranking member with Senator LANDRIEU, who is doing an excellent job as chairman.

I am a little worried about this in regards to the language—I am not a little worried, but I am concerned about the language of the Dorgan amendment which passed and the safety issue that is raised by the Cochran amendment, which I think is the better approach.

Basically, this amendment, for which I am a cosponsor, would require the Secretary of Health and Human Services to certify that prescription drugs that are reimported from Canada are indeed safe before—and that is the keyword, ''before,'' not after. You survey and you have some sort of a panel discussion and determine that at some date later we have a situation where some drug was imported from Canada and it indeed was unsafe. I would hate to think what would happen before we would take notice of that, even in terms of lives being lost. So the key word is ''before'' we allow my constituents in Kansas or the constituents of the distinguished Senator from North Dakota or the distinguished Senator from Michigan and others throughout the United States to receive them.

As I have indicated, as a member of the Select Committee on Intelligence, ranking member on the Subcommittee on Emerging Threats, I see reimportation as another way—I would not have thought of it before 9/11, but today I see it as another way for a terrorist organization to cause many human lives to be put at risk without the proper security measures in place.

One might say: Now, Senator ROBERTS, come on. Prescription drugs from Canada—this really represents a threat?

Well, we asked all the experts in the Emerging Threats Subcommittee some time ago, prior to 9/11, what keeps you up at night in this unsafe world? Bioterrorism came in No. 1, and I won't go into the rest of them. We could probably list 100 different threats and the terrorists in their own inimical way would say we are going to do 101. It is an asymmetrical approach. How easy would it be to reenact the Tylenol scare that happened some years ago in regard to some kind of a terrorist threat?

We have seen the situation at the Capitol of the United States in regards to anthrax. Dr. FRIST, the distinguished Senator from Tennessee, can give us about an hour lecture on that, what we saw then and what we see now in regard to what we have to do in terms of safeguards.

I remember Operation Dark Winter, which was done about 2 years ago, about the possibility of using a strain of smallpox from the former Soviet Union in Oklahoma City. Do you know how they distributed that? They did it by basically walking through shopping centers and spraying plants. How easy would it be to use imported drugs from Canada?

So this year and years past, during the reimportation debate, Members of both the House and Senate have received statements from people who ought to know in regard to the fact, is there a safety issue? That is from former FDA commissioners, the current and former heads of the Department of Health and Human Services. The statement was made about this administration, past administration—their testimony was exactly the same—and officials of the Food and Drug Administration.

They state they cannot assure the American people that reimported drugs are safe. Cheaper, yes. I understand that. I understand the compassion and the caring and the difference between drugs in regard to border States and Canada or, for that matter, any State and Canada. I hope we can bring the prices down.

However, are they safe? They have even recently given testimony, all the people I just talked about, as of July 9,

about a week or so ago, before the Select Committee on Aging. Why the Select Committee on Aging? Obviously, every letter read by the distinguished Senator from North Dakota was a senior citizen who desperately needs drugs. There is a quote by the Senator from Michigan indicating that Mr. Hubbard said, on balance, he would say it would be OK for somebody who is suffering from some malady to use a Canadian drug.

I suppose if I were not in your home State and I were in Canada and sick and I didn't have much of a choice, I would say: OK, Mr. Hubbard, I think that is OK. I think I will take my chances. He is the senior associate commissioner for policy, planning, and legislation at the Food and Drug Administration.

But he also testified, as the statement demonstrated by the distinguished Senator from Michigan:

FDA cannot assure the public that reimported drugs made in the U.S. have been stored under proper conditions or that they are even the real product because the agency does not regulate foreign distributors or pharmacists. Therefore, unapproved drugs and reimported approved medications may be contaminated, subpotent, superpotent, or counterfeit.

I don't know how the supporters of the underlying amendment can read these statements by these experts and possibly indicate we are trying to scuttle the bill. I don't want to scuttle the bill. I want to put in the proper safeguards. I don't want to put lives at risk without assurance to the safety of the American consumer.

The question is, Are we, the Members of the Senate, willing to put a new burden of proof on an agency or agencies having to deal with a new set of priorities since September 11? We know in terms of trying to put together a new Homeland Security Agency, it is like pushing a rope; that we will get it done, hopefully by September 11. Here we have yet another large-scale security undertaking that they, the Customs Service, in coordination with other departments and agencies, will have to administer without the resources, without the manpower and training available to them to stop the counterfeit drugs that will put human lives, or could put human lives, at risk.

An example from Mr. Hubbard's testimony outlines exact fears we should have in allowing reimportation without the safety guarantee. On May 14 of this year, the Ontario College of Pharmacists, which is a Canadian Government agency, filed charges under the Ontario law against the Canadian Drugstore, Ink. for unlawfully operating an unlicensed pharmacy and using an unregistered pharmacist in filling prescriptions for United States residents. The college also filed charges against a licensed pharmacy and physician in Ontario for helping to facilitate the delivery of prescription and nonprescription drugs to U.S. residents. A drug wholesaler was charged with supplying medications to a nonlicensed pharmacy.

Here is the key of the whole debate. As noted by Elizabeth Durant, the executive director of Trade Promotions for the U.S. Customs Service, at the same hearing on the Select Committee on Aging, Customs is working with the Food and Drug Administration to better identify adulterated or misbranded drugs entering our borders. However, she said, at this time they clearly do not have the manpower nor the infrastructure in place to ensure adequately and screen all of the prescriptions that would enter our borders.

As an example given in Ms. Durant's testimony, we have a program. Nothing has been said about this program during this entire debate, or at least I am not aware of it, and Customs has really initiated a program called Operation Safe Guard. During a recent phase of this program that took place at two international mail branches, 31 parcels containing 52 types of questionable pharmaceuticals underwent intensive analysis. The analysis shows that eight of the so-called pharmaceutical drugs—and, yes, they were less expensive—or 15 percent contained no identifiable active ingredient. They were phony. And 18 contained a substance that is regulated under the Federal Controlled Substances Act.

There is example after example of unscrupulous practices by individuals looking to take advantage of consumers desperately trying to find a more affordable way to get the prescriptions they must have. Yes, we need to provide relief to Kansas seniors, to Minnesota seniors, to West Virginia seniors, to Massachusetts seniors, to Michigan seniors, North Dakota seniors, Oklahoma seniors, and Tennessee seniors. But I cannot in good conscience support a measure that is a public health safety and security risk.

Instead of looking to our neighbors to the north for pricing relief and instead of relying on unsure and unsafe practices without the proper personnel and training in place to roll out a plan such as this, we need to focus on passing meaningful prescription drug legislation. Until I can assure my constituents in Kansas that the drugs they are receiving are indeed what is labeled on the package, or an FDA-approved package, I do not think the underlying amendment can be supported. This is why I urge my colleagues to support the Cochran-Breaux amendment.

The key word is ''before''; before a drug gets here, it is determined safe. That is what this argument is all about. That is what the debate is all about.

Mr. FRIST. Will the Senator yield?

Mr. ROBERTS. I am happy to yield.

Mr. FRIST. Mr. President, the Senator made the point which is important and I tried to introduce earlier today. In this environment where we do have a lower threshold for worrying about terrorism and worrying about what comes across our borders, he made the linkage, based on his experience dealing in the field of bioterrorism and the agriterrorism arena and the field of intelligence, that we are moving in one direction of bioterrorism to close our borders to the potential for counterfeit agents, potential bioterror agents coming in. I made the point earlier that we need to look at it in this new environment.

My question is, Does he agree with a recent op-ed published on July 16 in the Washington Times by a former FBI agent linking bioterrorism and prescription drugs and reimportation? The agent states:

During my 3 decades with the FBI, however, I worked with other Federal agencies whose main goal was preventing illegal narcotics from crossing our borders. When going after prescription drug shipments it usually was large quantities, mostly acting on tips. Neither we nor the 3 Federal agencies we cooperated with on such efforts—the U.S. Food and Drug Administration, the Drug Enforcement Administration, and the Customs Service—had enough personnel to go after prescription drug smuggling at the time. With the massive new threat of terrorism, we have even less resources to devote to such activities. Terrorists easily could use the cover of counterfeit drug smuggling to sneak lethal prescription drugs or worse, biological and nuclear weapons, into our country.

Do you agree with the thrust of the FBI's statement?

Mr. ROBERTS. In the Emerging Threat Subcommittee we heard from the Bremmer commission, the Gilmore commission, the Hart-Rudman commission, the Center for Strategic and International Studies Group, and the Rumsfeld commission. In virtually every one of those commissions, they indicated the need for greater border security with all of the threats you have mentioned.

We just had a hearing before the Senate Agriculture Committee, and Director Ridge just came before the committee. Secretary Ann Veneman of the Department of Agriculture came before the committee. It is another one of those cases where, as we try to reorganize the Department of Homeland Security, people get a little worried about their turf. People get a little worried about past practices. People say: Wait a minute; do we need to transfer that whole agency over to the superagency?

There is an agency within the Department of Agriculture called the Animal and Plant Health Inspection Service. As you know, in working with the bioterrorism bill, I had an agriterrorism section. We tried to ramp up the funding for our basic research universities: Athens, GA, for salmonella; Ames, IA, for the livestock industry; Plum Island, where you don't want to open up any refrigerator doors under any circumstance because of the pathogens that are there. We found now that we can use 3,200 of these employees who have the capability to take a closer look and provide the kind of security the Senator is mentioning, to the Department of Homeland Security, keep the rest of the employees so if a farmer from Kansas or, for that matter, North Dakota says, ''Hey, I

have wheat rust,'' he doesn't have to pick up the phone and call Tom Ridge. Or if he is going to try to enforce the Animal Welfare Act, there is no need to do that. But 3,200 more people are needed just to prevent some kind of problem with security and danger or agriterrorism and food security and how easy it would be for the terrorist to use the pharmaceutical that you are talking about to come in and do great damage in our country.

The issue is safety, and the higher bar that we must have, now, to guarantee it.

The whole thing is, we used to talk about we have to detect, we have to deter, and then, in the worst case scenario, we have to get into consequence management. Are we ready? The answer to that is no.

The new paradigm is we have to detect and preempt. We have to go on the offensive and then deter and then get into consequence management.

What the Senator from Mississippi has done is simply said to the Department of Health and Human Services, please guarantee the safety of these products before they come in, not afterwards; not after we see some evidence that something will happen. It is a before-and-after question. Sure, that senior citizen before may get a drug that is more inexpensive. He may die. That is a dramatic kind of statement, but it could happen.

That is how I would answer the Senator.

The PRESIDING OFFICER. The Senator yielded the floor. The Chair recognized the Senator from West Virginia. The Chair permitted a question. The question has been answered. The floor belongs to the Senator from West Virginia.

Mr. ROBERTS. I think the Senator already asked the question.

The PRESIDING OFFICER. The Senator from West Virginia is recognized.

Mr. ROCKEFELLER. We had an interesting and important discussion this afternoon for quite some time. I want to add a little bit to the discussion.

The PRESIDING OFFICER. The Senate will be in order. Senators will take conversations off the floor so the Senator can be heard, and others will be recognized thereafter.

The Senator from West Virginia.

Mr. ROCKEFELLER. I say to the Presiding Officer, I would like to put a little perspective in what I see at least as the prescription drug aspect of all this, which permeates part of this discussion, although it is not immediately apparent in the debate of this afternoon.

We have this historic opportunity to do something real in prescription drugs. We also have the historic opportunity to fail to do it or we have the historic opportunity to do it in such a way that it will make us feel good but will not do anything to help seniors. In other words, that we would pass something which we could say we passed when we went home in August but would not in fact really help seniors in ways that are meaningful, something that I will not have anything to do with, that kind of strategy.

I say to the Presiding Officer, who is my good friend over many years, that nowhere is the problem more visible with respect to prescription drugs, and therefore creating a sensible plan that will address the problem of prescription drugs, than in the State I represent where 30 percent of the seniors have no drug coverage at all and 19 percent have very little drug coverage; therefore, basically half are more or less untouched entirely or to a great degree.

About a third of rural seniors as opposed to about a fourth of urban seniors—this is a 10 percent difference, but it makes a difference—pay more than $500 out of pocket each year. So my first overriding concern is the 336,000 seniors in the State of West Virginia. I will yield or sit down to nobody in fighting for them and for a plan which works for them in one of the poorest States in the Nation.

The question is, seniors know there are no easy solutions. We talk as if there are, but there are not. We have to be honest with our constituents about that. I know there is an election coming up. So what. A prescription drug bill that passes is a prescription drug bill that lasts for a substantial period of time. We have to do it right. There are a variety of alternative plans. I am not going to be referring to any of them individually, but some of them are a whole lot better than others and people better start thinking about some of the issues involved. I am going to try to raise some of those issues.

Providing a real drug benefit to all seniors, a benefit that covers all seniors all the time for all drugs at a price they can afford, that is what we need to do. At the end of the day, to be quite honest with you, seniors are not really enormously moved and do not care tremendously about whether it is a Democratic bill or whether it is a Republican bill, whether it is a White House bill. That may have some short-term advantage, but in terms of the way it affects their lives, which is what I care about, which is why I am here in this body, it doesn't make any difference to them. They don't want to be promised something we cannot actually deliver. There is a lot of talk about that kind of stuff.

As seniors consider all the competing prescription drug bills, they need to ask a number of very basic questions. One of the matters which I think people need to focus on is that the most important issue in all this is the delivery mechanism. People say: What is that? It is the core of the whole argument. It needs to be explained. It is a question of, really, who takes the risk?

One of the plans we are looking at—that is the way I am going to refer to it, one, then another, et cetera—says that the insurance companies will take the risk. Chip Kahn was President of the Health Insurance Association of America. He says that is like insuring against haircuts. An insurance company is not in the business of taking risk. They can't, and they particularly can't where people are older, sicker, and frailer and are less likely to be able to afford either to join them or to pay what it is that they charge.

On the other hand, you can also have a system where you use what you call a government/private partnership, PPMs. That is in another plan. I happen to favor that. They don't have to make a profit. They can set the price on the medicine which is best for the senior. But the business of who takes the risk is really important in all of this.

You say: How can you prove that? I will prove it indirectly. Since we do not have this before us, in West Virginia we have one plan on Medicare+Choice. We have Medicare and we have Medicare+Choice. We have Medicare, but we only have one plan that affects one part of the State involved with one university and some counties right around it. It covers 2 percent of the people in the State of West Virginia. That means it does not cover 98 percent. That means 98 percent of the people in West Virginia are not covered at all. They have a cap in their plan of $500 on their drug benefit.

That means if you use up your $500, you have a catastrophic something or other, by February, March, April, or May that is it—there is nothing you can do. There is no more expended. You have to pay for it yourself.

One good thing, though, that can be said about Medicare+Choice is that, if the plan pulls out, the senior, the Medicare beneficiary, has the option of a fallback position. That is to go back to fee-for-service medicine. That is not included in any of the other plans. I use the word ''other'' in the prescription drug plans that are before us. It is included in one, but it is not included in the others. It is not included in the one from the House. It is not included in one of the several that are wandering around the Senate Finance Committee.

If you do not have a fallback position, you can't do anything. That means you are just out of it. The plan decides to pull out and you get nothing. If it is Medicare+Choice, and the plan decides to pull out because they can't make money, because you are poor, you have a lot of people using services, and at least, therefore, you have the fallback position and that is, you can go back to fee-for-service medicine. It is an extremely important aspect of all of this.

So the question that seniors ought to ask and we ought to ask ourselves is, first, does the final plan that we vote on cover all seniors? Does it cover all seniors? Medicare does; not prescription drugs but in other things it does.

Does it cover all seniors, as prescription drugs should? All seniors need to know that they won't be left out of the prescription drug bill just because they

come from a State that has a lot of rural area where the cost of providing services is much higher. The plan I support covers all seniors in every State.

Seniors can get their drugs through their local pharmacy, just as they do now. There is no difference. The government and the private sector would be working together to make sure all seniors are covered just like Medicare today. That makes sense to me. The other plans say that every senior is ''eligible'' for coverage. But, in fact, many seniors won't get any benefit at all under these other plans. That is because those plans leave up to private insurers the decision where and when and to whom they will offer coverage.

The experience of rural areas—and certainly in my State—is the plans and insurance companies have said they want to have nothing to do with ensuring prescription drug benefits. They made it very plain. The other plans pretend they haven't said that and go ahead and include them.

Private insurers are focused on profits. ''Profits'' is not a dirty word. But it becomes an important word when you are talking about the distribution and accessibility and the affordability of prescription drugs.

We know from experience that the insurance companies will simply not voluntarily ensure seniors in parts of the State of Minnesota. They will in others but they won't in other parts. Or insurance companies will have the ability to have certain kinds of benefits in these kinds of areas, and other kinds of benefits in other kinds of areas. In other words, nothing is defined, and nothing is consistent that people can really count on. That is really wrong in prescription drugs. If we pass a bill that does that, that is wrong. That is the wrong thing to do to seniors.

We need to think about that. Seniors need to be on the alert for exactly that kind of behavior.

Second, does the final plan cover all seniors all the time?

Seniors need a benefit that is universal. They do not know when they are going to get sick or have a catastrophic incident. They have to know that it is going to be there for them all the time. They need benefits that help them 365 days a year.

The plan I support covers all seniors, all year, without a gap in benefits, and with no gaps in coverage. Other plans stop after a senior's drug costs exceed $2,000, and even if it happens to be in the first month of the year, or gives seniors no coverage at all for costs between $2,000 and $3,700. That is called a doughnut. It is a very serious problem, and a very real problem.

When you say people do not know what you are talking about necessarily out there, even in here a doughnut is a bad thing to do. When you say that you are stop-loss at $2,000 through $3,700, you have to pay everything in between, that is a wrong policy. Some of the other plans have it. The House plans have that. One of the plans floating around in the Senate Finance Committee has that. It is wrong.

Third, does the final plan cover all seniors all the time for all drugs?

That is the third question seniors need to ask us and that we need to be asking ourselves as we evaluate what we are going to do, if we are going to do something.

Seniors want to make decisions about which drugs are taken on advice of their doctor. They don't want to have it done on the advice of their insurance companies. We have heard about that for years—doctors having to dial insurance companies to get permission to do something which they know they have to do. They resent it. They are denied. Nobody can do anything about it. Doctors and patients should make key health decisions. I think that is a moral compass for how we look at a prescription drug bill.

Under the plan I support, seniors have a guaranteed benefit. Seniors and their doctors will decide which medicines are best for them to take, and they will take those medicines.

The other plans, as I say, talk about a standard benefit—the beauty of words in the Congress. But the fact is they too often leave it up to the insurance companies to decide which drugs will be covered. And that is not a guaranteed benefit for all drugs.

We went through this in the Medicare Commission for a year. It was a question about do you have a defined benefit? Do you have an actuarial? People ask, What does actuarial mean? The point is that in one you get a benefit for all seniors all across America, and in others you get a certain amount of money. When the money runs out, you are on your own.

It is cruel. It is cruel. It is wrong. But it is in two of the three main plans that we are considering on prescription drugs, and people need to know about it.

Four, does the final plan cover all seniors all the time for all drugs at a price which they can afford?

None of these questions strike me as unreasonable, if we are doing something as stark as this.

We have been talking about this for 5 years. I have sat for the last 4 years in sometimes up to three meetings a day in Finance Committee meetings and with staff trying to discuss all of these things, and here we are again. That is fine, if we produce a decent product. I don't care. The senior Senator from Massachusetts has a theory that sometimes things take 10 or 12 years to pass. If you have to do that for prescription drugs, that is a bad thing because, in the meantime, a lot of people are dying and suffering needlessly. But the plan I support on this matter of affordability is the only one with the guaranteed affordable premium for every senior in the country of just $25 a month—not 50 percent; for every senior, therefore, in the country, just $25 a month, and no large, upfront deductible.

Seniors would pay $10 for any generic drug up to $40 for more expensive brand name drugs. That is fair. After $4,000 in total dollars in out-of-pocket spending, all drug costs would be covered by—guess what—the Federal Government. Yes, medicine is expensive. Seniors are important. They are growing in size and in frailty. We are involved in their lives.

Just as under Medicare, seniors pay the same amount regardless of where they live or how much their income is each year. Some people dispute that. It is the moral principle of a social contract.

The other plans, again, as I say, in the spirit of not being unkind, mostly provide what they call ''estimates,'' or ''averages,'' like the word ''actuarially.'' It is one of those good words that makes you believe that everything is in good hands, except when the time comes for this to work it just doesn't quite work. Rather than real costs, seniors can compare. They talk about ''estimates,'' or ''averages.'' But if you look at the details, it is clear that every one of those plans has a higher premium, and large, upfront deductibles and higher copayments. That is a fact.

For example, the premium under the House-passed bill is ''estimated'' at $33 a month. But the insurance companies can set it higher. Why? Because they are establishing the risk. They are setting the price. If they don't like the risk, the price goes up. If they are out in Westchester County, the price goes down. If they go to West Virginia, the price goes out of sight. So they don't come to West Virginia because they can't make any money.

We are not blaming them for it. It is a fact of the way the free enterprise system works. Should West Virginia seniors, if anybody is interested, pay more than those in other States?

The House bill also has a suggested $250 upfront deductible that seniors have to pay every year, although that could be set higher by these same insurance companies for the same reasons.

Again, it is the benefit of how you do the mechanism which sends these benefits out. If you do it through the insurance company, they do not like risk. They don't like old, frail people. For those eligible to do it through the PBM, they do not have to make money, and they look at it differently.

So, again, for costs between $2,000 and $3,700, seniors get nothing. That is a big gap in coverage. It means millions of seniors will pay thousands more under the House bill.

I am about to conclude.

Seniors have been waiting for more than a decade while we in Congress fight about all this. I want to repeat what I said when I started by saying some of my colleagues have suggested—my colleagues on my side of the aisle—that if we cannot achieve a fair and comprehensive benefit, then we should accept a weak and watered-down bill. And what is it that is getting us all worried?

We all know we are going to have to get 60 votes. We are going to have to get 60 votes. None of the plans has enough votes right now, so we have to get 60 votes.

So that is what leads you to a watered-down plan, just so we can go home in August and say that we have done something.

We all get good benefits. Seniors all across America being left with the results of a watered-down prescription drug bill is not something that I am going to be a part of, I say to the Presiding Officer.

We have a once-in-a-lifetime chance to do something extraordinarily meaningful for every senior and every American family. Anything else is, and should be, unacceptable to every single one of us.

In the end, I want to enact a bill that guarantees West Virginians the same access to lifesaving and life-enhancing prescription drugs as people in other States. But the bill has to be right, it has to be fair, and it has to cover the right aspects. If it does not, we should not do it.

I thank the Presiding Officer and yield the floor.

The PRESIDING OFFICER. The Senator from Nevada.

Mr. REID. Mr. President, we are now at a point where the Republican leader signed off on our being able to have a vote. We wanted to do that at 5:40. The last vote was at 2:30. We have been on this amendment, we have basically agreed to, now for 2½ hours.

My point is, I know Senator ENSIGN is in the Chamber and wishes to speak.

I ask my colleague how long he would like to speak.

Mr. ENSIGN. About 15 minutes.

Mr. REID. OK. Senator DURBIN, 10 minutes; Senator WELLSTONE—

Mr. WELLSTONE. Ten minutes.

Mr. REID. And 5 minutes for Senator KENNEDY. So that is 40 minutes, I think. Does anyone else on the Republican side wish to speak?

Mr. ENSIGN. I understand Senator BUNNING would like 15 minutes, and Senator ENZI would like 10 minutes.

Mr. REID. OK. If I could have someone add up that time, that is an hour and 5 minutes. I wonder if we could work that out to save a few minutes. We need to get to military construction tonight. So rather than an hour and 5 minutes, let's do an hour.

Do you think Senator BUNNING could go for 14 minutes? I bet he could. He is a good guy. Senator BUNNING for 14 minutes—I say to my friends in the minority, they have had most of the time this afternoon. I think if we can just cut a few minutes, and if I could stop talking, it would help a little bit, too.

So I am wondering if we could ask unanimous consent that the vote will occur at 6 o'clock, with the time proportionately taken from every speaker that has requested time—30 seconds, something like that, from every speaker. I think we can work that out. The vote would be on or in relation to the amendment, No. 4301, and the time is as indicated.

Mr. ENSIGN. If the Senator would yield, I will keep mine under 10 minutes.

Mr. REID. That will take care of the problem.

I say to my friend from Nevada, thank you very much.

So I ask unanimous consent that the vote occur at 6:05, as per the agreement, with no intervening amendment in order prior to disposition of the Cochran amendment.

The PRESIDING OFFICER (Ms. CANTWELL). Is there objection?

Mr. WELLSTONE. Madam President, I will not object. But I ask the Senator, you locked in time?

Mr. REID. Everybody has the time except Senator ENSIGN. He graciously took 5 minutes off his time.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

The Senator from Nevada.

Mr. ENSIGN. Madam President, while I support the underlying amendment, I want to talk about a prescription drug proposal that I believe, and the other authors of this bill believe, could be the answer that seniors are looking for around the country.

Senator HAGEL and Senator GRAMM and Senator LUGAR and myself have been working on a proposal that I have worked on for a couple years along with Senator HAGEL.

This proposal, to keep it very brief, has two major components. The first component of our proposal allows every senior to participate on a voluntary basis. They sign up for a $25 fee. This takes care of just the administrative costs. This $25 fee allows them to get a prescription drug discount card.

We use the private sector. The private sector will set up what are called pharmaceutical benefit managers. These managers will offer certain drug plans. Seniors can choose between those drug plans. The better the drug plan, the better chance they have of attracting seniors.

It is estimated there will be somewhere between 25 to 40 percent savings for seniors using this prescription drug discount card. The reason they will save money is, very simply, that they are taking advantage of volume buying.

We see volume buying all the time. HMOs buy in volume, in bulk. So seniors will get the advantage of this volume buying when they are on Medicare and they sign up for this card.

The second part of our plan caps out-of-pocket expenses.

The biggest thing that we hear from seniors these days is that they are afraid they are going to be bankrupt. We had an e-mail in our office that came in a little after 11 o'clock Pacific Coast Time last week. It was from a person who said that many seniors have to choose between rent and prescription drugs. So they were saying: Will you step up to the plate, the ''moral plate,'' as this person called it, and do something that seniors really need?

Our plan actually does something that seniors really need. It provides them the prescription drug coverage by capping out-of-pocket expenses.

Let me give a couple illustrations.

For a senior citizen who has now signed up for the plan, let's say they make anything less than 200 percent of poverty—which is, for an individual $17,700 per year; for a couple it is almost $24,000 a year—if they are below 200 percent of poverty, our bill caps their out-of-pocket expenses at $1,500, so basically $120 a month.

So let's take, for instance, somebody who has diabetes or somebody who is a cardiac patient or a cancer patient, and they have $4,000, $5,000, $6,000 a year in drug expenses. This is what they are going to pay. Those are the seniors who need it the most.

The nice thing about our plan is—we are hearing about cost estimates of the, quote, ''tripartisan'' bill as being somewhere around $370 billion over the next 10 years. Other plans are floating around out there, and that may be $650 billion-plus.

Our plan looks like it is going to come in at an estimate of about $150 billion over 10 years. The other plans, in the next 10 years, really skyrocket. Ours goes up, like every plan does, but it does not go up significantly.

This is something for which the next generation can afford to pay; the other plans that are being talked about, the next generation cannot.

The reason our bill costs so much less money is a simple fact: If you keep the senior citizen, who is going to be getting these prescription drugs—the Medicare recipient—in the accountability loop, that means when they are paying the first dollars out of pocket—up to, for the lower income seniors, $1,500 per year—they will be cost conscious. That means they will go out and shop. They will make sure those plans have the drugs they need at a price they can afford. So we will have seniors all across the country shopping for their prescription drugs.

If we just give them a plan and say we will cover everything, the seniors quit shopping. The market forces then don't keep the competition where it needs to be. Because about half the seniors in America have less than $1,200 per year in prescription drug costs, that is where the huge savings comes to the taxpayer in our plan. We are looking out for the senior with our plan, but we are also looking out for the taxpayer. For the future of the next generation and the generation after that, we cannot afford to ignore the taxpayer because somebody has to pay for this prescription drug benefit.

All of us want to take care of our parents and our grandparents, and we want to be taken care of someday. Especially for those who really cannot afford it and are having to choose between sometimes what they are eating

and whether they are taking their medicines or whether they are able to pay rent that month and whether they are going to be able to take their medicine, it is a real problem. But we have to do it in a way that is fiscally responsible. We think our bill does that.

I have a real life example—we have received some numbers—of a senior citizen who is around 68 years of age. This is a profile of a real senior, but we won't release any names because of privacy. This patient makes around $17,000, is being treated for diabetes, has no prescription drug coverage today, and pays a total of about $5,700 currently per year. Under the Democrat proposal, at least the parts we can tell from it, this person would pay around $2,100 a year, saving about $3,900 a year. Under the tripartisan proposal, the person would pay about $2,300, saving about $3,700 a year. Under our proposal, this person would pay about $1,900 a year, saving around $3,800 a year.

So for the person who really needs it, who has serious disease and has a lot of prescription drug costs, our bill actually saves that person more, by a couple hundred dollars at least, than either the Democrat proposal or the tripartisan proposal. Yet it does this in a way that is responsible to the taxpayer because our bill is literally hundreds of billions of dollars less than the competing proposals.

I am urging my colleagues to take a look at this plan. This plan would go into effect at least a year earlier than any of the other competing plans. It can go into effect on January 1 of 2004. The other plans don't go into effect until January 1, 2005. Our plan is permanent as well. One of the other plans is sunsetted.

Our plan is easy to understand. If you take a look at it, it doesn't sound that easy to understand except when compared to the other plans which are much more complicated. It is much easier to understand for the senior. It provides the benefit and most of the benefit to those who truly need it.

I reiterate—and this must be reiterated time and time and time again—it is responsible to the next generation. We cannot afford to pay for seniors today and forget about the next generation. We all want to take care of the seniors today, but we must do it in a fiscally responsible way.

To sum up, a $25 fee, you get into the plan. You get a prescription drug discount card which saves you 25 to 40 percent. Then, depending on income, we cap your out-of-pocket expenses. For those 200 percent of poverty and below, their cap will be $1,500. For those 200 or 400 percent of poverty, they are capped at $3,500 out-of-pocket expenses for the year. For those at 400 to 600 percent, they are capped at $5,500. And for the wealthiest, they can still participate. But for the Ross Perots of the world, they have to pay 20 percent of their income in prescription drug costs before they benefit. So the Ross Perots of the world, those people who do not need the coverage like that, will not get the coverage.

I yield the floor.

The PRESIDING OFFICER. The Senator from Minnesota.

Mr. WELLSTONE. Madam President, there are other Senators on the floor. I had spoken earlier. I think I can probably cover the ground in 3 or 4 minutes.

I think it is best to be as concrete as possible. Coumadin is a blood thinner widely used in the United States. A bottle is $20.99. For the same bottle, dosage, the Canadian price is $6.23. Zocor, which is a cholesterol drug, in the United States: $116.69; our neighbor Canada, $5.51; Permax, to manage Parkinson's disease, $398.24; Canadian price, $189.26; tamoxifen, breast cancer drug, $287.16; the Canadian price, U.S. dollars, 24.78.

That is what this amendment is about that Senator DORGAN and I, Senator STABENOW, and others have supported. Our amendment passed overwhelmingly.

I have heard so much said in the last couple hours. That is why it is hard to get started, because if you get started, it goes on and on.

Families USA came out with a study today that makes it pretty clear that by a 2-to-1 margin, pharmaceutical companies spend the money on advertising and marketing as opposed to research, with profits beyond belief—what I have described as Viagra-like profits—based upon the misery, sickness, and illness of elderly people.

The pharmaceutical industry hates this amendment that has passed. They don't want to see people in Minnesota or Illinois or anywhere in the country get this discount, and they don't want to see downward pressure on prices. They don't want this to happen. The industry would be happy for us to pump in as much money as possible, as long as we give them a blank check and they can fill it in.

The amendment we have before us, the Cochran amendment, basically says that this amendment we just passed, this legislation, only becomes effective if the Secretary of Health and Human Services certifies to the Congress that implementation of this section will ''pose no additional risk to the public health and safety and will result in a significant reduction in cost of covered products.''

I don't know about the ''reduction.'' I think it is pretty clear it is going to be a significant reduction.

I have two views about this. The first is, we have had two prior Secretaries of Health and Human Services—it creates such a loophole that they have refused to provide the certification. The pharmaceutical industry, which is so powerful and has always gotten its way, it gives them the perfect opportunity to lobby against it and stop it—no question about that.

This amendment may have passed with all of our votes, although I must say I will vote for it with very mixed feelings because I believe in my heart of hearts that this Secretary of Health and Human Services will do everything to block implementation of the legislation we passed earlier today.

However, there are at least two or three things that are different, and now the optimist in me will conclude. One is that we are only talking about Canada. Anybody who really looks at this with any kind of rigor will realize it is hard to argue when you don't have the same stringent health and safety guidelines, and all of this has to be FDA guidelines in any case, No. 1.

Second of all, expectations are up. If you don't think this isn't a big deal to people—to have a dramatic reduction in the price of prescription drugs so they can afford it—you are wrong.

Therefore, I believe what has happened today—this amendment will pass overwhelmingly, close to a 100-percent vote. It has raised people's expectations. I don't mind that. I would rather have expectations raised than lowered around the country. And it is not just senior citizens; it is all citizens who benefit from this.

My final message to the Senior Federation of Minnesota and the other citizens groups who have been fighting so hard is that we should have an overwhelming vote for prescription drug reimportation, and then a strong vote for the Cochran amendment. I think we have more to deal with on health and safety issues, but we have to do it this way. But if this Secretary of Health and Human Services should block this in perpetuity—and it is clear he has no intention of certifying this—or any Secretary of Health and Human Services, representing either party—as a couple colleagues on the other side of the aisle give me that look—I say to the seniors of Minnesota, and all other citizens, all those buses you have been taking to Canada, take them right here to Washington, DC. Come right to the office of the Secretary of Health and Human Services and demand that he or she not block this in the future.

We are expecting Secretary Thompson to move on this. We are not expecting him to use the Cochran amendment as a gigantic loophole to block the legislation we passed today that would provide a serious discount and would provide many more affordable prescription drugs to people.

As a Senator from Minnesota, I will join the buses if we need to go down to the office of the Secretary of Health and Human Services. Let's hope we don't need to go.

The PRESIDING OFFICER. The Senator from Kentucky is recognized.

Mr. BUNNING. Mr. President, I rise today to talk for a few minutes about adding a prescription drug benefit to the Medicare Program.

Over the next few weeks, the Senate will debate one of the most important issues we will consider this year whether to provide a medicare prescription drug benefit to seniors.

But I am afraid that if we do not get our act together and start really working together it will all be a huge waste of time.

I think we can all agree that something needs to be done. The cost of drugs is going up and up. It is the fastest rising medical expense that seniors and many other Americans face.

And it is clear that medicare now is not set up to deal with this problem.

Medicare is still basically a 1965 program that is struggling to keep up with health care in the year 2002.

Health care has changed dramatically in the last three and a half decades.

When Medicare was first set up, prescription drug costs were low. People were more concerned about being able to afford hospital stays.

Now because of medical advances and the amazing things we can do with these medicines, the relative costs of hospital stays are less important. But the cost of prescriptions are rising.

However, the medicare fee structure is not flexible enough to adapt to this change.

It must change.

In a perfect world, we would be debating a broader Medicare reform bill now along with a prescription drug benefit.

It would be the most effective way to go, and it is something I hope we can address before too long.

But for today, we are talking about a drug benefit. We are all for it. The question is: How do we set it up and how do we pay for it?

Before I get into the substance of this issue, I think we need to first talk about process.

The Senate is built on procedure. Here we still follow precedents and rules that were handed down over two centuries ago.

It is important, and it makes a big difference when it comes to passing legislation.

In the case of the bill before us today, that process has not worked very well.

In fact, it hasn't worked at all.

I hope we have a long, thorough debate to make sure that members have time to closely examine the base bill.

After all, it doesn't even have a committee report attached to it to allow Members and staff to fully examine and assess what is in the legislation.

It was rushed through the help committee and to the floor for this debate because the committee of jurisdiction—the finance committee—couldn't agree on its own Medicare proposal.

Finance has had problems because this is a tricky, complicated issue. And the only way the majority could start today's debate was by bringing up the generic bill instead.

In my book, that is putting the cart before the horse. This is too important an issue not to get right.

We have to be careful.

Procedurally, we got off on the wrong foot, and while it might not seem that important on the surface, little twists and turns like this can make a difference when it comes to the fine print of the legislation.

We all know this is going to end up really being a debate about a prescription drug benefit. Generics are part of that, and I have no objection to considering this issue in the Senate.

That is why we are here—to legislate and make the tough calls.

But when the bill before us today is brought to the floor in such a backwards way it makes me nervous.

The fact is that we are doing the body a disservice by not letting the finance committee finish its work.

They have the most expertise in this area.

They have been wrestling with this the longest. I sure hope the majority does not try to rush them, and the full Senate, anymore into writing a bad bill.

This is a pattern we have seen before, and the results have been bad.

Virtually the same thing happened with the energy bill.

In that case, the majority leadership didn't like how things were going in the energy committee, so they brought their own separate bill to the floor and bypassed the committee.

In the end we passed legislation, but I know that it was not as good a bill as we could have passed if the committee of jurisdiction had been able to finish working its will.

We have seen this happen again and again—on the farm bill, the economic stimulus bill, the railroad retirement bill, and the patients' bill of rights.

In each case, we passed something. But we as a body didn't do our best work.

It is just as important to get things right than to get them done fast.

In the case of Medicare and prescription drugs, the majority is pushing us and pushing aside the only bipartisan prescription drug bill.

That should tell you something. And it can make a big difference when it comes to the substance.

We all know that many older Americans are faced with making some tough choices when deciding how to pay for their prescription drugs.

We have all heard of the sacrifices seniors make to afford their prescription drugs.

Some cut their pills in half to make their medication last longer or cut back on their grocery purchases to have enough money left over for another month's supply of their medication.

Many seniors can't get their doctor's prescriptions filled because they simply cannot afford them.

These are decisions that no American living in the year 2002 should have to make, and we in Congress have a moral obligation to pass a prescription drug bill this year, and get it to the President to sign.

I support the tripartisan plan that has been put together by several members of the Finance Committee.

In a nutshell, this proposal establishes a new voluntary prescription drug benefit in the Medicare Program, along with making some changes to the Medicare+Choice program to make it more competitive.

Monthly premiums are relatively low—$24. There is an affordable deductible of $250 per year.

Those who need the most help—those seniors living 150 percent below poverty receive extra assistance with costs.

And there is extra protection when out-of-pocket costs skyrocket too high.

It is a sensible proposal that means real relief to all seniors.

It is these seniors who benefit the most from this bill, and we have a responsibility to help them today—not tomorrow or the day after. But now.

Because of the way this issue is being handled on the Senate floor, we could very easily end up at the end of this prescription drug debate with no bill at all.

Because it has been rushed to the floor—because the Finance Committee is still working on a number of competing proposals—there is no real consensus about what to pass.

This could mean that no one bill gets a majority of the votes and nothing passes.

If that happens, we'll be back exactly where we started—with no relief for American seniors.

Congress can pass a prescription drug bill this year, and we can start helping seniors with their prescription costs in the near future.

We have been talking about it for years. Now we have a chance to do it.

But it is going to take real dedication by all Members of this Chamber to actually pass a bill.

And it is going to take more respect for the process, for the time and chance to make thoughtful, deliberative decisions.

Personally, I hope we don't succumb to playing politics with what is literally a life or death issue for many older Americans.

While the process we are working under looks like it has been set up to fail, I still think and hope we can come up with some sort of proposal.

Madam President, I thank you for the time, and I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Madam President, all here today have the same goal in mind, and that same goal is to be sure we have the lowest priced, best, and most available prescription drugs in the world. We do want to make sure the cost is as low as possible. How we get there we have some disagreement over, and I would like to take a moment to address the first-degree amendment that is before us right now, which I hope will be corrected with the second-degree amendment.

The first-degree amendment would allow for pharmacies and pharmaceutical distributors to reimport drugs

from Canada. I continue to have two major concerns about the amendment.

First, as my colleague from Mississippi has articulated, there is no way to assure the safety of drugs reimported from Canada. Experts, including two Secretaries of Health and Human Services, said it cannot be safely implemented for consumers. That is probably even more true since September 11 and the anthrax attack. Safety is the reason we do not have it right now.

I believe we are presently operating under the Prescription Drug Marketing Act of 1987, which expressly bans the reimportation of drugs to protect the public health and the integrity of the distribution market in the United States. It passed the Senate unanimously. That means everybody who was here on March 31, 1988, agreed for it to go through.

Former Senator Al Gore was a cosponsor, and on the House side it was implemented and backed by such outstanding conservatives as Representative JOHN DINGELL and Representative HENRY WAXMAN. They were the key House sponsors of the legislation. The finding in the bill as passed did focus on the risk of reimportation to consumers.

I ask unanimous consent that the findings from that bill be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

SEC. 2. FINDINGS.

The Congress finds the following—

(1) American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective.

(2) The integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs.

(3) The existence and operation of a wholesale submarket, commonly known as the ''diversion market'', prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases.

(4) Large amounts of drugs are being reimported to the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping.

(5) The ready market for prescription drug reimports has been the catalyst for a continuing series of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs.

(6) The existing system providing drug samples to physicians through manufacturer's representatives has been abused for decades and has resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

(7) The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.

(8) The effect of these several practices and conditions is to create an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers.

Mr. ENZI. Madam President, I will read a couple:

(1) American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective.

(2) The integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs.

(5) The ready market for prescription drug reimports has been the catalyst for a continuing series of frauds against American manufacturers and has provided the cover for importation of foreign counterfeit drugs.

It is interesting; some of the people who debated in favor of doing that—and, as I mentioned, it passed unanimously—we are having that same debate right now, and the same arguments are valid for why that would not provide a good solution for consumers.

I also mention S. 2244 would create a second route for transporting drugs into the United States outside the existing regulatory system. The bill would allow pharmacists and wholesalers to purchase drugs from Canadian sellers over which the United States authority, the FDA, and others have no jurisdiction or control. It provides the threat of counterfeits and does not depend on the integrity of the product itself but on the integrity of those handling the product.

Even worse, the bill would require drug manufacturers to disseminate their drug formulations and chemical fingerprints to potentially thousands of pharmacies and wholesalers. This information, currently protected as a trade secret, could be worth millions of dollars per drug on the black market.

Counterfeiters could obtain drug formulations and learn how to make their fake drugs look real and survive chemical analysis. Notwithstanding these very real safety concerns, it is unlikely the bill would achieve the goal of bringing cheaper drug products to U.S. consumers.

The cost savings we talk about might be obtained but more likely would be absorbed by the fees that would be charged by the exporters, the wholesalers, the pharmacists, and the testing labs.

The bill also requires Canadian sellers to register with the FDA. However, because the FDA has no authority to inspect foreign facilities, the agency will have no way of knowing whether these registered firms are legitimate, whether they handle and store drugs properly, or whether the drugs were manufactured under current good manufacturing practices. That is the first reason.

I hope our colleagues who support the amendment and have been on the floor today urging us to support the amendment so seniors can have access to the drug pricing structure that Canada has imposed on drug companies will look a little bit at Canada. Canada, which operates a socialized national medical system, has imposed price controls on prescription drugs. Canada has also imposed rationing in other health care services, such as dialysis for elderly patients suffering from kidney failure. But we probably do not want to import that policy.

I know a lot of people from Canada who come down to the United States to get their health care because they cannot get all of the choices the United States has, and even when they can get the choices, have to wait in line for it. I think it has already been covered a little bit by my colleague from Pennsylvania that in Canada they bid for the drugs.

You do not get all of the drugs. You get the one drug that will handle that general practice, and the country gets competition by bidding among the several people who try to handle that particular ailment. By bidding on it, they are able to drive some of the prices down. They also eliminate choices for doctors and for consumers, ultimately the consumers.

If what we are trying to do is price controls, we can do price controls, too. We probably ought to be debating them as price controls, legislate them, affirmative approval, and setting U.S. price controls. I hope we do not do that. I am not serious at all in suggesting that because when my wife and I first went into the shoe business, it was at the time that Nixon was in office and they talked about price controls. As soon as they talked about price controls, the companies that were supplying us with shoes did a 30-percent increase in the price of the shoes. Then, as soon as price controls went into effect, they did the 20-percent increase that they were allowed to do.

People were paying 50 percent more for shoes than they should have been just because the companies were worried about how they were going to be able to continue their profits. I can say that each and every year on the date they were allowed to raise their prices, they raised their prices. It had nothing to do with what the cost of the shoes were, but it affected the consumer dramatically.

Passing the Dorgan amendment is not only having Canada legislate for America, it is denying Congress and the American people the opportunity to fairly debate the matter. I do not think we are ready to do that yet. We all want to have the lowest priced pharmaceuticals we possibly can, but we do want to have the safety factor, and I do not think we want to have price controls or the Canada method of doing health care.

I yield the floor and reserve the remainder of my time.

The PRESIDING OFFICER. The Senator from Illinois.

Mr. DURBIN. Madam President, if I understand the unanimous consent, I am entitled to 10 minutes; is that correct?

The PRESIDING OFFICER. That is correct.

Mr. DURBIN. Madam President, this debate about prescription drugs really comes down to a very fundamental issue. It is an issue about whether or not the pharmaceutical companies will prevail and continue to charge the highest prices in the world to American consumers or whether the consumers of America, the families and the small businesses, will prevail and finally bring to this marketplace some competition, some form of oversight, that gives them a fighting chance.

America believes in its drug industry. We understand the miracles that have occurred because of research and hard work within that drug industry. Look at the money we pump every year into the National Institutes of Health, taxpayer dollars spent by this Congress at the National Institutes of Health, to find new cures for diseases—last year, $23.5 billion. I supported it. I will support it again this year; it is money well spent to find cures for diseases that plague Americans and the world.

Look at what we do as well: We say to these pharmaceutical companies we will give them a tax credit for research and development. We give them a tax break to continue to find new cures, and then we say we will give them a tax break for advertising and other costs of business.

Our Government is friendly, supportive, and encouraging of the drug industry, as it should be. What do we get in return? Well, American consumers get the highest drug prices in the world. That is right. Our taxpayers invest more money in this industry and pay more back to it than any other country in the world.

Take a look at this chart. It was prepared by the House Committee on Government Reform. They said, if Americans pay an average of $1 for a pharmaceutical product, how much would that same product cost in other countries around the world? In other words, the American pill that we have paid the research money on and the tax credits for, that cost us $1, well, what does it cost in the other countries around the world?

In France, it is 55 cents; Italy, 52 cents; Germany, 65 cents; England, 69 cents; in Canada, 62 cents.

What is wrong with this picture, Americans? We are the ones subsidizing this industry, and we are paying the highest prices. Our thanks to PhRMA for giving them all of this assistance, all of this encouragement, and in return being asked to pay the highest prices in the world. Why? Because, frankly, we as a government have never stood up and said we have had it.

The Canadians have. I heard an allusion earlier to the socialism of Canada. Well, I do not consider them to be lockstep Fabian Socialists. This is a country which decided a long time ago that when it came to the health of Canadian citizens, they were going to do everything they could to make it affordable and available, and one of the first things they did was to say to the American drug companies: If you want to sell the same pills that you are charging so much for in America, if you want to sell them in Canada, you are going to have to face price restrictions. We will not let you sell them at those inflated prices that you charge your own American citizens.

As a result, the same drugs made by the same companies, subject to the same inspection, cost a fraction in Canada of what they do in the United States.

When you take a look at some of these drugs, for example—and you will recognize these names, incidentally, because they are all over your television screen, they are in every magazine you pick up now, newspapers, every single day.

Paxil: Feel a little anxious this morning? Take your Paxil. If you take it, it is $2.62 in the United States. Go to Canada, and it costs $1.69. It is a beautiful ad they have on television. Americans, you are paying for that ad. You are paying for it about a dollar more a pill.

Zocor, $3.75 in the United States, $2.32 in Canada; Prevacid, $3.91 in the United States, $2.24 in Canada, because the Canadian Government said: We are not going to let you rip off Canadians. You can rip off Americans. They will pay for it, no questions asked. Do you know why? Because PhRMA, this lobby, has a death grip on Congress. Congress is not going to rock the boat. It is not going to pass a law to protect American consumers as the Canadian Parliament did, no way. That is what this debate is all about.

The Dorgan amendment basically says we are so despondent, we have reached the point of despair where we are going to allow people to bring in drugs from Canada, the cheap drugs from Canada, because we cannot hold the American pharmaceutical companies to a standard of charging Americans a fair price. Boy, have we really reached that point, where we have to rely on the Canadians' bargaining authority to give American consumers a fighting chance? It appears we do. But that amendment passed 69 to 30. It shows you the desperation of the Senate, that we will not pass a law demanding fair prices for Americans; we are going to piggyback on the Canadians who have the political courage to do it.

Now comes the Cochran amendment. Senator COCHRAN of Mississippi is my friend. He is an honorable man. There are two ways to look at this amendment. Let me look first at the positive side. He has said the Secretary of Health and Human Services has to be able to certify that if these drugs come in from Canada, they are going to be safe for American consumers. Well, I hope so. Most of them are exactly the same drugs we sent to pharmacies all around our country.

The second thing is that if we import them from Canada, there is a significant reduction in price for the consumer.

I think both of those tests would be met, and if that is the case, it is hard to vote against Senator COCHRAN. I am going to support him. I think it is a good standard. I sincerely hope this is not part of an agenda by the pharmaceutical companies that believe if they cannot win a vote on the Senate floor and they cannot win a vote on the House floor, they may be able to persuade one member of the President's Cabinet to put an end to the reimportation of drugs from Canada.

Think about that for a second. This one person, man or woman, serving as Health and Human Services Secretary, will have the power to stop the discounted drugs from coming from Canada into the United States. It is a considerable amount of authority.

We have had statements from Dr. Kessler at the FDA, and from people currently at the FDA, who say the Canadian drugs are safe, there is going to be no problem. And we know they are cheaper. This should not be anything other than a formal decision saying the approach of the Dorgan amendment—which I am proud to cosponsor—is an approach which is good for America.

Step back for a minute and look at this debate. Look at the fact that this Congress and this President cannot pass a law that gives the American consumer a fighting chance when it comes to the cost of prescription drugs.

We are going to rely on the political courage of the Canadians to stand up to the same companies and hope we can bring in discounted Canadian drugs into the United States. Is this upside down or what?

I hope we go further than this underlying bill on generic drugs, than the Dorgan amendment on Canadian reimportation, and actually put in place something we can be proud of, something that says to every American, rich or poor, they are not going to die, they are not going to be forced into the hospital because they have to choose between food and medicine. Is that a radical, socialist notion? I don't think so. It sounds like an American notion that we believe in this land of compassion, that we can find the resources and the wherewithal to help our people.

I have seen them. I have met them. Every Senator in this Chamber has met them. They are men and women who have worked hard all of their lives, have retired in their little homes with their savings accounts, and want to live in happiness, follow the sports page and tend to their garden and enjoy their retirement. Then comes an illness—unexpected, perhaps. The doctor tells that person—your mother, grandmother, father or grandfather—this pill will keep you out of the hospital. They go to the local drugstore and realize they cannot afford to take the medicine that keeps them out of the hospital.

That is a fact of life in America.

Meanwhile the drug companies—there will not be any tag days for the drug companies—are making a lot of

money. They are in business for a profit and deserve a profit. Look at this chart showing the profitability of Fortune 500 companies in the last 10 years: The drug industry, 18.5 percent; the median for other Fortune 500 companies, 3.3 percent.

Drug companies are doing extremely well. They say: We need to make a lot of money because we have to put the money into research for new drugs.

But look at this chart which shows how much they are spending on marketing and how much on research. The blue line is research; the yellow line is marketing. Look at the disparity in companies such as Merck, Pfizer, Bristol-Myers Squibb, Abbott, Wyeth, Pharmacia, Eli Lilly, and Schering-Plough. They make Claritin. You have seen that. They have switched over to the brand new drug called Clarinex. They used to show on television the people skipping through a field of wildflowers: I am taking Claritin and will never sneeze again.

Schering-Plough spent more advertising Claritin than PepsiCo spent on Pepsi-Cola.

Let us hold them to a standard in which we believe. The drugs are safe and will save the American consumer money.

The PRESIDING OFFICER. The Senator from Pennsylvania.

Mr. SANTORUM. I say to the Senator from Illinois, half the money in advertising for drug companies is for free samples, samples to physicians that end up going to patients for free medication. Just understand half of that money, roughly half, is for free samples given out to hospitals and doctors. That is a way many people who do not have prescription coverage end up getting some medication.

I find it remarkable the Senator says that PhRMA has the Congress in a death grip, and then says somehow the bill that passed last year over PhRMA's objection will pass this year both in the House and the Senate. He says PhRMA has us in a death grip, but at the same time they are passing legislation willy-nilly. I find that inconsistent.

I also find it inconsistent when the Senator says somehow or another we are relying on the courage of the Canadians—that is an often used term—to stand up to the drug companies. What courage is he talking about? He is talking about price controls. He was very forthright in saying we do not have the courage in the Congress to do price controls, so this is the next best thing. We all know how successful price controls are in America. They are an abject failure. We tried that in the 1970s. We have not tried it since because of the horrible disasters that occurred in our economy because of it.

What we are doing here is trying to impose price controls. On whom? We are trying to impose price controls on an industry that invests more on saving lives and preserving the quality and quantity of people's lives than any other industry in America. How are we doing that? We are doing it by reimporting drugs. And the safety issue is clear.

I encourage everyone to vote for the Cochran amendment. That is not going to be enough. Under this measure, the Dorgan proposal, drugs from all over the world—from terrorist countries—can come through Canada into this country without anybody inspecting them in Canada, no one. The law in Canada says they do not have to inspect it. As long as it is not to be used in Canada, all they have to do is mark it Canadian and ship it to the United States, and God knows what will be in the drugs. It could be terrorists, but it could be just phony drugs. We have no ability to check.

This is a huge safety issue. While the Cochran amendment gets at it, it is very important we need to do other things on this legislation to ensure that we are not opening up another avenue for terrorism, another avenue for people to die. The Dorgan amendment says we are not going to do anything to stop the reimportation of drugs until we have a pattern of people dying. So if one person dies, we will keep going until we see three, four, or five? This is remarkable. For what? So we can get lower prices on pharmaceuticals.

Understand what that means. The Senator from Illinois held up a picture of all the countries that have low prices for drugs. Every one of them have price controls, every one of them. They have price controls. They say to the company: Sell at the price we want you to sell it at or you cannot sell it.

In Canada, yes, you pay a lower price. If the company does not take the lower price, No. 1, they cannot sell their drug in Canada. No. 2, if they do not take the lower price, Canada can go ahead and license someone in Canada to make it and infringe on their patent.

What choice does the drugmaker have? None. He is absolutely correct. We in America subsidize that. He is absolutely right on that. There is no bone of contention. The question is, If we don't, what are the consequences? The consequences are very clear. There will be a dramatic reduction in the amount of research that is done. There will be less new drugs coming to market. There will be less cures. There will be less improvement of the quality of people's lives. That is a tradeoff.

But to sit up here and say this is somehow the big bad drug companies against poor patients who cannot get their drugs because of the expense of the drugs here, we have to go to Canada to get them, is a false choice. The choice is, giving that drug at a lower price, yes; putting price controls in it. If that is what the Senator from Illinois wants, he ought to offer an amendment. The choice is less research and less cures in the future.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Madam President, in just a few moments we will take a vote on the Cochran amendment. I intend to support the Cochran amendment.

I thought it might be useful to sum up where we are on the issue of trying to get a handle on the costs of drugs in the United States and also on the availability and the accessibility of drugs for our population.

There has been prescription drug legislation before the Senate for 5 years. Four years of this 5 years we were under the Republican control of the Senate, both in terms of the Finance Committee and the floor of the Senate. During that period of time, the Republican leadership found all kinds of ways to circumvent various committees to prioritize issues they wanted to do, but they never did it with regard to the availability of prescription drugs.

And now our Republican friends have been complaining all afternoon. We just heard another complaint.

This debate is about is how we are going to reduce the cost of prescription drugs, and hopefully on how we will increase the availability and the accessibility of prescription drugs.

The underlying amendment is the Dorgan amendment. It will mean many billions in terms of savings for consumers.

Mr. CORZINE. Mr. President, I rise in strong support of the Cochran amendment to allow reimportation of drugs from Canada with important safety protections, and in opposition to the Dorgan amendment, which would allow such reimportation without these important precautions.

As so many of my constituents, I am very concerned about increasing drug costs. Spiraling costs have a real impact on not just seniors but all Americans and health care costs generally.

That is why we need to find ways to contain costs. And Congress needs to enact a Medicare prescription drug benefit that will ensure that all seniors have access to the medicines they need.

Reimportation would allow American consumers to benefit from lower priced drugs available in Canada. It would provide much needed relief for seniors, and it would also provide assistance for the 39 million Americans who have no health care coverage at all.

Reimportation is not without risks, however. I feel strongly that opening our borders without ensuring that adequate protections are in place puts in danger our national security and the health and safety of our citizens. That is why I supported the Cochran amendment, which would enable the Secretary of Health and Human Services to fully assess and determine the safety of drug reimportation before allowing it to go into effect.

I opposed the Dorgan amendment because it lacked these safety precautions and could result in Canada becoming the portal for dangerous counterfeit drugs. In fact, this concern is only heightened now that we face bioterrorist threats, which we witnessed firsthand in New Jersey, where we found ourselves on the front lines of the anthrax attack.

The bottom line is that without a prescription drug benefit seniors will continue to struggle to afford all of their drugs—be they brand name, generics, or reimported drugs. Before us now, we have the opportunity to pass a prescription drug benefit that ensures the safety of our pharmaceuticals and provides access to affordable medicines for our seniors.

For those who are watching this debate, let me share some figures. I want to tell the cancer patients who are watching this debate that, as a result of the pharmaceutical companies abusing the Hatch-Waxman Act and what is called the evergreening of payments, we have seen a 19 month delay of the generic drug Taxol at a cost to consumers of $1.2 billion. Families watching and those affected with breast cancer should know they paid $1.2 billion, because the pharmaceutical companies abused the Hatch-Waxman bill.

For those families affected with epilepsy, the 30 month delay of Neurontin has cost them $1.4 billion. For patients with depression, six evergreened patents have delayed the generic drug Wellbutrin for 31 months, at a cost to consumers of $1.3 billion. For the many seniors with high blood pressure, collusive agreements have delayed generics for months, costing them hundreds of millions of dollars.

For Americans who are watching now, let me say that we are going to do something about it. That is, the underlying bill will do something about it. And we are committed to doing something about it, in spite of all the opposition we have heard this afternoon from those on the other side.

We have the Dorgan amendment, which will make a difference for all the reasons that have been outlined by Senator DORGAN, Senator DURBIN, and others. It will help to put pressure on the drug companies.

Now we are anticipating that, after this vote we will consider the Stabenow amendment. The Stabenow amendment will permit States to bargain with drug companies in order to make available to low-income, uninsured seniors and needy people, necessary drugs at the lowest possible prices.

With all these measures we are trying to give some assurance to the American people that we will make every possible effort to see a damping down on the high costs of prescription drugs.

There are other amendments which we will have an opportunity to debate through tomorrow and into Friday. Hopefully, next week we will have the opportunity to ensure the American people that they are going to have access to prescription drugs that will be dependable and affordable.

I was here in the Senate when we passed the Medicare bill in 1965. I was here in 1964 when it failed by 16, 18 votes, and about 8 months later it passed with 4 or 5 votes to spare. There was a switch of 22 votes in the Senate.

In 1965, the Senate went on record. What we did was to give an assurance to the American people that, if they played by the rules and paid their share, that when they turned 65 they would have health security. We have provided that in terms of hospitalization and physician care.

Prescription drugs are just as important as hospitalization and physician care. Can anyone believe that if we had left out physician care or hospitalization and instead included prescription drugs in 1965, that we would not be debating including hospitalization or physician care tonight in the Medicare system? Of course we would.

When we achieve it, people will say: Why did it take so long? What was the big deal about it? It is absolutely essential to our senior citizens.

Finally, I think this is also a moral issue. When we find that we have prescription drugs that can be life sustaining for our fellow citizens—the elderly and the sick, the men and women who fought in World War II and lifted this country out of a depression and sacrificed for their children—and they can't afford them, that we must act. We have the ability to help improve their quality of life and to reduce their suffering, and we are talking about sending bills to subcommittees and committees? And it is out of order?

It is about time we address this issue. That is what the American people want us to do. That is what they are challenging us to do. That is what the Democratic leader pledged we will do. And we will continue to battle and fight in the days ahead.

I believe our time has expired and under the previous order a roll call vote has been ordered.

The PRESIDING OFFICER (Mr. CORZINE). The Senator from Pennsylvania.

Mr. SANTORUM. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The question is on agreeing to amendment No. 4301. The clerk will call the roll.

The legislative clerk called the roll.

Mr. NICKLES. I announce that the Senator from North Carolina (Mr. HELMS) is necessarily absent.

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 99, nays 0, as follows:

[Rollcall Vote No. 180 Leg.]

YEAS—99

Akaka	Bunning	Conrad
Allard	Burns	Corzine
Allen	Byrd	Craig
Baucus	Campbell	Crapo
Bayh	Cantwell	Daschle
Bennett	Carnahan	Dayton
Biden	Carper	DeWine
Bingaman	Chafee	Dodd
Bond	Cleland	Domenici
Boxer	Clinton	Dorgan
Breaux	Cochran	Durbin
Brownback	Collins	Edwards
Ensign	Kohl	Santorum
Enzi	Kyl	Sarbanes
Feingold	Landrieu	Schumer
Feinstein	Leahy	Sessions
Fitzgerald	Levin	Shelby
Frist	Lieberman	Smith (NH)
Graham	Lincoln	Smith (OR)
Gramm	Lott	Snowe
Grassley	Lugar	Specter
Gregg	McCain	Stabenow
Hagel	McConnell	Stevens
Harkin	Mikulski	Thomas
Hatch	Miller	Thompson
Hollings	Murkowski	Thurmond
Hutchinson	Murray	Torricelli
Hutchison	Nelson (FL)	Voinovich
Inhofe	Nelson (NE)	Warner
Inouye	Nickles	Wellstone
Jeffords	Reed	Wyden
Johnson	Reid	
Kennedy	Roberts	
Kerry	Rockefeller	

NOT VOTING—1

Helms

The amendment (No. 4301) was agreed to.

Mr. COCHRAN. Mr. President, I move to reconsider the vote, and I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. REID. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. REID. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

AMENDMENT NO. 4305

Mr. REID. Mr. President, I send an amendment to the desk on behalf of Senator STABENOW.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Nevada [Mr. REID], for Ms. STABENOW, proposes an amendment numbered 4305.

Mr. REID. Mr. President, I ask unanimous consent that further reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment is as follows:

(Purpose: to clarify that section 1927 of the Social Security Act does not prohibit a State from entering into drug rebate agreements in order to make outpatient prescription drugs accessible and affordable for residents of the State who are not otherwise eligible for medical assistance under the medicaid program)

At the end, add the following:

SEC. . CLARIFICATION OF STATE AUTHORITY RELATING TO MEDICAID DRUG REBATE AGREEMENTS.

Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended by adding at the end the following:

''(1) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as prohibiting a State from—

''(1) directly entering into rebate agreements that are similar to a rebate agreement described in subsection (b) with a manufacturer for purposes of ensuring the affordability of outpatient prescription drugs in order to provide access to such drugs by residents of a State who are not otherwise eligible for medical assistance under this title; or

''(2) making prior authorization (that satisfies the requirements of subsection (d) and that does not violate any requirements of this title that are designed to ensure access to medically necessary prescribed drugs for individuals enrolled in the State program under this title) a condition of not participating in such a similar rebate agreement.''.

MILITARY CONSTRUCTION APPROPRIATIONS ACT, 2003

Mr. REID. Mr. President, on behalf of the majority leader, pursuant to the unanimous consent agreement previously entered into, and after having consulted with the Republican leader, I ask unanimous consent that Calendar No. 486, H.R. 5011, the military construction bill, be called before the Senate.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (H.R. 5011) making appropriations for military construction, family housing, and base realignment and closure for the Department of Defense for the fiscal year ending September 30, 2003, and for other purposes.

Mr. REID. Mr. President, before the Senators start discussing this bill, Senator MCCAIN has asked for 5 minutes in the morning rather than having his 20 minutes now.

I ask unanimous consent that when the Senate resumes consideration of H.R. 5011 on Thursday, there be 15 minutes of debate time with the time divided as follows: 5 minutes each for Senators FEINSTEIN, HUTCHISON, and MCCAIN; that upon the use of that time, without further intervening action or debate, the Senate proceed to vote on passage of the bill, with all other provisions of the previous order remaining in effect.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. REID. I thank the Chair.

The PRESIDING OFFICER. Under the previous order, all after the enacting clause is stricken and the text of S. 2709 is inserted in lieu thereof.

The Senator from California is recognized.

Mrs. FEINSTEIN. Mr. President, I am pleased to join with my ranking member, Senator HUTCHISON of Texas, to bring the Fiscal Year 2003 Military Construction Appropriations bill to the Senate for consideration. This is a balanced, bipartisan bill intended to meet some of the most pressing infrastructure requirements of our military forces.

This bill provides $10.6 billion in new budget authority. It represents an increase of less than one tenth of one percent over last year's $10.5 billion military construction bill. But it is nearly 10 percent more than the President's 2003 budget request.

The 2003 budget request submitted by the President severely underfunded the Guard and Reserves. The request was 52 percent below last year's request. Congress is left to make up the shortfall. As all Members know, the Defense Emergency Response Fund funded all projects identified by the President as necessary for the war on terror. While it may be tempting to blame the decrease in military construction funding on the costs of fighting a war on terror, the fact is that the war on terror is fully funded through the Defense Emergency Response Fund.

This bill was coordinated carefully with the Armed Services Committee, and each project in this bill is included in the National Defense Authorization Act passed by the Senate. All of the projects in this bill meet the stringent standards for military construction funding set by the Senate. Every project we funded is in the Services' Future Years Defense Plans, and every project is a top priority of the installation commanders.

Mr. President, the bill was unanimously reported out of the Appropriations Committee on June 27. The package before the Senate today includes technical and conforming changes in the bill and report, as authorized by the full Committee. These changes include clarification of report language as needed and, in one instance, a correction in the tables to delete an unauthorized project that was inadvertently included in the committee print.

The bill provides $5.6 billion—53 percent of the total—for military construction for active and reserve components. Included in this funding is $1.1 billion for barracks; $26 million for child development centers; $137 million for hospital and medical facilities; $159 million for the Chemical Demilitarization Program; and $610 million for the Guard and Reserve components.

An additional $4.23 billion, or 40 percent of the total bill, goes to family housing. This includes $1.33 billion for new family housing units and improvements to existing units; and $2.9 billion for operation and maintenance of existing units.

This bill also includes two new military construction initiatives. The first is the Army and Air Force Transformation Initiative, which sets aside funding for the Army and the Air Force to be used for infrastructure requirements.

For the Army, the funding is allocated for construction related to the Interim Brigade Combat Teams. The Interim Brigades, which were just recently renamed Stryker Brigades, are essential to the Army's effort to become a lighter, more mobile, more effective fighting force. Army officials testified before the Defense Appropriations Subcommittee earlier this year that current levels of military construction funding are not adequate to meet the Army's time line for these brigades.

Likewise, the Air Force is in need of additional funding to move forward quickly with the beddown of aircraft associated with its Air Mobility Modernization Program. The Air Force is facing a serious shortfall in airlift capability. The Air Mobility Modernization Program, which encompasses the acquisition and upgrading of C–17s, C–5s, and C–130s, is urgently needed.

Simply put, the timetables for Army and Air Force transformation that were in place prior to September 11 are no longer adequate. The war on terror has placed pressing new demands, not only on personnel and equipment, but also on infrastructure. The large increase in defense funding that has occurred since September 11 reflects those demands. Under the transformation initiative, the committee has made $100 million available each for the Army and Air Force to be used for infrastructure requirements of the Stryker Brigades and C–17 Air Mobility programs, as determined by the Services.

The second major initiative in this bill is the BRAC Environmental Cleanup Acceleration Initiative. This initiative provides an extra $100 million above the fiscal year 2003 budget request to accelerate the cleanup of dangerous contaminants at military bases that have been closed or realigned as part of the BRAC process. Until the environmental cleanup process is completed, these closed bases are the equivalent of giant white elephants. The services no longer need them, but the communities cannot complete the conversion of them to productive use. In some cases, the lengthy cleanup process presents a problem far worse than just an economic drain on the Services and the communities—in some cases, the contaminants polluting the soil of closed military bases present a serious hazard to human health and the environment.

In my home state of California, for example, plutonium contamination at McClellan Air Force Base continues to present a hazard to the community and to impede progress towards profitable reuse of the property. In Texas, toxic groundwater that has migrated to nearby neighborhoods from the former Kelly Air Force Base has raised fears among residents that the pollution could be causing health problems. These are only two of many examples. The fact is, we have a responsibility to the American people to clean up the buried ordnance and hazardous wastes that contaminate many of our closed or realigned military installations. And I believe that we have a responsibility to act expeditiously. Although the President requested only $545 million for BRAC environmental cleanup, the Services, at the request of the Committee, identified another $237 million in environmental cleanup requirements that could be executed in 2003 if funding were made available. We could not provide the full $237 million needed, but the extra $100 million we recommended will help to speed the cleanup process. Simple common sense indicates that the military should finish the cleanup from the first four rounds of BRAC before diverting scarce resources and creating additional cleanup costs in another round of base closures.