PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

The ACTING PRESIDENT pro tempore. Under the previous order, the Senate will resume consideration of S. 1082, which the clerk will report.

The bill clerk read as follows:

A bill (S. 1082) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

Pending:

Landrieu amendment No. 1004, to require the Food and Drug Administration to permit the sale of baby turtles as pets so long as the seller uses proven methods to effectively treat salmonella.

Dorgan amendment No. 990, to provide for the importation of prescription drugs.

Cochran amendment No. 1010 (to amendment No. 990), to protect the health and safety of the public.

Stabenow amendment No. 1011, to insert provisions related to citizens petitions.

Brown (for Brownback/Brown) amendment No. 985, to establish a priority drug review process to encourage treatments of tropical diseases.

Vitter amendment No. 983, to require counterfeit-resistant technologies for prescription drugs.

Inhofe amendment No. 988, to protect children and their parents from being coerced into administering a controlled substance in order to attend school.

Gregg/Coleman amendment No. 993, to provide for the regulation of Internet pharmacies.

The ACTING PRESIDENT pro tempore. Under the previous order, there will be an hour for debate prior to a vote on the motion to invoke cloture on amendment No. 990, with the time equally divided between the Senator from North Dakota, Mr. DORGAN, and the Republican leader or their designees.

Who yields time?

The Senator from Massachusetts.

Mr. KENNEDY. Would the Senator from Wyoming yield me 3 minutes.

Mr. ENZI. Certainly.

Mr. KENNEDY. Mr. President, we now have an agreement that we are going to vote on cloture on the Dorgan amendment. The Senator from North Dakota will be here to speak on that. He has a half hour. To bring our colleagues up to date, we have made very good progress during the evening, clearing matters with the Members. There are still a number of items that we will want to accept. We will indicate to the Members the topical areas so they will be familiar with the areas that we are moving ahead on. But we have narrowed the areas of controversy to probably four or five important areas where we may very well have votes during the day. The rest we will announce the agreements that have been made with the particular Senators on these issues.

We want to thank all of our colleagues. This has been very constructive. A number of these suggestions and ideas are extremely valuable. We will tell our colleagues the areas and the content of these agreements as we move on through the day.

We are in touch with a couple of Senators so we will be able to make a judgment decision at the conclusion of this vote on the cloture. We will be ready to go so we will not miss any opportunity to make progress on the bill.

I thank the Senator. The Senate will now debate the underlying cloture motion.

The ACTING PRESIDENT pro tempore. The Senator from Iowa.

Mr. GRASSLEY. Mr. President, I have not had an opportunity to speak with the Senator from North Dakota. I hope I am not abusing my privilege of working with him and having some time this morning. I yield myself 7 minutes.

The Dorgan amendment is the moment American consumers have been waiting for. I am here to urge my colleagues to vote for cloture so we can finally legalize drug importation.

As I said yesterday, the Dorgan amendment is the result of a collaborative effort by myself, with Senators DORGAN, SNOWE, and KENNEDY, to finally make drug importation legal. This is a golden opportunity that we have been waiting for years to accomplish. The bill before us is the vehicle this year to get it done.

The bill we are debating is a must-pass Food and Drug Administration bill. The Senate should send a strong message that we are committed to finally getting it done this year. This is what we have been working to accomplish today.

Making it legal for Americans to import their prescription drugs is a top priority at the grassroots of America. It needs to be a top priority here in Washington.

It is something that shows up in almost every one of my town meetings throughout Iowa. I have long advocated allowing American consumers access to safe drugs from other countries. I have always considered this more a free trade issue than I have a health or prescription drug issue.

Imports create competition and keep domestic industry more responsive to consumers. In the United States—so that I explain why I consider this a free trade issue more than a health issue—we import everything. We allow everything that consumers might want to buy; based upon the quality they choose and the price they choose, we have allowed it to come into the country if Americans want to buy from overseas. Hopefully, they want to buy American-made products. But we have considered free trade something that has given consumers the best deal they can get. So why not do it for pharmaceuticals as well as any other product people want to buy?

Consumers in the United States now pay far more for prescription drugs than consumers in other countries. If Americans could legally and safely access prescription drugs from outside the United States under a regulation that we established to guarantee safety, drug companies will be forced to reevaluate the price strategies that they have for American consumers. They would no longer be able to gouge American consumers by making them pay more than their fair share for the high cost of research and development. I sort out research and development because I think Canadians are getting a better deal from American pharmaceuticals. Germans are getting a better deal from American pharmaceuticals. They get such a low price. They don't pay the fair share. The American consumer of pharmaceutical products pays for most of the research and development that benefits the entire world. It is not fair to the American consumer.

It is true that pharmaceutical companies do not like the idea of opening American consumption of drugs to the global marketplace. They want to keep the United States closed to other markets in order to charge higher prices here. They would argue: We have to charge higher prices here. The Government directs what we pay the consumers or charge the consumers of Germany. Well, that is not fair to the American to pay for that sort of research.

However, with the Dorgan amendment—and this is what we are talking about on this important vote coming up—prescription drug companies will be forced to compete, forced to establish a fair price here in America.

Some don't want this to happen. I want to reiterate that there is an attempt to kill drug importation, as has been done many times before in this Chamber. I am referring to an amendment to make sure there is certification of health and safety. That amendment is designed to kill drug importation once again. It is a clever amendment, but it is a poison pill. Our effort develops an effective and safe system. This amendment requires all imported drugs to be approved by the Food and Drug Administration. That is the right thing to do. The amendment sets a stringent set of safety requirements that must be met before Americans can import drugs into this country, and there are stiff penalties for violation. Don't be fooled by this poison pill amendment. Voting for that amendment is a vote to kill drug importation. That amendment surely will be up if we get beyond the cloture vote, the next vote. It is important that people vote for cloture.

With the Dorgan amendment, we are getting the job of safety done. We need to make sure Americans have even greater, more affordable access to wonder drugs by further opening the doors to competition in the global pharmaceutical industry. We must make sure they have access to affordable prescription drugs.

I urge my colleagues to vote for cloture.

One additional editorial comment that is legitimate to maybe criticize GRASSLEY for voting for this amendment but a criticism that I think I would now explain; that is, that comes

from a very good fellow Member and friend of mine in the Senate who came up to me yesterday and said: Then wouldn't I be for having all restrictions against ethanol coming into this country done away with because I represent a State that is very high in ethanol.

I said the answer to that is twofold: No. 1, all restrictions ought to go off when ethanol is no longer an infant industry, and it is still an infant industry. Secondly, and more importantly, there is already a free importation of ethanol in this country of up to 7 percent of our production, and we have not even reached that 7 percent importation of ethanol. I will debate that issue when the leeway within present law allows.

So I do not think there is an inconsistency on my part in what I said about the free entry from the mature industry of pharmaceuticals—maybe not mature in biotechnology but surely mature in pharmaceuticals.

I yield the floor.

The ACTING PRESIDENT pro tempore. Who yields time?

Mr. DORGAN. Mr. President, I suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. DORGAN. Mr. President, I suggest the absence of a quorum and ask unanimous consent that the time in the quorum call be charged to both sides equally.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. DORGAN. Mr. President, let me yield myself 5 minutes from the time allotted.

Mr. President, the vote that will occur at 10:30 or thereabouts is a vote that will determine whether we can proceed to have a vote on my amendment. It is called a cloture vote—to shut off debate so we can move to the amendment I have offered. I wish to remind my colleagues again of what this amendment is.

This amendment is a bipartisan amendment sponsored by 33 Senators, Republicans and Democrats—Senator GRASSLEY, who just spoke, myself, Senator SNOWE, Senator MCCAIN, Senator KENNEDY, Senator STABENOW; a wide range of Senators, Republicans and Democrats—who believe U.S. citizens ought to be able to purchase FDA-approved prescription drugs, the identical FDA-approved drugs that are sold in other countries for a fraction of the cost of what they are sold for in this country. We believe the American people ought to be able to make the global economy work for them and ought to be able to access those same prescription drugs as long as they are in a chain of custody that makes them safe and as long as they are FDA approved.

I described them yesterday, and let me, again, ask unanimous consent to describe to my colleagues these two bottles.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. DORGAN. In these bottles is the medication called Lipitor. Lipitor is made in Ireland. It is a common cholesterol-lowering drug taken by a good many Americans. As you can see, when made in the plant in Ireland, it is put in these bottles—identical bottles—with a label that is blue in this case, red in this case, otherwise identical. The difference in this situation is that this blue bottle is sent to Canada from Ireland, this red bottle is sent to the United States. It is the same pill, same bottle, made in the same manufacturing plant, FDA approved.

The difference? Well, the American consumer is told: You get to pay twice as much for the identical drug. You get to pay twice as much.

It describes a serious problem of what I believe is the overpricing of prescription drugs in this country. We pay the highest prices in the world for prescription drugs. I do not know of anyone in this Chamber who stands up and says: Let me sign up for that. Let me tell you, I think it is right, I think it is fair, and I think it is important that the American consumers pay the highest prices in the world for prescription drugs.

I do not think anybody stands up here and claims that. What they claim is, if they do not get that kind of money, they will shut down research and development, and they are forced to charge lower prices overseas because those governments overseas won't allow them to make money.

Let me show you what happened a while ago. This Chamber—without my support because it was a foolish thing to do—said: Do you know what. We want to say to the biggest economic interests in our country, the biggest companies that have moved American jobs overseas and make investments overseas, we want to say to them that if you make profits overseas, we will allow you to repatriate those profits into this country, back here, and you get to pay a special tax rate.

Normally, when a company repatriates its profits made elsewhere, it pays normal income tax rates. But this Congress said to them: Do you know what. We will give you a special deal, a big fat tax break. If you repatriate your foreign profits, you get to pay a 5.25-percent income tax rate. Nobody gets to pay a 5.25-percent income tax rate. I would love to pay that. Everybody else would, as well. But the biggest companies in our country got to repatriate a massive amount of money and save, I estimate, about $100 billion in taxes that should have been paid because they got a 5.25-percent sweetheart deal.

So let me just turn to one drug company—Pfizer, a good company, one of the world's biggest drugmakers. This is from the New York Times of June 24, 2005. It said it would return ''$8.6 billion in overseas profits.'' So the combined repatriation of $36.9 billion—it had already announced $28.3 billion—so that makes it $36 billion they are repatriating in profits they have made overseas. The New York Times says that is four times what Pfizer spent on research and development last year.

But isn't it interesting that they charge lower prices for prescription drugs in other countries, they say they do not make money in other countries, yet when they get a big fat sweetheart deal to pay a 5.25-percent income tax rate, they repatriate $36 billion. That is on the profit they made in other countries. It looks to me as if it is profitable selling these drugs at lower prices in foreign countries. So much for that argument.

The price discrepancy I have indicated previously. I used Canada as an example, but I could use France, Italy, Germany, Spain—it would not matter. Lipitor, 96 percent higher prices for Americans; Prevacid, 97 percent higher prices for Americans; Nexium, 55 percent higher prices; Zocor—the fact is, we are paying the highest prices for brand-name prescription drugs in the world, and it is unfair. We are trying to change that.

What we are saying is: Let's let the global economy work for everybody, not just the large pharmaceutical industry. How about allowing it to work for regular folks, to buy a safe FDA-approved prescription drug, for example, from a Canadian pharmacy.

Can anybody give me one reason why a U.S.-licensed pharmacist should not be able to go to a licensed pharmacist in Winnipeg, Canada—both licensed, both with an identical chain of custody—why a U.S.-licensed pharmacist should not be able to go to a licensed pharmacist in Canada and acquire an FDA-approved drug, such as Tamoxifen, at one-fourth or one-fifth of the price charged in the United States and pass the savings along to the consumer? I am not asking for five reasons. I am asking: Can anyone give me one reason why that should be prohibited? I think the answer is that there is not a good reason why we should prohibit that sort of thing.

So we will have a vote on this amendment. My hope is we will be able to invoke cloture so we will be able to proceed to the amendment. There will be a Cochran amendment to my amendment, a second degree, and then a vote on my amendment. My hope is we will be able to do that today.

Mr. President, I yield the floor.

The ACTING PRESIDENT pro tempore. Who yields time?

The Senator from Wyoming.

Mr. ENZI. Mr. President, I yield 10 minutes to the Senator from Mississippi.

The ACTING PRESIDENT pro tempore. The Senator from Mississippi.

Mr. COCHRAN. Mr. President, I am on the floor to urge the Senate not to invoke cloture. This is a very serious amendment the Senator from North Dakota has proffered and is being considered by the Senate, and it should attract the attention and careful review of all Senators.

I noticed in the Washington Post, in an article on Thursday, May 3, the editorial writer says—of the amendment the Senator from North Dakota has offered, which ''would allow the importation of prescription drugs from other countries,'' which he claims and other supporters claim ''would let cut-rate pharmaceuticals flow into the United States'' allegedly ''saving ailing Americans untold amounts of money.'' But here is the catch, and I quote from the editorial:

> This is a mirage; importation will not solve the problem of drug pricing. U.S. drug firms sell prescription medications to countries such as Canada at low prices, a situation that would quickly change if Canadian distributors started to recycle large quantities of drugs back to the United States.

Another fact in this debate that should not be overlooked is that President Bush has threatened to veto the bill if it contains this language.

So to achieve our goal of helping to ensure safe and unadulterated prescription drugs marketed in the United States are safe, we need to have the Federal agencies that have the responsibility of assuring that safety to be in charge of certifying that.

So I have offered an amendment to the Dorgan amendment—if cloture is invoked, it will be subject to consideration—that says unless the Food and Drug Administration or the Department of Health and Human Services can certify and vouch for the safety and efficacy of imported drugs, this amendment would not be operative. And we have been told by administration officials they cannot make that certification. They do try. We all try to help by working together to ensure that what the consumers are buying is what the labels on the drugs say they are. But we have seen in recent years a growing threat from counterfeit drugs that are made in other countries—not Canada necessarily but other countries—which could be transshipped through Canada or could be mailed directly to purchasers in the United States that aren't what they say they are. Some are even dangerous. Some contain nothing at all—nothing that is effective to do what the drug is supposed to do.

So we are already confronted with a serious problem. This is going to make it much worse and exceedingly difficult for those who are charged with certifying the efficacies of drugs, protecting our citizens from dangerous drugs, counterfeit drugs, to do their job. This is going to make it much more difficult.

This is not the first time the Senate has been asked to make a decision on this amendment or amendments similar to it. On three different occasions the Senate has, without objection, or on a vote—one vote was 99 to nothing—rejected this amendment. There have been votes that have been closer. Recently, I think Senators have gotten the message this is not an amendment that is going to achieve the goals that the proponents who are offering it say it will. There will be some cheaper drugs coming into the country—but maybe temporarily—for the reasons that have been pointed out by others and in the Washington Post editorial this morning.

So I am hopeful Senators will carefully look at the situation we face. The intent, of course, is certainly laudable, but we have an overriding responsibility to make sure medications purchased by American citizens in the United States are safe and that those are decisions made by the regulators and the inspectors in the United States who have the responsibility of making those decisions. So I am hopeful the Senate will not vote to invoke cloture. If it does, we will talk a little more about the situation. But up until that point, I hope Senators will review the history of the Senate on this subject and vote against the motion to invoke cloture.

The PRESIDING OFFICER (Mr. OBAMA). The Senator from Wyoming is recognized.

Mr. ENZI. Mr. President, I yield 5 minutes to the Senator from New Jersey.

Mr. LAUTENBERG. Mr. President, we have an interesting challenge in front of us today. All of us support drug availability at affordable prices. The challenge that brings us to the floor today is how to ensure that prescription drugs used by Americans are both affordable and safe. That is the goal for all of us, I believe, in the Senate.

We trust the drugs we get at our local pharmacies, our neighborhood pharmacies, are safe because they go through a rigorous FDA approval process, and a series of tests and inspections are done before they reach our medicine chests. Those drugs improve, extend, and save lives.

I am proud so many of these drugs originate in my home State. In fact, more than half the medicines approved by the FDA in 2001 were developed by 70,000 hard-working people employed in the pharmaceutical companies of New Jersey. These companies have received more than 11,000 patents for their products since 1985 for their innovative work. Many of these products are life-extending and limit often painful and debilitating conditions.

When we look at the prospects these companies are offering, we want to encourage the research. I heard this morning about an inoculation that could be sufficient, given one time to women, that could prevent osteoporosis. What a wonderful thing. Recently, we have had a product come to the market called Gardasil. It says that young women who receive an injection of Gardasil can be protected against cervical cancer for their lives. What a wonderful thing that is. Lipitor has been known for some time to reduce plaque gathering in the valves and the veins that lead to the heart. We want to encourage that kind of development, and our goal is to make sure these workers continue developing life-saving medications and at the same time lower costs and increase access to these drugs.

I support the efforts to lower prescription drug prices, and I understand the appeal of reimportation, as long as we are absolutely assured of the safety and efficacy of these products. So if we are going to trust drugs imported from other countries, we need to be sure they are as effective and completely safe. We cannot put our citizens in the position of buying medicine they think will lower their cholesterol or prevent heart disease only to find out years later the drug was a fake.

According to the World Health Organization, up to 10 percent of all drugs sold across the globe are counterfeit. We heard debate about the countries that some of these drugs come from. If we want to give consumers the chance to buy drugs imported from other countries, we have to insist these drugs are authentic, reliable, and safe.

That is why the Senate has, on three prior occasions, required the Department of Health and Human Services to certify that importation be without additional risk to the public health while it reduces costs. That is why I intend to support the Cochran second-degree amendment, and I encourage my colleagues to do the same thing. Let's make sure what we are telling the public to buy is absolutely safe, harmless, and can improve life's qualities.

The PRESIDING OFFICER. The Senator's time has expired.

Mr. LAUTENBERG. Mr. President, I ask unanimous consent for 30 seconds more.

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

Mr. LAUTENBERG. Mr. President, the Cochran amendment would require the same certification this body has approved three times before—to guarantee prescription drugs and provide consumers peace of mind, knowing that the drugs they are taking are safe and effective no matter where they originated.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Mississippi is recognized.

Mr. COCHRAN. Mr. President, I ask unanimous consent that the article I referred to from the

washingtonpost.com be printed in the RECORD, and I thank the distinguished Senator from New Jersey for his excellent statement. We urge the Senate to reject this motion to invoke cloture.

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

[From the Washingtonpost.com, May 3, 2007]

ALMOST THE RIGHT RX

Legislation to give the FDA important new powers can do without one provision

While most attention this week has been focused on the Iraq supplemental appropriations bill, the Senate also has been debating far-reaching legislation to give the Food and Drug Administration a long-needed increase in its regulatory powers. A very unneeded amendment, however, is threatening the bill.

The bill would reauthorize the system of user fees that the FDA charges pharmaceutical companies and manufacturers of medical devices. Congress approved this arrangement in 1992 to speed FDA decision making and get needed drugs onto the market more efficiently. User fees account for a large portion of the FDA budget, but the agency's authority to collect them expires in September. There is broad support not only for maintaining the system but for increasing the amount of fees that the FDA can collect.

Attached to the must-pass user fees measure are a number of important enhancements to the FDA's regulatory authority and responsibilities. Under the legislation, the agency would be required to collect massive amounts of data on prescription drug use from public and private sources after drugs have been approved, to detect harmful side effects and other dangers that testing before approval might have missed. The FDA would also be able to require drug companies to alter warnings and other information on labels. And, critically, the agency would have the power to order drug trials after a drug's approval in certain cases.

All of these reforms would lead to better-informed regulators, patients and doctors. Everyone has an interest in enhancing the data available to the government and, ultimately, the public on prescription drugs after they enter the market. Compiling more evidence more quickly would help detect problems with new prescription medications faster and with greater accuracy and assist consumers in making reasoned choices about the drugs they take.

Complicating the bill's prospects for passage, however, is an amendment from Sens. Byron L. Dorgan (D–N.D.) and Olympia J. Snowe (R–Maine) that would allow the importation of prescription drugs from other countries, a proposal that supporters claim would let cut-rate pharmaceuticals flow into the United States, saving ailing Americans untold amounts of money. This is mirage; importation will not solve the problem of drug pricing. U.S. drug firms sell prescription medications to countries such as Canada at low prices, a situation that would quickly change if Canadian distributors started to recycle large quantities of drugs back to the United States. Further, President Bush has threatened to veto the bill if it contains such language. For the sake of common sense, and to enhance the chances of urgently needed legislation, the Senate should reject the importation amendment before passing the bill.

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

Mr. BURR. Mr. President, if I could ask the ranking member for a few minutes to speak about reimportation.

Mr. ENZI. I yield 4 minutes to the Senator from North Carolina.

Mr. BURR. Mr. President, I thank the ranking member.

I find it somewhat ironic that we are on the floor to discuss an amendment to a drug safety bill which would allow drugs to be imported freely from any country around the world. Maybe I am the only one who finds some irony in that. We are constructing a mechanism in this country to set up a system of surveillance, to recognize red flags that may suggest to us we need to look deeper into the unintended consequences of drugs that have already been proven safe and effective; and we go even further than that and codify into law a very regimented process for the Food and Drug Administration to go through if, in fact, it is triggered that there might be a problem. Then, in the same bill, because of the outrage over the concerns we have for prescription drugs, now we are going to say to the Chinese: continue to manufacture, continue to ship in, and these products may not even have an active ingredient.

We adopted Senator DURBIN's amendment that related to pet food safety standards. Well, what this suggests to me is that for us to consider the importation or reimportation of drugs is to say we put pet food above the drug chain for the American people, that we are willing to put more standards on pet food today than we are on the importation of these drugs.

Passage of the Medicare prescription Part D plan, which was a year ago, lowered significantly the pressure that was felt to obtain drugs over the Internet or drugs from other countries. Why? Because in the first year, we have seen a 33-percent reduction in the price of those pharmaceuticals for our Medicare-eligible population. It is not that all the pressure is off, but I am not sure the remaining pressure is going to be alleviated by providing a drug supply that has no active ingredient or that denies consumers the security of knowing they are going home and they are taking their drugs but then they suffer the consequences of ending up in an emergency room because they didn't get the active ingredient they needed.

Last year, 1.7 million tablets of counterfeit Viagra were uncovered; 1 million tablets of Lipitor that were, in fact, counterfeit; and a half a million tablets of Norvasc were seized in China.

What is unfortunate is China is not the only country in the world where we have created a cottage industry of producing drugs that look just like the ones we sell in a pharmacy but that we regulate at a gold standard that many on this floor have tried to protect every time we debate legislation that is about the Food and Drug Administration. We are here today to assure the American people that we are raising the gold standard—that it is not just the bar of where we determine safety and efficacy but we are raising the standard when the population at large is exposed to that medication to make sure that, in fact, unintended consequences are fully investigated. To accept the importation of foreign drugs is to open the door for a cottage industry today to become a mega industry tomorrow by supplying counterfeit drugs with no active ingredient, with the potential that there are ingredients in it that are adulterated, that will not only not solve the health problems but, as has been proven in the pet food supply, could kill. Now, when people die, we put the standards higher than we do the standards of reimportation or importation of drugs. I urge my colleagues to at least accept the Cochran amendment which puts a safety standard in, but do not pass this importation legislation.

The PRESIDING OFFICER. The Senator's time has expired.

The Senator from North Dakota is recognized.

Mr. DORGAN. Mr. President, my colleague is apparently going to win a debate we are not having: that this is a bill that will allow the import of prescription drugs from any country around the world. I don't know of that piece of legislation, but if it exists, I will be happy to vote against it. That is not what this amendment is. This amendment doesn't allow imported drugs from anywhere around the world at all. So I am not interested in losing a debate I am not involved in. This debate is about a piece of legislation, carefully constructed, in which we allow imported drugs from countries which have been judged to have a safe supply of drugs.

Let me give an example of testimony from David Kessler. I would say if you could find an expert better on these subjects than David Kessler, I would like to hear the name. He ran the FDA for 8 years and has been identified by everybody as an outstanding FDA Commissioner. Here is what he says. The Dorgan-Snowe bill provides:

A sound framework for assuring that imported drugs are safe and effective. Most notably, it provides additional resources to the agency to run such a program, oversight by the FDA of the chain of custody of imported drugs back to the FDA-inspected plants, a mechanism to review imported drugs to ensure that they meet FDA's approval standards, and the registration and oversight of importers and exporters to assure that imported drugs meet these standards and are not counterfeit.

All of this discussion about counterfeit that is happening today, under today's rules, without importation. That is a specious issue. Dr. David Kessler says it provides a sound framework for assuring that imported drugs are safe and effective.

Let me show you a chart from Dr. Rost. I mentioned earlier that they have been doing this for 20 years in Europe. Dr. Peter Rost, former vice president of marketing at Pfizer, said:

During my time responsible for a region in northern Europe, I never once—not once—heard the drug industry, regulatory agency,

the government, or anyone else saying that this practice was unsafe—

He was talking about importation of prescription drugs. If you are in Germany and you want to bring a drug in from France, you can do it through what is called parallel trading. If you are in Spain and want to bring a drug in from Italy, you can do that. So he said not once has anybody raised the issue that this practice was unsafe.

He also said:

Personally, I think it is outright derogatory to claim that Americans would not be able to handle reimportation of drugs, when the rest of the educated world can do this.

That is the fact. One other thing: the Congressional Budget Office says this amendment will save $50 billion in 10 years. The leading expert says there is no safety issue. We have a regime in this bill that provides for safety. So the question isn't on all of these ancillary issues—by the way, the Washington Post doesn't take on this issue with respect to safety. It says there is, in fact, a problem with drug pricing. I will read it. They don't want this passed, but the reason is they are worried it will undercut the underlying bill because the President will veto it.

Here is what the President said when he was running in 2000. He was asked:

What about importing drugs?

The President said:

Well, if it is safe, then it makes sense.

Obviously, he was telling those at that debate that he thinks it makes sense if it is safe. How about consulting Dr. David Kessler, who says it is safe and effective, as we have described it in this legislation. So what the Washington Post says—because the President threatened to veto the bill—they are talking about ''importation will not solve the problem of drug pricing.''

Apparently, the Washington Post thinks there is a problem in drug pricing. What is that problem? To respond to my colleague's comments, in the first quarter of 2007 we had the largest price increase in prescription drugs in this country in 6 years. The American Association of Retired Persons, AARP, said in 2006 the price of prescription drugs rose four times the rate of inflation. There is no problem? I think there is a problem. The Washington Post says there is. The numbers show there is a problem.

The question is, Are we going to solve the problem, or are we going to punt it down the road one more time?

Mr. President, I yield 5 minutes to my colleague from Vermont.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. SANDERS. Mr. President, I congratulate my colleague from North Dakota for the extraordinary and comprehensive outline of this issue that he has made not only today but in the past.

Mr. President, every single day in this Congress, and throughout America, people sit down and eat their lettuce and tomato and their salads. Their tomatoes come from Mexico, Latin America, and their lettuce comes from Latin America. Other foods they eat come from as far away as China. Billions of dollars of food imports come into this country, but I don't hear anybody in this body standing up and saying, oh, we have a problem about food safety or food coming from other countries. They come in.

There is a problem—and I don't hear it too often here, but somehow the U.S. Government, with the FDA, cannot regulate a small number of drug companies so that we can safely bring in prescription drugs from Canada and other industrialized countries so that, as a result, we can substantially lower the cost of medicine for millions and millions of Americans. This is absurd. Of course, we can safely regulate the flow of medicine coming into this country.

The real issue is not the safety of medicine. The real issue is the power of the pharmaceutical industry, the most powerful industry in terms of lobbying impact in the United States of America. If you think the oil companies are powerful, take a look at the drug companies. If you think the banks are powerful, take a look at the drug companies. Today, we are living under a Medicare Part D prescription drug program that was written by the drug companies, for the drug companies. Today, billions of dollars of taxpayer money goes into research and development for new medicines that go to benefit the drug companies, while the American people do not get reasonable prices for the products they help to produce.

Mr. President, since 1998, the pharmaceutical industry has spent over $900 million on lobbying activity—$900 million. That is more than any other industry. Today, there are over 1,200 prescription drug lobbyists right here on Capitol Hill and throughout this country. Do you know what their job is? Their job is to make sure in the United States of America we continue to pay, by far, the highest prices in the world for the medicine we use.

If you have a chronic illness, there is a strong likelihood you will be paying two times as much for the same medicine as our friends in Canada or Europe pay. Why is it that the same medicine, manufactured in the same factory, costs us, in some cases two times, and in some cases three times, as much money as it costs our Canadian and European friends?

The answer is pretty simple. It has everything to do with the power of the pharmaceutical industry and the enormous amounts of money they spend on lobbying, on campaign contributions, on advertising, and the pressure they put on Members of the United States Congress.

Mr. President, I have been involved in this issue for a number of years. I have been involved in it in an emotional way because I was the first Member of Congress to take constituents over the Canadian border to purchase, in that case Tamoxifen, which is a widely prescribed breast cancer drug that ended up costing Vermont women one-tenth the price they had to pay in the United States.

In our country today, there are people struggling very hard with terrible illnesses who have no health insurance and who need their prescription drugs. Some of them simply cannot purchase their prescription drugs. Some are taking money out of their food budget to buy their prescription drugs. We are a great nation in many respects. But the time is long overdue for Members of the Senate, for Members of the House, to reclaim this institution from the powerful special interests.

Today is a day of reckoning. This is very important legislation. This can drive the price of prescription drugs down by 25 to 50 percent. Let's stand together and, for those Members who are wavering on the issue, who think they cannot vote for it, I hope at least they will support cloture to allow us to continue this debate and to finally lower the cost of prescription drugs for the American people.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Mr. President, what is the time situation?

The PRESIDING OFFICER. The Senator from Wyoming has 10 minutes. The Senator from North Dakota has 3½ minutes.

Mr. ENZI. Mr. President, I rise to oppose cloture on the amendment. I find it ironic that in the midst of the work on the biggest drug safety reform in the last decade, perhaps longer than that, we are even considering the issue of drug importation.

Our drug safety bill is an acknowledgment that we don't have things quite right in our domestic drug safety system. I am baffled that we want to take on all the hard work and effort to fix our drug safety problems and throw it away by opening our borders to foreign drugs.

When I was Chairman of the HELP Committee, we held three hearings on drug importation. The witnesses at the hearings raised a number of problems and questions about importation in general, and this bill in particular. In fact, one of those hearings was entirely about this bill. At that time, I asked my colleague from North Dakota if he would work with me to develop a State-based pilot program for drug importation. He turned me down. He was convinced then, as he is now, that this bill is the way to go. I would like to take these kinds of proposals in small chunks, if we are going to have to take them, to ensure we don't create a large-scale disaster. I hope we are not going to create a disaster here by accepting this amendment without further consideration.

I respectfully suggest that this bill is not the way to go, and even if it were, this isn't the time for it to go there. We have heard a lot of comments about the Washington Post editorial, and I refer people to that editorial. They

cover a number of factors, but they do emphasize that the main bill, the safety bill—the FDA safety reform bill that we are working on—is a very important bill. They do recognize this amendment would add some very strong complications to it. The Senator from North Dakota suggests we read the bill. You know, that is a good suggestion for anything we cover around here. I make an effort to read all of the bills we do, and I have read this one. I hope everybody takes a look at this one.

I think you will vote against cloture if you read the bill. It is a roadmap to loopholes. Yes, every time somebody brings up a potential safety issue, they stick another clause in there that might cover that gap. But it shows where the gaps are most likely. They keep adding paragraphs to try to patch up these loopholes. We have an amendment that would have been a second degree, but it was too late for it to be submitted as a second degree, so it is a first-degree amendment that would deal with anti-counterfeiting.

That is another area that has to be looked at carefully. The Senator from Vermont talks about taking people into Canada to buy drugs. Well, you know they are going to the exact pharmacy at that point. They are not going through the Internet or through the telephone. These drugs can be intercepted—there are false sites that are set up out there, and people may think they are getting drugs from Canada, but are actually getting them from Saudi Arabia and other places around the world. It is so easy to get information and believe it is coming from a particular location—they may even imply it is a particular location to get the consumer's confidence. There are so many ways they can mislead consumers and it may not be that location. To try to solve some of that, Senator GREGG has an amendment that would perhaps tighten up the Internet problems. But look at that, too, and you will see there are problems if you are not getting it directly from the pharmacy.

I am a strong supporter of people getting drugs from their local pharmacist, the one who will help you interpret all of the sheets of paper that come with the prescription. They are going to know what other drugs you are taking and if there are possible interactions. Local pharmacists are the most valuable asset we have in the entire pharmaceutical chain. But bills like this work against them and may have consequently put them out of business. That is going to be a tragedy for America.

I have read the amendment. I encourage people to read it and look at the complexity of the amendment and look at the loopholes they are suggesting they have fixed. See if you think this patchwork fixed them. But I also ask that you look at what the Washington Post said, and I am not one of those who normally advocates that you listen to what they say. But it is definitely food for thought on this bill. It will take away a major reform that we could have by throwing something else in that we need to discuss more.

I ask my colleagues to oppose cloture for the sake of the safety of our drug supply. Let's get it fixed at home before we try to open it up to the world.

Mr. President, how much of my time remains?

The PRESIDING OFFICER. The Senator has 5 minutes.

Mr. ENZI. Mr. President, in order to allow the Senator from North Dakota to have the final word, since it is his amendment, I ask people to vote against cloture.

I yield back the remainder of my time.

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. DORGAN. Mr. President, I thank my colleague from Wyoming. I regret he cannot be a supporter of cloture and the amendment. I respect and understand his position. We disagree, and I do so respectfully.

I do wish to mention one thing with respect to a pilot program. Following that hearing, I did put together a pilot project and went to Tommy Thompson. I went down to his office and made a presentation of a northern plains pilot project on prescription drugs. He felt like he couldn't move forward with it.

I do want to say what he said to me after he left Health and Human Services. I met him in the elevator outside the Senate Chamber one day after he left being Secretary. I badgered him a lot about the issue of reimportation. As I got off the elevator and he was getting on, we greeted each other. I liked him. I thought he was a good Health and Human Services Secretary. He said: By the way, Byron, you keep working on the imported drug issue. You are right about that. That was after he left Health and Human Services.

Let me again respond with respect to David Kessler. All this talk about safety. First of all, this is where this amendment belongs, on this bill. This improves the bill. It doesn't detract from safety issues at all. It does address something not addressed in this bill, and that is a serious pricing problem with prescription drugs in our country.

There is no answer to this that I have heard in all the discussion. David Kessler, head of FDA for 8 years—I think he is the expert on these issues—said: The Dorgan-Snowe bill ''provides a sound framework for assuring that imported drugs are safe and effective.''

He says they will be safe and effective. Why would someone go to some fraudulent Web site, as was discussed, or maybe go to a bad Web site, why would somebody go to a bad Web site in order to import prescription drugs if a Web site by the FDA exists that would describe where they can access these prescription drugs safely? Those are specious arguments.

The Congressional Budget Office says this amendment will save $50 billion over 10 years. Why would they say that? Precisely because the Washington Post acknowledges there is a pricing problem with prescription drugs in our country. There will be a $50 billion savings over 10 years.

I mentioned that in the first quarter of this year the price of prescription drugs had the largest increase in 6 years in this country. Last year, 2006, according to AARP, it rose four times the rate of inflation.

There is a pricing problem with prescription drugs. The identical drug FDA approved, same pill, put in the same bottle, made by the same company, is sent virtually every other place in the world at a lower price, and the American consumer is told: You know what, we have a special deal for you. You get to pay the highest price in the world.

The question is whether this Congress will decide that special deal of the highest price in the world ought to stop. I hope this Congress will decide we are going to stand with the consumers. Yes, we are going to insist on safety, but we are going to stand with consumers. There is a pricing problem. This amendment is one way to fix that problem in a manner that is safe and effective.

Finally, Mr. Rost says that for 20 years, they did this in Europe. He said:

> I think it is outright derogatory to claim that Americans would not be able to handle reimportation of drugs, when the rest of the educated world can do this.

Of course, we can do this. Of course, we can allow someone to go to Canada and buy from a Canadian drugstore that has as safe a chain of custody as we do and buy prescription drugs, in this case Lipitor, for half the price that is being charged 5 miles south across the border.

Why on Earth should the global economy not be able to work for average folks? The pharmaceutical industry imports all of these drugs. Why should the average person in this country not be able to put downward pressure on prescription drug prices by being able to access FDA-approved drugs from other countries, such as Canada and other countries, that have a supply of safe drugs. That is what our amendment does. It is the right thing to do.

Mr. President, how much time remains?

The PRESIDING OFFICER. The Senator's time has expired.

Mr. DORGAN. Then I yield the floor, Mr. President.

CLOTURE MOTION

The PRESIDING OFFICER. Under the previous order, pursuant to rule XXII, the Chair lays before the Senate the pending cloture motion, which the clerk will report.

The assistant legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule

XXII of the Standing Rules of the Senate, hereby move to bring to a close debate on the Dorgan amendment No. 990 to S. 1082, the FDA Revitalization bill.

Byron L. Dorgan, Dick Durbin, Claire McCaskill, John Kerry, Ted Kennedy, Amy Klobuchar, Sherrod Brown, Ken Salazar, Mark Pryor, Daniel K. Inouye, Chuck Schumer, Harry Reid, Ron Wyden, Dianne Feinstein, Carl Levin, Blanche L. Lincoln.

The PRESIDING OFFICER. By unanimous consent, the mandatory quorum call has been waived.

The question is, Is it the sense of the Senate that debate on amendment No. 990, offered by the Senator from North Dakota, to provide for the importation of prescription drugs shall be brought to a close?

The yeas and nays are mandatory under the rule. The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from Delaware (Mr. BIDEN), the Senator from New Mexico (Mr. BINGAMAN), the Senator from Connecticut (Mr. DODD), and the Senator from South Dakota (Mr. JOHNSON) are necessarily absent.

I further announce that, if present and voting, the Senator from Delaware (Mr. BIDEN) would vote ''yea.''

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from South Carolina (Mr. GRAHAM), the Senator from Utah (Mr. HATCH), the Senator from Arizona (Mr. MCCAIN), and the Senator from Virginia (Mr. WARNER).

Further, if present and voting, the Senator from Utah (Mr. HATCH) and the Senator from South Carolina (Mr. GRAHAM) would have voted ''nay.''

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

The yeas and nays resulted—yeas 63, nays 28, as follows:

[Rollcall Vote No. 150 Leg.]

YEAS—63

Akaka	Feinstein	Nelson (NE)
Baucus	Grassley	Obama
Bayh	Harkin	Pryor
Boxer	Inouye	Reed
Brown	Kennedy	Reid
Byrd	Kerry	Rockefeller
Cantwell	Klobuchar	Salazar
Cardin	Kohl	Sanders
Carper	Landrieu	Schumer
Casey	Lautenberg	Sessions
Clinton	Leahy	Shelby
Coburn	Levin	Smith
Coleman	Lieberman	Snowe
Collins	Lincoln	Specter
Conrad	Lott	Stabenow
Corker	Martinez	Tester
Craig	McCaskill	Thune
DeMint	Menendez	Vitter
Dorgan	Mikulski	Webb
Durbin	Murray	Whitehouse
Feingold	Nelson (FL)	Wyden

NAYS—28

Alexander	Cochran	Gregg
Allard	Cornyn	Hagel
Bennett	Crapo	Hutchison
Bond	Dole	Inhofe
Bunning	Domenici	Isakson
Burr	Ensign	Kyl
Chambliss	Enzi	Lugar
McConnell	Stevens	Voinovich
Murkowski	Sununu	
Roberts	Thomas	

NOT VOTING—9

Biden	Dodd	Johnson
Bingaman	Graham	McCain
Brownback	Hatch	Warner

The PRESIDING OFFICER (Mr. BROWN.) On this vote, the yeas are 63, the nays are 28. Three-fifths of the Senators duly chosen and sworn having voted in the affirmative, the motion is agreed to.

AMENDMENT NO. 1010

Mr. COCHRAN. Mr. President, I have an amendment at the desk. It is to S. 1082. I propose this amendment in my behalf and in behalf of Senators CARPER, NELSON of Nebraska, HATCH, BENNETT, ENZI, BURR, and MENENDEZ. I ask the amendment be stated or reported.

The PRESIDING OFFICER. The amendment of the Senator is already pending. The Senator may proceed.

Mr. COCHRAN. Mr. President, the purpose of this amendment is to require, before importation can be undertaken, a certification by the Secretary of Health and Human Services or the Food and Drug Administration that the importation of the drugs will indeed have an economic benefit to the consumers who buy those drugs and that they are safe and not harmful for human consumption.

We have had discussions over the last several years, really, with administration officials who have been very concerned that the importation of drugs that would be permitted by the Dorgan amendment needs to be balanced by the interest we have in protecting the integrity of the marketplace so no counterfeit drugs are imported, creating the impression that they are something that they are not.

This is a very real problem. I recall having meetings here in the Senate with members of the committees with jurisdiction, learning about the growing problem and the continuing increase in instances where postal inspectors and others who are charged with the responsibility of enforcing our laws and protecting American consumers are finding that drugs which are manufactured in other countries—not Canada necessarily but in India, in Asia, in South America—are counterfeit. They look like the real thing. The labels look like the legitimate and ordinary labels you see on the drugs being purchased, but they are not what they say they are.

This is a very difficult issue to deal with. What we are asking in this amendment is that the Senate insist that if drugs are going to be imported, then there has to be a certification by the FDA or the Department of Health and Human Services that they are safe for human consumption, that they have not been tampered with, and that they are not counterfeit.

I hope the Senate will approve this amendment to the Dorgan amendment. I don't know of anything else to say. I submitted, in earlier comments, a washingtonpost.com article, which is printed in the RECORD now, which supports this effort and talks about the importance of certification to the consuming public. We have a lot of information. We will be happy to discuss the details with any Senator who is undecided about approving this amendment, but I hope the Senate can adopt this amendment.

The PRESIDING OFFICER. The Senator from Wisconsin is recognized.

AMENDMENT NO. 991

Mr. KOHL. Mr. President, I ask unanimous consent to set aside the pending amendment so I may call up my amendment, amendment No. 991, and I ask for its immediate consideration.

The PRESIDING OFFICER. Is there objection?

Mr. ENZI. I object.

The PRESIDING OFFICER. Objection is heard.

Mr. ENZI. There is still a lot of work being done on this amendment. Senator KYL and others are involved in it and would not want the debate until we had more chance to work on it.

Mr. KOHL. I will offer the amendment after that.

Mr. President, I rise to speak to amendment No. 991, which is supported by Senators GRASSLEY and LEAHY. I thank my colleagues for their support. Our amendment is in almost all respects identical to S. 316, the Preserve Access to Affordable Generics Act, which passed the Judiciary Committee unanimously earlier this year.

Our amendment will prevent one of the most egregious tactics used to keep generic competitors off the market, leaving consumers with unnecessarily high drug prices. The way it is done is simple—a drug company that holds a patent on a brandname drug pays a generic drugmaker to not put a competing product on the market. The brandname company profits so much by delaying competition that it can easily afford to pay off the generic company. And the generic company can also make much more money by simply accepting this pay-off settlement. The losers are the American people, who would continue to pay unnecessarily high drug prices for years to come.

Our amendment is basically very simple—it will make these anticompetitive, anticonsumer patent payoffs illegal. We will thereby end a practice seriously impeding generic drug competition, competition that could save consumers literally billions of dollars in health care costs.

Despite the FTC's opposition, recent court decisions have permitted these backroom payoffs. And the effect of these court decisions has been stark. In the year after these two decisions, the FTC has found, half of all patent settlements—14 of 28—involved payments from the brandname to the generic manufacturer in return for an agreement by the generic to keep its drug off the market. In the year before these two court decisions, not a single patent

settlement reported to the FTC contained such an agreement.

When brandname drugs lose their patent monopoly, this opens the door for consumers, employers, third-party payers, and other purchasers to save billions—63 percent on average—by using generic versions of these drugs. A recent study released earlier this year by Pharmaceutical Care Management Association, showed that health plans and consumers could save $26.4 billion over the next 5 years by using the generic versions of 14 popular drugs that are scheduled to lose their patent protections before 2010.

We have heard from some in the generic drug industry that on occasion these patent settlements may not harm competition. That is why our amendment includes a new provision not contained in S. 316. This new provision would permit the Federal Trade Commission—the guardians of competition in this industry—to exempt from this amendment's ban certain agreements if the FTC determines such agreements would benefit consumers. This provision will ensure that our amendment does not prevent any agreements which will truly benefit consumers.

It is also important to note that—contrary to the arguments made by some—our amendment will not ban all patent settlements. In fact, our amendment will not ban any settlement which does not involve an exchange of money. Our amendment will do nothing to prevent parties from settling patent litigation with an agreement that a generic will delay entry for some period of time in return for ending its challenge to the validity of the patent. Only the egregious pay-off settlements in which the brandname company also pays the generic company a sum of money to do so will be banned.

We understand that several of our colleagues would prefer alternative versions of this proposal. As I have said all along, we continue to be willing to consider modifications to this measure as long as this legislation will be effective to ensure these anticonsumer pay-off settlements stop. I am happy to work with my colleagues to find an effective manner to do this. I have directed my staff to work with the staff of other interested Senators in this regard, and I am willing to continue to engage in this process. Short of such an effective alternative being presented to me, we will ask for a vote on adoption of this amendment.

In closing, we cannot profess to care about the high cost of prescription drugs while turning a blind eye to anticompetitive backroom deals between brand and generic drug companies. It is time to stop these drug company pay-offs that only serve the companies involved and deny consumers to affordable generic drugs. I urge my colleagues to join me in this effort by supporting this amendment. I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

Mr. KENNEDY. Mr. President, the Kohl amendment seeks to end abuse of the system for bringing generic drugs to the market. Under Hatch-Waxman, there is a sensible and balanced system for rewarding generic drug makers who enter the market first, but some companies have subverted this balanced system.

Instead of allowing market forces to bring medicines to consumers at lower prices, companies collude to deny consumers the benefit of the lower cost drugs through ''reverse payments.'' Essentially, there is a payoff from the brand drug companies to the generic companies to split the benefits of the incentives provided under Hatch-Waxman.

Everyone benefits under these arrangements, except consumers. Brand drug companies get further protection from competition, generics get payoffs and a guaranteed market. Only consumers get left behind, stuck with high prices and lesser competition.

The Judiciary Committee reported legislation on this important issue. I commend Senator KOHL for his leadership. I know Senator SPECTER and Senator HATCH have important recommendations. I am sure we can work these matters out in a proposal to include the best ideas.

We understand there are members of the Judiciary Committee who may want to speak to this amendment. I would hope the Senator would withhold further comments until we can see if there are members of the Judiciary Committee who want to address this amendment. I hope we will be able to include it and adopt it.

I yield the floor.

The PRESIDING OFFICER. The Senator from Mississippi is recognized.

Mr. COCHRAN. Mr. President, I ask unanimous consent the Senator from New Mexico, Mr. DOMENICI, be added as a cosponsor to my amendment.

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

The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

The PRESIDING OFFICER. The Senator from Michigan.

Ms. STABENOW. I ask unanimous consent that the order for the quorum call be rescinded.

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

Ms. STABENOW. Mr. President, I send to the desk a modified version of amendment No. 1001 to the desk. We are adding Senator KOHL, Senator HATCH, and Senator COBURN as cosponsors of the amendment.

Mr. ENZI. I object.

The PRESIDING OFFICER. The objection is heard.

The Senator from North Dakota is recognized.

Mr. DORGAN. Mr. President, as was indicated earlier, the Cochran amendment, with cosponsors, is currently pending, I believe, or has been appropriately offered and is pending. I would like to make a couple of comments about the vote we will have at some point in the future on the Cochran amendment. And what I would like to do is go through so that all of our colleagues understand what is in the underlying bill.

I indicated earlier that one of my colleagues stood up and said the legislation we had offered would allow drug importation from any country in the world, and that is not true. There is no such debate on a bill that doesn't exist.

Mr. President, I have a piece of information distributed by Pfizer Corporation that is opposed to my amendment. It describes various problems with the drugs that are purchased online and counterfeit drugs, and so on. Interestingly enough, all of these problems would be solved by the legislation I have introduced with all of the safety issues involved. You know these are specious issues because the underlying legislation would address all of those issues.

Now, let me go through a list—this is the list; you won't be able to read it, but I will go through them—of the safety provisions in this legislation. First of all, with imported drugs, drugs imported from other countries, which, as I have indicated, Europe has done for 20 years with no safety issues at all, so we are as competent as the Europeans are in being able to do this.

Our bill would require that all imported drugs be approved by the Food and Drug Administration. So we are not talking about any renegade drugs, all FDA-approved drugs, all of them imported be approved by the FDA.

It creates a process to approve medications sold outside the United States which are identical to FDA-approved products. It sets a process by which the FDA may approve medications which differ from the domestic version of the drug; provides that no imported drug may be misbranded or adulterated, and requires compliance with GMP. It requires the FDA to enter into agreements to monitor drug recalls and approval status changes; establishes a set of standards which countries must meet to be a ''permitted'' country. With respect to pharmacies and wholesalers on this list, we say it provides for registration and regulation of exporting pharmacies and importing wholesalers, only by licensed operators in both cases; requires registrants to pay an application fee, submit to evaluation, and post a substantial bond; requires pharmacists and wholesalers to be fully compliant with applicable local, State, provincial, and national laws; requires the FDA to perform inspections of operations, including facilities and records, at least 12 times per year; requires exporting pharmacies to verify prescriptions, to review medications for interactions, to ensure privacy; requires pharmacies to maintain records for 2 years for FDA review.

Exporting pharmacies must preserve samples of each lot of a drug for the FDA to utilize for testing. It gives authority to FDA to monitor and inspect the full chain of custody of a drug; sets penalties for violation, including suspension, lifetime revocation, and criminal penalties. It requires every imported drug to have a full record of the chain of custody, which is a pedigree. That is very important. Every imported drug will have to have a pedigree, full record of the chain of custody.

It requires every package to have an FDA-approved label affixed, and every product must clearly be identified as ''imported.'' Drug labeling would also include the name of the registrant who handled the medication and the product lot number as a part of that pedigree. Any differences in the imported drug, even in an inert ingredient, must be noted on the label.

It requires packaging to include anticounterfeiting or track-and-trace technologies. Exporters must provide the FDA with prior notice of shipments of prescription drugs to the U.S. importing wholesalers.

It provides, for the first sale of a drug, it may not be shipped outside of the permitted countries. It requires the FDA to provide information to consumers to identify the safe and legal directed sources of approved imports. It gives Customs Service the authority to seize and destroy any unauthorized shipments; blocking elicit electronic payments to unauthorized foreign pharmacies by Customs; full funding for FDA to facilitate the drug import regulatory operations through a 2½-percent user fee.

It provides implementation of drug pedigrees for domestic medications by 2010, which do not exist now, by the way; requires the packaging of all prescription drugs to incorporate a standardized numerical identifier unique to each package of a drug and counterfeit resistant technologies.

When one reads through these safety features and then alleges that this is unsafe, I mean it just—it baffles me how one can reach that conclusion.

Tommy Thompson, Secretary of Health and Human Services, said: In order to import drugs from any country, and especially Canada, I have to certify that all of those drugs are safe. That is an impossible thing. If Congress wants to import drugs, they should take out that provision.

Well, let me ask this question: Would it be possible for the Health and Human Services Secretary to certify that all drugs sold in this country, FDA-approved drugs, are safe? Does one think the HHS Secretary could certify that? The answer is, no, of course not.

I can give you examples of metal traces and things in pharmaceuticals that were sold in this country, FDA-approved, by major manufacturers. Could a Health and Human Services Secretary certify that the existing drug supply is ''safe,'' possess no ''risk''? They can't do that for pet food. They could not do that for lettuce. They could not do it for carrots. They could not do it for celery. They could not do it for imported vegetables. They can't do it for imported meats. They can't do it for domestic production to say, there is no risk.

The issue of requiring certification is an attempt to kill the legislation. It is perfectly appropriate for some to say: The current system works fine, don't change it. I don't quarrel with that. I don't agree with it, but I respect those who hold that view. But I do believe it is hard for anyone to, with great merit, make the case that with what we have done in this legislation, on a bipartisan basis, it still renders this to be an unsafe process.

The experience in Europe, of course, undermines that argument. They have done it for 20 years. It has been perfectly safe. Also, let me go back to David Kessler's statement. I don't know of an FDA Commissioner who comes to his belt buckle, let alone his shoulders in terms of capability.

I thought David Kessler had been an extraordinary FDA Commissioner back for 8 years. I worked with him when he was there. He said this: The Dorgan-Snowe bill ''provides a sound framework for assuring that imported drugs are safe and effective.''

Now, we can talk all day about these drugs being unsafe, but, obviously, that does not change the facts. It does not change Dr. Kessler's opinion. It does not change the circumstances of the safety provisions we put in the bill. They are there. They are there for a very specific reason. We took the interests and concerns of Secretary Shalala and Secretary Thompson. We wrote them into this bill dealing with safety provisions.

The fact is, this bill will make our domestic supply of prescription drugs safer. That is the plain fact. Then we will have a pedigree for all prescription drugs, imported or domestic. That is just a fact.

Now, the second part of the amendment says it has to be assured that it will save money and pose no risk. Well, ''save money,'' that is easy. The Congressional Budget Office has said it is going to save $50 billion in 10 years. And $6.1 billion—I thought it was 5—$6.1 billion of that is savings to the Federal Government.

We just have a new estimate by the Congressional Budget Office that if the Cochran amendment is passed, that savings goes to zero. Why? It undermines the bill. It means this will not have impact. Importing won't happen. Not because anyone wants to import an unsafe drug because, in fact, the safety provisions we have included will make this supply, the drug supply, domestic supply included, as well as imported drugs, safer. That is the point.

This issue is not horribly complicated. The question is, should the American people have the ability in this global economy to access a drug that has been produced, in many cases by an American company, with research in many cases paid for by American taxpayers, produced in many cases in a plant here in the United States, and then sent to another country at a much lower price? Should the American consumers be able to access that FDA-approved drug that is sold for a lower price elsewhere? Stated another way, should American consumers continue to accept the notion that they should pay the highest prices in the world?

Some say: There is not a problem here. They cite the Washington Post editorial today. That editorial says there is a problem with respect to drug pricing. The first 3 months of this year saw the highest price increases on prescription drugs in the last 6 years. In 2006, it was six times the rate of inflation, the price increase in prescription drugs. In addition, we pay the highest prices of all the other countries. Does that make sense? It doesn't to me.

I want to have somebody stand up on the other side of this issue and say: I disagree; I think the American people should pay the higher prices; I think that is fair.

That is the alternative, it seems, because that is the reality. I am not interested in debating some fiction. The reality is this: We pay prices that I believe are wrong. I said yesterday, I don't come here with any disrespect for the pharmaceutical industry. I have met many of these people. I know the head of PhRMA, former Congressman Billy Tauzin. I used to serve with him. I like him. I don't come here disrespecting the industry. They do important work. I have a profound disagreement with their pricing policies because they are unfair to consumers in this country. That is my difference and my beef. Their pricing policies are wrong.

Why should an 80-year-old woman have to go to Canada every 3 months as she is fighting breast cancer in order to buy Tamoxifen at a price she can afford? Why should you be able to cross an imaginary line into Canada and discover that you could pay one-fifth the price you have to pay for Tamoxifen in this country? The pricing policy is wrong, and we ought to fix it. This is an approach that will fix it.

We will have other debate. I do not disrespect the pharmaceutical industry. I have great respect for what they do. I have a profound disagreement about their pricing policy. I don't disrespect those who have a profound disagreement with my amendment. I respectfully think they are wrong.

In the end, the question for the Congress is, do you think what is happening with respect to drug pricing is appropriate? My answer is no. The American people are being disserved by a pricing policy that the pharmaceutical industry can make stick. They have the capability to control prices. They do it behind a law that says the

only interest that is able to import prescription drugs is the manufacturer of that drug. Europe doesn't require that. Europe hasn't required that for a long while. They allow parallel trading so the consumer can take advantage of price shopping among the countries of Europe. Only this country has decided, no, the consumer doesn't have this right. The manufacturer has the right but not the consumer.

I say let's let the consumer, let's let the American people have access to the benefits of the global economy as well. Yes, let's make it safe. We have done that. This legislation with the safety precautions I have described in some detail, if passed, this amendment, if passed, would significantly improve the safety of the domestic drug supply and significantly improve safety of the reimportation that now occurs on an occasional basis by people driving back and forth across the border, those who are fortunate enough to live near a border.

We have just gotten a Congressional Budget Office score on the amendment I have offered. It says the amendment, if passed, will save the Federal Government $10.6 billion in a 10-year period. I believe it is a $50 billion savings in total for consumers. I will put in the CONGRESSIONAL RECORD the specifics. But I do know the Congressional Budget Office has just scored this amendment. It will save consumers tens of billions of dollars. The specific savings to the Federal Government itself, as a result of savings through our programs and expenditures, will be $10.6 billion.

I yield the floor.

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

Mr. COCHRAN. Mr. President, for the information of Senators, I will seek to define in more specific terms exactly what the Dorgan-Snowe prescription drug amendment does.

Before proceeding to that, I ask unanimous consent that the Senator from Pennsylvania, Mr. SPECTER, be added as a cosponsor to amendment No. 1010.

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

Mr. COCHRAN. Mr. President, the Dorgan-Snowe bill, pending before the Senate as an amendment, eliminates language from the Food, Drug, and Cosmetic Act that allows importation to take effect only if the Secretary of Health and Human Services can demonstrate to Congress that it will pose no additional risk to the public health and result in a significant reduction in the cost of covered products to the American consumer.

The amendment I have offered to the Dorgan-Snowe bill would restore this language. The Senate has overwhelmingly voted on three occasions to include a safety and savings certification provision in prescription drug importation legislation for the purpose of protecting the public health. Following passage of the safety and savings certification requirement, no Secretary of HHS, Democrat or Republican, has been able to demonstrate that importation is safe or will lead to cost savings. Both Secretary Shalala in the Clinton administration and Secretary Thompson in the Bush administration could not demonstrate that importation poses no additional risk to public health or would lead to significant cost savings.

Back in 2000, Secretary Shalala concluded it was ''impossible . . . to demonstrate that it [importation] is safe and cost effective.''

Secretary Thompson reached a similar conclusion in the next year, 2001, by saying he could not ''sacrifice public safety for uncertain and speculative cost savings.''

The Dorgan-Snowe bill contains numerous provisions that would expose Americans to harmful or adulterated imported drugs—could expose. In particular, the bill permits the importation of drugs that originate in such countries as Latvia, Estonia, Slovakia, Greece, Hungary, and the Czech Republic. These are outside the control of the manufacturers and outside of the jurisdiction of the Food and Drug Administration.

The bill also permits the importation of drugs that are not FDA approved and are not equivalent to FDA-approved products. Some of the drugs that could be imported under this provision would violate Food, Drug, and Cosmetic Act requirements against adulteration and misbranding.

Canadian law has been discussed here. It permits the transshipment of unapproved prescription drugs from any country in the world through its borders to the United States. These shipments move across borders, free from examination from Canadian regulators who have said their Government will not ensure the safety and effectiveness of exported drugs. The FDA and Customs officials have seized counterfeit drugs entering the United States from alleged Canadian pharmacies that are established for the purpose of permitting transshipments from other countries outside of Canada into the United States. These places where the drugs have originated include countries such as India, Pakistan, China, and Thailand.

If my amendment is not adopted, the underlying bill, as amended by the amendment of the Senator from North Dakota, would permit transshipment and severely restrict the ability of border officials to stop suspected drug shipments entering the United States. My amendment would not allow importation to begin unless these safety concerns are resolved and the Government can assure the American public that imported drugs will not endanger their health.

There is no guarantee that American consumers will experience reductions in their prescription drug costs if the Dorgan bill takes effect, because middlemen have shown they may keep the savings. The amendment I have offered ensures that consumers would benefit from importation before weakening consumer protections against potentially unsafe drugs.

In conclusion, the Dorgan bill requires the FDA to allow importation from Canada within 90 days of enactment, whether the FDA has had time to set up an appropriate regulatory framework or not.

In addition, the bill places an arbitrary cap on user fees collected to oversee the importation system. My amendment would ensure that an importation program would take effect only after a regulatory system has been put in place to protect American consumers.

I hope the Senate will approve my amendment.

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. DORGAN. I won't speak at length. I do want to make one point. The Senator from Mississippi indicated the amendment I have offered would allow for the reimportation of drugs that are not FDA approved. I don't know where that information comes from, but it is demonstrably untrue. I don't want there to be a mistaken impression on that. I ask my colleague from Mississippi if we could at least resolve that issue. The intent of this, the written version of this, is very clear. No drug will be imported into this country unless it is FDA approved. My colleague indicated this amendment would allow drugs to come in that are not approved. I don't know where that information comes from. If he and I could at least exchange information so that we resolve that, I would appreciate that.

Mr. COCHRAN. Mr. President, if the Senator will yield, I am advised that the FDA has said it could not put a regulatory framework in effect to guarantee what my amendment insists it should guarantee; that is, the effectiveness of the drug, the fact that there will likely be savings that will result for American consumers if the Dorgan amendment is adopted.

Mr. DORGAN. Mr. President, that is a different issue. The amendment itself, whether there is a regulatory framework or not, will not allow a drug to be imported that is not FDA approved. That is the written provision in the amendment itself.

Second, with respect to cost, we may have a disagreement on that, but I again observe that the Congressional Budget Office this morning has given us another score, and the score from the Congressional Budget Office says this will save the Federal Government $10.6 billion in a 10-year period. I believe the global savings—the rest would be for consumers—is slightly over $50 billion in 10 years. So it seems to me it is self-evident. If the Congressional Budget Office is putting out information to the Senate this morning that describes the amount of savings, in this case averaging about $5 billion a year,

it is quite clear, someone is going to save something somewhere. I think we also can resolve the cost issue at some point down the road.

Let me say, I respect the Senator from Mississippi. He is a very worthy legislator, cares passionately about the things he works on. I do the same. I think the way to resolve this is to talk through what are the safety provisions in the bill. If they are inadequate, demonstrably inaccurate, I will accept that we would make some changes. But I do not believe that is the case. I do not believe it has been demonstrated.

As I have indicated previously, Dr. David Kessler, who ran FDA for 8 years, says this bill provides a sound framework for assuring that imported drugs are safe and effective. I understand the pharmaceutical industry does not say that. I understand some others do not believe that. I understand and respect that. But I also believe, very strongly, that the evidence is overwhelming. We have added the safety provisions that were raised by Secretary Shalala. We have added the provisions raised by Secretary Thompson.

I believe—and 33 of my colleagues in this Chamber, Republicans and Democrats, believe—we have done a very good job in resolving those issues. This issue almost has a gray beard. It has been around a long time. We have been trying a long time. It is hard to win on this issue. I accept that, and I understand it. But I am hoping that perhaps this is the year in which we might give the American consumer an opportunity to be able to participate in the global marketplace in a safe and effective way, just as the Europeans do, and be able to access a lower price of FDA-approved drugs.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from North Carolina.

Mr. BURR. Mr. President, I agree with my colleague that this issue has been around for a long time. One of the reasons we continue to debate it is because we continue to have real-life examples of a product that comes in that is adulterated. I am not sure we have done anything to eliminate the ability to counterfeit, other than to confuse it even more, because, in fact, today we basically say it is almost impossible, unless you are an individual crossing the border, to bring in drugs from another country.

We are challenged at Customs today with immigration. Oh, we are just as challenged at Customs today on the shipment of pharmaceutical products that come into this country from abroad. It is not held to a single country.

I do not believe the reason we embrace this bill is because the Europeans do it. There are a lot of things the Europeans do today that I would not necessarily suggest are right for America. As a matter of fact, we have some international treaties that suggest we should harmonize our drug standards with the European Union. What we found was, for the European Union, with 22 members, they accept whichever country the application was applied for. If that country approves it, then it is good for the EU. If you look at some of the standards throughout the 22 countries, it would be dismantling the gold standard of the FDA.

So for those who suggest what we would do in this amendment maintains our gold standard, it would not happen. The reality is, as you accept what they do—which does not come close to the gold standard of the FDA for safety and efficacy—over time it would bring further deterioration to the confidence of our drug supply. When every American goes to their local pharmacy and they have their prescription that is written by a doctor, they go in with 100 percent confidence of knowing there is an active ingredient in it, that it is not adulterated, that their health is not going to be affected adversely when they take it.

We are on the floor today. This is part of the drug safety bill. Why? Because in some cases when products are approved and given to a much larger population, that larger population experiences different side effects because every person is genetically different. There are no two alike, unless we change the cloning laws in this country. The reality is, I do not think we are going to do that, so we do not have it to worry about. But we are here trying to strengthen the safety of the product. We currently can maintain the chain of custody because it is manufactured, it is distributed, and every product has a case lot number.

What have we experienced with counterfeit drugs? They have been able to make a pill look identical to the pills we go to the pharmacy and buy—identical in not just the pill but the packaging. As we shift packaging, so do those who are trying to game the system. The reality is, the person who is on the receiving end—and I sympathize with exactly what the Senator from North Dakota has claimed; that in many cases, pharmaceuticals are not affordable for some people. That is why we created Part D Medicare. That is why over 30 million Americans who are Medicare eligible now have coverage—coverage that has brought down the price of pharmaceuticals 33 percent in the first year.

For any other area for which we would propose legislation, if we saw a trend like this, we would be embracing the fix we put in. But no, we are going to delude it even further and confuse seniors across the country and say: Now just go on the Internet and buy it because we have said it can only come in if it is an FDA-approved product. Well, FDA-approved products are the only things we write prescriptions for in the country. The reality is, the only counterfeit product that counterfeiters are making are FDA look-alikes.

There is nothing in the Dorgan bill that says somebody cannot counterfeit anymore. There is nothing in the bill that says if we do not catch it at Dulles Airport when it flies in and test it immediately to find there is no active ingredient, we have not put somebody's life in danger. There is no assurance in this bill that if there is an adulteration of some kind that affects somebody's health—in the host of millions of pills that come in, if we do not catch it, there is somebody on the receiving end who is going to be adversely affected health-wise.

So I appreciate the fact that everybody wants cheaper drugs. We all do. But there is a reality about the United States of America: We protect intellectual property; therefore, we attract companies. And it is not just limited to pharmaceuticals. I guess the next thing we are going to do is claim Microsoft software is too expensive, so we are now going to allow that to come in from somewhere else. Well, we protect handbags. We protect clothing. We protect the copyrights, the intellectual property. There is even more of a reason to do it in pharmaceuticals. It is because there is a safety component.

I think when many people think they might be buying a counterfeit handbag—if they buy it on the streets of this town or some other town—they probably think: Well, if I get a year's use out of it, based on the price, that is OK. I do not think you can apply the same standard to pharmaceuticals. If it does not have the active ingredient, somebody might die. In fact, we beefed up, in the drug safety bill, dog food higher than what this importation provides for our pharmaceutical supply in this country.

We are going to have plenty of time to talk about it. And just as the Senator from North Dakota brings a lot of facts and figures to the floor, there are a lot of facts and figures from the 8 years—maybe more—we have debated this issue. It has not been Congress that has turned it down, it has been the American people. At the end of the day, they send us here to make decisions that are positive in relation to their health and their future. I do not think Americans want to take a pig in a poke on pharmaceuticals. But that is what this amendment will allow to happen.

This will probably change America being the innovator of drugs and medical devices because we will ignore patents and copyrights. We are advantaged by that. There are many countries in the world where you do not have access to the drugs and biologics and devices we have in this country. Yes, they are expensive because they are expensive to develop, but we put more value on quality of life, the ability for us in this country to treat what others are not able to treat because we believe that, in the overall scheme of our system, we save more money in health care if, in fact, we give somebody a pill. If that was not the case, we would not have programs for HIV/AIDS. But every time we supply that

therapeutic for an HIV/AIDS patient, we know they are not going to have one case a year with some type of retinal infection. We know they are not going to be admitted to the hospital for a week because of pneumonia. We know the savings over that incident is probably going to be $15,000 or $20,000, and that is before we put any cost on the quality of life of the patient who is affected by the disease.

Well, I would imagine we will see counterfeit HIV products because they are expensive. It is one of those diseases that does not stay in the same place. It is smart. It changes itself within somebody's body, and it means that over a period of time, you can take a drug that is very effective or a combination of drugs that is very effective, and after 2 or 2½ or 3 years, the disease has now changed, and if you do not change with new therapies, the reality is there is going to be a deterioration of that person's quality of life and a further advance of the disease.

Right now, we have companies that are excited about working on the next product that will continue to take a disease we cannot cure today but for which we can stop the progression right in its tracks. What we are going to say to those companies that spend hundreds of millions of dollars, if not billions of dollars, is: Well, the United States does not put any value on that anymore. Say that to the population that is affected by the disease. Say that to the population of any group of Americans that is affected by a disease, that we are not going to have the policies in place that advance the development of drugs, biologics, and devices. When we do this, that is what we are saying.

Again, I appreciate the authors' attempts to try to assure us that safety is at the forefront. But that is only there if we are smart enough to catch it. If we were that smart, we would not have an illegal immigration problem in this country. If we were that smart, we would know that we caught 100 percent of what was coming in the country. But I do not think there is anybody who is going to take this floor and suggest to the American people that we catch 100 percent of the adulterated or counterfeit drugs. There is certainly nobody who can come to the floor, even with our food safety standards where they are—where the FDA is in charge and USDA is in charge and DHS now has some responsibility for it—and suggest to the American people that we catch 100 percent of the contaminated food before it finds its way to the shelf or to a plate in our house.

The reality is, we have had 12 examples just in the last year where we are just not that good. We are not perfect. I would suggest to you, to try the system, by setting up a program that cannot be policed—and I think that is what my colleague from Mississippi was saying. Time and time again, we have had the debate. We have pulled in the experts. They have said this is just something which is undoable for us. We cannot do it.

My hope is that as this debate goes on, more and more Members will realize it sounds good, but it is not a risk we should take in this country. It is a risk that affects people's lives.

I yield the floor.

The PRESIDING OFFICER (Mr. TESTER). The Senator from North Dakota.

Mr. DORGAN. Mr. President, one of the observations I made when I was privileged to come to the Senate is that virtually everyone here is a pretty effective communicator. I am reminded of that every day. I hear debate by people who really are effective, and I always appreciate it, and it is always interesting to me.

I do think—certainly everybody is entitled to their opinions; I respect their opinions—not everybody is entitled to their own set of facts. We have to deal with a common set of facts.

My colleague just made a statement, a philosophical statement, about what he believes. I respect that. But the statement included thoughts like that this piece of legislation would probably abrogate or not respect copyrights. Nothing could be further from the truth. There is nothing in here that would abrogate copyright protection, and so on. In fact, this amendment provides the requirement of serial numbers on lots and samples by those who are engaged in this sort of thing that has been prevented from occurring inside this country. It requires it for importation, and it requires it for domestic medicines. This will dramatically change the safety of the drug supply here and with respect to that which would be imported.

With respect to the American people, the American people are not undecided on this issue. Mr. President, 70 or 80 percent of them believe there ought to be allowed the importation of prescription drugs. This is not something the American people are undecided about. It is only in this Congress that it has not been decided. So I think that is something we should understand. Why would the American people believe they should be able to import FDA-approved drugs? Because they believe it is fair for them to be able to do it.

Let me describe where the prescription drugs come from by the manufacturers of the drugs. If you are taking Lipitor, that is not made here; that is made in Ireland. If you are taking Toprol XL, that is made in Sweden. Nexium is made in France. Altace is made in Malta. Vytorin is made in Singapore and Italy. These drugs are already imported. Regrettably, by the way, I might say they are imported without the protections that would exist in our amendment. It would require the manufacturer—the manufacturer of the drug—to have serial numbers on the lots, to have samples of every lot reserved, to have a pedigree for every medicine that is moved. That is for domestic consumption. I am not talking about the imported drugs under my bill; I am talking about the drugs that are made in these countries and other countries that ship them into this country, and every drug that is produced in this country will require the same.

The fact is we have tried to get that same requirement on domestic drugs and have been blocked for a long time. This legislation will make the drug supply in this country far more safe than it currently is.

We all know the amendment that is being offered about risk. Were that amendment to be offered with respect to new prescription drugs that come from research to say, you can't put a drug out there if there is risk, do you think you would have a new drug on the market anytime soon? Do you think a Health and Human Services Secretary or an FDA administrator can say: By the way, I am approving this drug and there is no risk. Of course, they can't. Of course, they would not. We know that. Drugs have risks. In fact, some drugs are put on the marketplace, and we discover later they should not have been there—a substantial risk. Vioxx. An official at the FDA says he believes 50,000 to 70,000 American people died of heart attacks as a result of Vioxx being put on the market. Further, he says—this isn't me, this is an official at the FDA—that Vioxx was widely advertised and widely promoted as some wonderful new drug, when in fact it was not a new class of drugs that had any significant benefit over existing drugs. The point is this: If one were to ascribe this risk category to new drugs, there would be no new drugs.

I know all this talk about counterfeiting—and man, have we talked a lot about counterfeiting in this Chamber in the last couple of days—all this talk about counterfeiting ignores the point that it is occurring under today's laws. The way to fix that and the way to stop counterfeiters is to do what we do in this amendment: You require on every prescription drug that is sold, that it have a pedigree. You require in every circumstance there be serial numbers on lots and samples. It is incontrovertible, in my judgment, that this will dramatically improve the safety of domestic prescription drugs as well as imported prescription drugs.

One final point with respect to the issue of research. My colleague said: Well, if we pass this amendment, what the Senate has said is there is no value to research on prescription drugs. I don't have the foggiest idea where that concept comes from. We spend a lot of money on research. I was one of a group of Senators who said: Let's double the amount of money at the National Institutes of Health, and we did, in 5 years, to dramatically improve and increase the amount of research at the National Institutes of Health. I am a big supporter of research. We do a lot of wonderful research, some in the public sector, some in the private sector.

At the NIH, by the way, we do the research and often much of that research is used by the pharmaceutical industry to produce lifesaving drugs. But lifesaving drugs save no lives if you can't afford to get them, if you can't afford to have them, and if you can't afford to take them.

It is true none of us have a problem, in this Chamber, dealing with the price of drugs; we have health care policies and those kinds of things. But there are a lot of folks all over the country who are taking a lot of different prescription drugs. I think prescription drugs are wonderful. They keep people out of an acute care hospital bed, the most expensive kind of health care. Interestingly enough, in many cases they are taking 10 or 12 different kinds of prescription drugs to manage various diseases. As a result of that, we passed Part D; my colleague is correct about that. Part D provides drug benefits to those who have reached the age of Medicare. Regrettably, of course, there was nothing in Part D that would put downward pressure on prescription drug prices. I would say look at the increase in prescription drug prices in the first quarter in this country. Look at the increase in prescription drug prices in 2006, and then ask yourself whether all of this is working to put some downward pressure on pricing. It is not. It is just not.

So as I said earlier this morning, I hate to lose a debate I am not having. I would love to have a debate in which we are both debating the same bill, but a suggestion somehow that this bill allows drugs to come into this country that are not FDA-approved means that you are off debating some other bill someplace. Well, fine. Win that debate if you want. It is not the bill that is on the floor of the Senate. It isn't. The same is true with a number of statements that have been made about respecting copyrights, and so on. In fact, what we have required is a regulatory burden that the industry doesn't like—I understand that—but it will, in fact, protect them and protect their copyright because it will make it much harder for anyone to counterfeit. That is a fact.

One of the interesting aspects of this country is that we are seeing some unbelievably good news. The good news is people are living longer and better lives. In a century, in 100 years, we have increased the lifespan by somewhere around 30 years, from 46 years old to about 76 years old. That is good news. People are living longer and better lives. A significant part of that, I think, is being able to, at an advanced age, manage diseases. A significant part of that is prescription drugs. There are some who don't have that. I have an uncle I have described before who is now 86 years old. He and his wife take no prescription drugs at age 86. The fact is, as I have also described to my colleagues, he is a runner. He runs in the Senior Olympics at age 86. He used to run in his seventies and early eighties the 400 meter and the 800 meter. Now he tells me he is a specialist in the 100-meter dash, at age 86. He has a good life. He is healthy. He likes life. He is very active. He is not riding his motorcycle so much anymore, but he has one of the biggest motorcycles you can get sitting in his garage. He doesn't need to take prescription drugs. Good for him.

We have a lot of folks who reach their eighties and nineties. We know about that because in our part of the country, my State of North Dakota ranks No. 1 in the Nation in the number of people 86 years of age or older as a percent of the population. We rank No. 5 in the country in the number of people 65 years of age or older as a percent of the population. So a lot of people are living a lot longer. That is good news. It puts some drain on Social Security and Medicare.

A quick way to fix Social Security and Medicare is to go back to the old life expectancy, go back to age 46. We wouldn't have any trouble. I am digressing a bit, but when Social Security was created, on average, people lived to be 63. So we created a system that says: When you retire, you get benefits at 65. Well, I went to a small school, but I understood enough in math to think that works out real well. You pay taxes and, on average, you are going to live to age 63, and when you retire at 65, you get some benefits. That is not a system that is going to have financing trouble at all. But then the problem is people began living much longer. That is not a problem. That is a success. So good for them.

At any rate, prescription drugs about 40 years ago became a much larger part of the discussion in modern life, to keep people out of the acute care hospital beds and to manage their diseases. So that is a wonderful thing. I have said before, and I will say it again: The pharmaceutical industry is a fine industry; I have serious problems with their pricing strategy. I think it is wrong. I want them to succeed. I want them to research. I want them to do the research on prescription drugs. I would like them to stop advertising early in the morning when I am shaving and brushing my teeth and getting ready for work, telling me what I ought to go talk to my doctor about. They have all these pills they want me to ask the doctor if they are right for me. I get confused. I am not sure I need them. But there is a lot of advertising going on and a lot of promotion.

I want them to find new medicines to unlock the mysteries of dread diseases. I want the Federal Government, through the NIH, to substantially invest in new research and development. I want all of those things. But I also want, even as I compliment the pharmaceutical industry and I compliment the NIH and all those who are spending their days—today, Thursday—trying to figure out how do you unlock the mysteries of ALS or diabetes or cancer or heart disease, even as I do that, I say to the pharmaceutical industry: I think your pricing strategy is wrong and it is unfair to the American people. We ought not be paying the highest prices in the world for prescription drugs. That is unfair.

The amendment I have offered with 33 of my colleagues, Republicans and Democrats, would change that. No, it wouldn't shut down research, not at all. No, it wouldn't exacerbate counterfeiting, not at all. The fact is this will be fair to the American people, if we pass this legislation. It will continue, I think, to see substantial research. It will also, in my judgment, contribute to shutting down the counterfeiting of prescription drugs, but most importantly, it will finally say to the American people that we are on your side on this issue. We believe in fair pricing and we finally are going to insist on it.

I yield the floor, and I make a point of order that a quorum is not present.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

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

Mr. SANDERS. Mr. President, I rise in strong opposition to the Cochran amendment. We should be very clear. For anybody who is interested in prescription drug reimportation, for anybody who is interested in lowering the cost of prescription drugs in this country from 25 to 50 percent, for anybody who is interested in standing up for the working families of this country who are getting ripped off every day by outrageously high prescription drug costs, the Cochran amendment is a poison pill. To vote for the Cochran amendment is to vote against prescription drug reimportation; it is to kill the Dorgan amendment.

The idea of asking permission from the Secretary of Health and Human Services, from the Bush administration, who have already gone on record rather firmly and decisively in opposition to reimportation, is to simply mask your vote. The Bush administration represents the pharmaceutical industry. They will kill prescription drug reimportation. To ask their permission to go forward is simply to kill prescription drug reimportation. So anyone who is serious about lowering the cost of prescription drugs will not be supporting the Cochran amendment.

The unfortunate reality is, in the United States of America we continue to pay, by far—it is not even close—the highest prices in the world for prescription drugs. Because of the escalating cost of medicines, many of our fellow Americans, many working people, many people with chronic health problems, simply do not get their prescriptions filled. I am sure in Montana the experience is the same as it is in Vermont. People tell me they walk into the drugstore and cannot believe

the prices they are being charged. They can't afford those prices. I have talked to pharmacists, as I suspect the Chair has as well, who have been embarrassed. They have seen tears coming out of people's eyes when they have told them the cost of their medicine.

Meanwhile, as a result of the power of the pharmaceutical industry, we have the highest prices in the world, and those prices are rising every single day. In fact, tomorrow, if an American walks into a pharmacy and the pharmacist says to that person: I am sorry to have to tell you this, but the cost of your medicine went up 50 percent, or 75 percent, we can do nothing about it. Unlike the rest of the industrialized world—Canada, Europe—where they understand prescription drugs are an integral part of a whole strategy regarding health care, we let the drug companies do anything they want to do.

As the first Member of Congress to take constituents across the Canadian border to enable them to pay substantially lower prices than they were paying in the United States, I have seen firsthand what it means to people's lives when they get the drugs they need at a price they can afford. I will never forget—never forget—when in 1999 I brought a busload of Vermonters over the Canadian border. Many of the women there were struggling with breast cancer, fighting for their lives, and they didn't have a whole lot of money. They went to Montreal and purchased Tamoxifen, a widely prescribed breast cancer drug, which at that time—at that time—was one-tenth the price they were paying in the United States. Imagine that. Fighting for your life, not having a lot of money, and needing a drug. Suddenly, they looked at the price they were paying and they literally could not believe it.

Mr. President, I ask unanimous consent that a chart which compares prices in the year 2005—so the prices may be different today, but as of April 2005, a price comparison between United States prices and Canadian prices, and United States prices and German prices.

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

SOME PRICE COMPARISONS AS OF 4/06/2005

Drug (in US $)	Illness/condition	US price	Canadian price
Actos (15mg, 90)	diabetes	296.89	257.97
Cardizem CD (240mg, 90)	heart	215.89	88.03
Celexa (20mg, 30)	depression	81.99	52.05
Clarinex (5mg, 30)	allergies	74.99	37.31
Fosamax (10mg, 100)	osteoporosis	242.89	178.62
Imitrex (50mg, 27)	migraines	503.89	365.08
Nexium (20mg, 30)	heartburn	144.99	87.77
Norvasc (5mg, 90)	blood pressure	127.59	135.32
Prevacid (15mg, 30)	ulcers	129.99	74.40
Prilosec (20mg, 30)	ulcer	128.99	74.50
Procardia XL (30mg, 30)	heart	53.99	33.84
Relafen (500mg, 200)	arthritis	340.19	183.86
Tamoxifen (20mg, 30)*	breast cancer	68.59	40.21
Ticlid (250mg, 60)	stroke	171.99	101.36
Vasotec (10mg, 60)	heart	70.99	63.30
Zocor (20mg, 30)	cholesterol	131.99	74.65
Zoloft (50mg, 100)	depression	227.49	182.04
Zyrtec (10mg, 30)	allergies	69.99	41.87

Drug (in US $)	Illness/condition	US Price	German price
Actos (15mg, 30)	diabetes	116.64	50.62
Celexa (20mg, 30)	depression	85.46	35.72
Clarinex (5mg, 30)	allergies	77.06	38.64
Imitrex (50mg, 9)	migraines	166.40	102.67
Nexium (20mg, 30)	heartburn	145.33	60.25
Norvasc (5mg, 30)	blood pressure	54.83	35.72
Prevacid (15mg, 30)	ulcers	146.47	35.22
Zocor (50mg, 30)	cholesterol	85.39	23.83
Zoloft (50mg, 30)	depression	89.44	54.98
Zyrtec (10mg, 30)	allergies	73.02	34.33

All prices found via www.walgreens.com and www.canadadrugs.com.
*Price found at www.cvs.com.

Mr. SANDERS. Mr. President, let me talk about a few of the drugs.

Actos is a drug for diabetes. As of 2005, in the United States, the price of that drug was $116. For the same number of pills and the same milligrams, it was $50.62 in Germany. Twice the price—same product, same company, same factory, but less than half the price in Germany.

For Celexa, a drug for depression, it was $85 in the United States and $35 in Germany. Same company, same product. Clarinex was $77 in the United States and $38 in Germany. On and on it goes—sometimes more, sometimes less but often half the price in Germany, and different prices in Canada but often the same end result.

The very simple question the Members of the Senate have to ask themselves is: Why is it that in the United States we have to pay the highest prices in the world for our medicine? Why is it that at a moment in history when we are eating food products from farms in Mexico and in Latin America, produced in China, and they are coming to our kitchen tables today, why is it that anybody here can say with a straight face it is OK for products all over the world to come into this country from tens of thousands of farms, but in terms of a handful of major drug companies, somehow we cannot regulate the flow of those medicines from Canada, for goodness' sake, into the United States?

Give me a break. That argument is so totally absurd as to be almost beyond the laugh test. This debate has nothing to do with drug safety. All of us are concerned about drug safety, and the Dorgan amendment has page after page after page of regulations making sure the FDA-approved medicines that come into our country will be safe.

What saddens me very much is that in many ways the American people have given up on this issue in terms of the ability of their own government to act, and they have taken matters into their own hands. I don't know what goes on in Montana, but in the State of Vermont thousands of people in our State go over the Canadian border. They go to the Canadian drugstores and buy the products they need. It is not a big deal, and they save substantial sums of money.

There was an estimate a few years ago, and I don't know what those numbers are today, but there was an estimate several years ago that about 2 million Americans were buying their medicine in Canada. What the Dorgan amendment is about is simply saying that it is a little bit absurd for Americans to have to get in their cars and drive to Canada to get the drugs they need; that it might make more sense for our pharmacists to be able to purchase that medicine, our prescription drug distributors to be able to purchase that medicine so, in fact, Americans could take advantage of the lower prices at their own local drugstore.

That is what we want to do. We don't want all of America to have to go to Canada or Germany to buy reasonably priced medicine. We want those products sold in this country at an affordable price.

I think many Americans are wondering: Well, how does it happen that a product made by an American drug

company—at a time when the taxpayers of this country, by the way, spend billions of dollars in research and development for drugs that go to the drug companies—that in the midst of all this, how does it happen that we pay two or three times as much as our neighbors in Canada or our friends in Germany or throughout Europe? How does that happen?

Well, the answer is pretty simple. The answer is pretty simple. The answer has everything to do with the way we do politics in this country and the enormous power of large multinational corporations and the enormous power of lobbyists who represent those corporations. Let me quote from a Washington Post article of Friday, January 12, 2007. It is a front page article. This is what it says. This is January 12, 2007:

This month alone [i.e. January] the Pharmaceutical Research and Manufacturers of America [PhRMA] spent more than $1 million on full-page newspaper ads touting the success of the existing Medicare drug system.

Drug companies spent more on lobbying than any other industry between 1998 and 2005—$900 million, according to the nonpartisan Center for Responsive Politics. They donated a total of $89.9 million in the same period to Federal candidates and party committees, nearly three-quarters of it to Republicans.

''You can hardly swing a cat by the tail in Washington without hitting a pharmaceutical lobbyist,'' said Senator Charles E. Grassley, Republican of Iowa, a key sponsor of the 2003 legislation that created the current program.

That is what we are dealing with today, and we should not kid ourselves. The pharmaceutical industry, year after year, turns out to be one of the more financially successful industries in our country. According to Fortune magazine, the top 19 pharmaceutical companies in 2005 made $42.1 billion in profit; in 2004 the profit margin was almost 16 percent, three times higher than the average Fortune 500 company.

That is what you have. We have a situation where millions of Americans are struggling to pay their prescription drug costs. We have a situation where many Americans simply cannot afford the medicine they desperately need. We have a pharmaceutical industry which, year after year, enjoys some of the highest profits of any industry in this country. We have an industry which pays its CEOs very exorbitant salaries. We have an industry which has an estimated 1,200 paid lobbyists in this country, many of them former leaders of the Republican and Democratic Parties. We have an industry that makes huge amounts of campaign contributions. We end up with a situation in which we pay by far the highest prices in the world for prescription drugs.

Senator DORGAN quoted a study from the CBO, I believe it was, that suggests we could save some $50 billion over a 5-year period if we move to prescription drug reimportation. In this body we have people who get up every day and tell us how wonderful they perceive unfettered free trade to be. It is not a problem when American workers are thrown out on the street because factories are moved to China where people are paid 30 cents an hour; hey, that is part of the global economy. No problem there. There is no problem when food comes into this country from China and our farmers lose money. No problem. That is part of the global economy.

But somehow, amazingly enough, when an aspect of free trade works for the average American and not for a large multinational corporation, suddenly we do not like unfettered free trade. Suddenly we cannot reimport prescription drugs from Canada—from Canada, which neighbors us, obviously—from a handful of drug companies. We cannot do that. I think that argument is very absurd.

Let me conclude. A vote for the Cochran amendment is a vote to kill prescription drug reimportation, pure and simple. The Bush administration has said they will not go forward with reimportation. Let us defeat the Cochran amendment. Let us pass the Dorgan amendment. Let us lower prescription drug costs in this country by 25 percent to 50 percent. Perhaps even more important, let us show the American people that the Congress has the courage to stand up to the most wealthy and powerful lobby on Capitol Hill.

I yield the floor.

I suggest the absence of a quorum.

The PRESIDING OFFICER (Mrs. MCCASKILL). The clerk will call the roll.

The bill clerk proceeded to call the roll.

Ms. MIKULSKI. I ask unanimous consent that the order for the quorum call be rescinded.

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

Ms. MIKULSKI. As a member of the HELP Committee and someone who was an active participant in shaping this legislation, I rise to let everyone know it is very important that we pass this bill. This legislation is perhaps one of the most important bills in more than a decade to improve drug safety. I am very distressed that for a variety of ideological reasons, this bill is being impeded. Yet drug safety should not be impeded. Drug safety is one of the most important issues we face. The recent testimony of two former FDA commissioners—one appointed by a Republican, Dr. Mark McClellan, and the other appointed by a Democrat, Dr. David Kessler—discussed the need for this legislation as one of the most important items to come before the Senate.

Congress has a unique opportunity to change the way we monitor the safety of drugs. We can't afford to miss this chance. We owe it to consumers, physicians, and patients, who rely on FDA to be the gold standard, to pass this legislation. This is about protecting the American people. There are countries all over the world that can't afford an FDA so they look to us to see what drugs are approved.

I have long been a supporter of the Food and Drug Administration. It is in my State, and I am very proud of it. I have fought hard for the employees at the FDA; for the resources to maintain the mission of the FDA. Through the years we have done a variety of things to improve FDA but nothing as important as this bill.

When we began to work on this legislation, I wanted to know what impact I could make. I was concerned about the fact that FDA seemed to have lost its way. It seemed not to have the right leadership, and it certainly didn't have the right monitoring for drug safety—particularly post-market surveillance. So we ended up with the Vioxx situation. We ended up with drugs to treat young adolescents triggering suicidal thoughts and worse. The issue of drug safety is paramount in America. When I looked at this legislation before the HELP Committee, I wanted to find a way to strengthen the FDA but not create a whole set of regulations that were bureaucratic and technocratic but without efficacy. So where did I turn? I turned to the Institute of Medicine. The Institute of Medicine is the premier agency that often gives advice and direction to the larger community.

They published a report called ''The Future of Drug Safety.'' It had been commissioned by the FDA itself. As I read this report, I was struck by its commonsense provisions. I was also struck by the fact that we have endless reports. We have lots of commissions that Congress asks to be created, but we never act upon them. Just yesterday, the Journal of the American Medical Association ran an editorial about how the Institute of Medicine developed the right prescription for FDA, but no one is going to act on it.

Well, I acted on it. I took the prescription to help the ailing FDA. While our leadership, through Senators KENNEDY and ENZI, was working a comprehensive bill, I brought to their attention these recommendations. By working in a civilized, collegial way, my amendments were adopted. It is not about my amendments. It is about the Institute of Medicine recommendations. Isn't it great when we can take the best thinking, work on a bipartisan basis, and put it into action to protect the American people. To me, that is what it is all about.

Today when I look at this bill, I am so proud of the provisions we included. It strengthens science. It increases transparency. It improves drug safety. Yet it doesn't shackle the FDA.

Let me share the recommendations of the Institute of Medicine. In terms of strengthening science, they were very clear and said that science must be strong to protect the public and to keep the best and brightest scientists at FDA. What did we do? No. 1, we created the Office of Chief Scientist at the

FDA. A single scientist will now oversee all of the offices to be sure they have strong scientific guidance from the very top of the agency. This Chief Scientist will work with a strengthened Scientific Advisory Board who will make sure the Commissioner and the Center Directors are getting the best scientific advice. Imagine, the FDA didn't have a chief scientist. We have a chief scientist at the National Space Agency. We should certainly have a chief scientist at the Nation's drug safety agency.

Then we made sure that all new drugs would be reviewed by an Advisory Committee. That means all new drugs will receive a comprehensive review. You might ask: Don't they now? No. Most got an advisory committee review, but under this legislation, there will be an advisory committee review of ALL new drugs to help assure that as a drug moves into clinical practice, it will be as safe as it can be. Remember, the FDA has a job to make sure drugs do two things: are safe and effective. These Advisory Committees will help make sure the drugs do no harm but also make sure they do good.

We also reinforced the ability of scientists at the FDA to publish their scientific papers. One might ask: Can't they now? No. If you work at the FDA, you often can't publish articles unless your boss says it is OK. Imagine that. We are talking about allowing scientists to publish in peer-reviewed scientific journals. This might sound kind of wonky, but it is important to morale. Its important for Scientists who now work at the FDA and important for recruiting new scientists that the FDA desperately needs.

The other actions we took were to improve transparency. Transparency at the FDA is critical, especially throughout the drug approval process where all scientific views, even dissenting ones, should be made public. I added provisions to make sure this will happen. Through language I had incorporated in the bill, we will make summaries of the drug approval process available to the public on the Internet. A summary will be available 48 hours after the drug is approved and the whole drug review package will be publically available within 30 days. If there are dissenting scientific views, they will also be made available as well. If you are a scientist, a researcher, even if you are a consumer, you will be able to know the history of a particular drug and review its approval process. You can learn if there were there flashing lights raised during the approval process about which you can talk to your doctor.

This is big. I know the distinguished presiding Senator was the attorney general for the great State of Colorado. I know he would also be very concerned about protecting proprietary information. This is not going to be about that. It is about safety issues, and they will be made public. We are also going to make sure patients and consumers help to make sure the FDA is communicating well with the public by creating an Advisory Committee on Risk Communication. This is modeled after two committees at the NIH and will facilitate getting FDA's message out to the public.

We also made additional changes that will directly improve drug safety. Throughout the approval process, it is important to include scientists who know how to follow drugs after they are approved. This takes me to one of my most important considerations. This legislation will strengthen the Office of Surveillance and Epidemiology to make sure it is part of the drug process from the beginning and all the way through.

This legislation will also generate additional money for drug safety. Provisions in this bill would add $29 million in PDUFA fees and up to an additional $65 million specifically for monitoring drug safety.

In sum, there are about 15 IOM drug safety recommendations we added to this bill. By working together, we have improved safety, we have improved transparency, we have improved morale, and we have improved resources. This is a good bill.

I say to my colleagues on the other side of the aisle: I don't know what you are cranky about. I don't know why you are holding up this bill. I will tell you what I am cranky about. I am real cranky when a drug goes out into clinical practice, and all of a sudden kids have problems. Kids have problems because they are trying to be like other kids. They are taking medication and it triggers something biomedical in their brain and gives them very dark thoughts. We don't want them to do dark things to each other. I am cranky when we have a doctor working in a rural part of my State, who doesn't have the time to read every medical journal but is relying on the fact that the drug he is prescribing to a patient for a heart condition has been approved by the FDA. He relies on the FDA to make sure that drug is as safe and as reliable as that doctor is in his own clinical practice.

I get cranky, real cranky, when we cannot improve drug safety. If we want to talk about that, we have to get back to mission and to purpose. It is the mission of the FDA to stand sentry over our food and drug supply to ensure safety and efficacy. It is incumbent upon us to give them the right policy framework and the right resources. I think we ought to get into action and pass this bill. Let's work together to make sure that when we talk about defending America, we defend Americans by passing this bill.

I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

Mr. GREGG. Mr. President, I wanted to speak briefly, partially in response to statements made on the other side of the aisle, specifically by the Senator from Vermont whom I had the good fortune to listen to and whom I always enjoy listening to—the junior Senator from Vermont. Although I always enjoy listening to him, the junior Senator, I enjoy listening to the senior Senator, too, but in this case it was the junior Senator, a very eloquent individual and a neighbor.

I did want to make a couple of points. He said, or implied—in fact, he said—that the Cochran amendment was essentially a poison pill to the efforts of Senator DORGAN to generate reimportation language which would be effective in allowing Americans to purchase drugs from Canada, or over the Internet for that matter. Then he said this was a result of the fact that the Bush administration was basically a tool—those are my words, but I think that is a characterization that is fairly accurate—a tool of the pharmaceutical industry, and the Cochran language was a reflection of that sort of attitude.

I think it is important to understand what the genesis of the Cochran language is. The Cochran language did not come from the Bush administration. The Cochran language actually came from the Clinton administration. I was here when it was originally proposed, and it was supported by President Clinton and by his Secretary of Health and Human Services—I believe it was Donna Shalala—because they felt very strongly, as does the Bush administration, that the FDA should not have two standards of safety. It should not have a standard of safety that says the products that are sold in the United States have to be subject to FDA review to make sure they are safe, but for products which somebody goes out of the country and buys and brings back to the United States, the FDA will be forced to turn a blind eye and will not review that product's safety.

The language is simple. It says if the Secretary of Health and Human Services cannot assure, through the FDA, a product coming into the country is safe and effective, then the product cannot be brought into the country. That is pretty reasonable language. That is what we asked the FDA to do. That is why the FDA was created, to protect American citizens who are purchasing pharmaceutical products or medicines. What this language which Senator COCHRAN is proposing would do is simply extend that language, should the Dorgan amendment pass, to products which are purchased outside of the United States and brought into the United States the same way, the exact same way, the FDA is required to review the safety and efficacy of a product which is purchased in the United States. That is all the language does.

Yes, it will have a significant impact on the Dorgan language because, yes,

both under the Clinton administration and under the Bush administration the Secretaries of Health and Human Services have said it is going to be extremely difficult, with the resources they have, with the authorities they presently have, to assure the safety and efficacy of drugs that are being reimported into this country.

But it is truly an inaccurate representation to say this is a Bush initiative, the purposes of which are to protect the pharmaceutical industry. It is just the opposite, in fact. This was an initiative created by President Clinton and his administration to protect the American consumer from purchasing drugs which the FDA doesn't have the wherewithal to determine whether or not they are adulterated.

Now, the response to this, of course, the substantive response versus the pejorative response, which is that it is just a pharmaceutical stalking horse—the substantive response to this from the Senator from North Dakota is, we are not suggesting anything that gets purchased isn't FDA approved. It has to be an FDA-approved drug. That is what the language in his amendment says. Yes, that is true; that is what the language of his amendment says. But the practical way it works is the FDA can't assure you, the American customer, my constituents, they can't assure that customer who goes to Canada the product they purchase in Canada is FDA approved, is the FDA-approved drug it says it is because the FDA has no ability to monitor that drug in Canada.

In the United States, it can absolutely guarantee if you buy—the Senator from North Dakota has been using the example of Lipitor—if you buy a bottle of Lipitor, that it is going to be Lipitor. But if you buy that bottle and you cross the border and bring it back into the United States, the FDA has no way of knowing or being able to manage the question of whether that is the drug that is supposed to be in that bottle. That bottle can be bottled in a way that puts a drug that has been adulterated into the bottle and then claim to be FDA approved. That is not a projection. In fact, that is exactly what is happening today.

Yesterday, for example, the FDA put out a press release citing the fact that there are 24 pharmacies that are online today people use in America that are not American pharmacies, that are international, and they now have absolutely firm evidence those pharmacies, or the group of pharmacies, the group that manages those pharmacies, is selling drugs representing that they are one type of drug but actually what is being delivered is something entirely different. In some cases it was just starch. It wasn't a drug at all. Even though it was claimed to be an FDA-approved drug, with the certification on it, with the batch number on it, with the expiration number on the package, it turned out it was starch.

In another instance it turned out it was an entirely different component than the drug which was allegedly being sold, which could do significant harm to you if you took it. In fact, we have innumerable anecdotal examples of people being harmed by purchasing drugs both over the Internet and by crossing the border because those drugs turned out to be fabrications. They turned out to be counterfeit. They turned out to be basically fraud on that consumer. So the purpose of the FDA is to ensure that doesn't happen.

What this language says very simply is, the FDA will assure that doesn't happen by giving the authority to the Secretary to make the decision—the same authority asked for by President Clinton and his Secretary of Health and Human Services—to make the determination as to whether a drug coming into this country through reimportation is safe and effective. That is what we charge the FDA to do. To claim it is some sort of an attempt to undermine the purpose of keeping consumers safe is just the exact opposite of what it is.

The purpose of this amendment is to make sure American consumers, when they buy a pharmaceutical, whether they buy it in the United States or whether they go over the border and buy it and bring it back into the United States, can be confident that pharmaceutical is safe and effective as determined by the FDA. So it is extremely reasonable language. It is not language that was proposed, as was represented by the Senator from Vermont, by the Bush administration as a stalking horse for the drug industry. It is, in fact, language which was proposed by President Clinton, President Clinton's Secretary of Health and Human Services, supported by them. They asked for the authority, and it is now the same position which has been taken by this administration, the Bush administration.

Mr. President, the Senator from Georgia has been very courteous in allowing me to go forward and taking this time before he and the Senator from Arkansas were to speak. So at this time I will reserve my comments and yield the floor so the Senator from Georgia can take his time.

The PRESIDING OFFICER. The Senator from Georgia is recognized.

Mr. CHAMBLISS. Mr. President, I thank my good friend from New Hampshire for yielding. I certainly agree with everything he has just been speaking about relative to the bill that is on the Senate floor now.

(The remarks of Mr. CHAMBLISS pertaining to the introduction of S. 1283 are located in today's RECORD under ''Statements on Introduced bills and Joint Resolutions.'')

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

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

Mr. SANDERS. Mr. President, the debate we are now having is an extraordinarily important debate; in fact, it will be one of the most important votes we will be casting this year.

This vote is about whether we stand with the American people, millions of whom are having a very difficult time paying their prescription drug bills or whether we stand with the most powerful and greedy lobby on Capitol Hill, and that is the pharmaceutical industry which has spent extraordinary sums of money to make sure the American people pay outrageously high prices for the medicine they desperately need.

I wish to briefly examine a chart which talks about the very high profit margin of the pharmaceutical industry. One of the reasons why the pharmaceutical industry can spend so much money on lobbying, on campaign contributions, on advertising is because of the profits they make year after year.

In 2004, drug companies ranked as the third most profitable industry in the United States with a 15.8-percent profit margin, which is about three times higher than the profitability of a median Fortune 500 company, which is at about 5.3 percent. This is in 2004. This comes from the Kaiser Foundation.

What we can also see, and what this chart tells us, is the extraordinary profits the drug companies are making from particular drugs. Epogen is the drug. Amgen is the company with profits of $2.5 billion. Taxol is the drug; the firm is Bristol-Myers Squibb, $2.1 billion for one drug, and on it goes. They are profitable year after year. The pharmaceutical industry continues to be one of the most profitable industries in this country.

I have another chart. One of the issues I look forward to discussing with Members of the Senate is the fact that as taxpayers in our country, we contribute billions and billions of dollars to the National Institutes of Health, the universities, the foundations for the very noble and important purpose all of us support: to create drugs that will address the major illnesses facing us, whether it is cancer, diabetes, AIDS, whatever it may be. We have spent billions and billions of taxpayers' dollars in a sense subsidizing the drug companies and, in fact, taxpayers do not get any reasonable price returns from them. We just give them the money.

Here is an example. Taxol is a very important and widely used medicine. According to a 2003 GAO report, the NIH spent $484 million on research for Taxol, Bristol-Myers Squibb spent $1 billion and subsequently earned $9 billion in profits.

In other words, American taxpayers are paying twice: once in the form of underwriting pharmaceutical research and the second time in the form of monopoly prices.

When we talk about the drug companies, we should also deal with the issue they often bring up. PhRMA is a very powerful lobbying group, the most powerful trade group on Capitol Hill. What they tell us is they need these very

high prices, they need all of the taxpayers' money because they are putting all of that into research and development. Don't we all want new drugs for diabetes, cancer, AIDS, and a dozen other terrible illnesses? This chart tells us something a little bit different.

This chart tells us the pharmaceutical industry spends far more for marketing—and goodness knows we have seen their ads on television over and over again, and guess who is paying for those ads. We are, in terms of high prices for the drugs, far more for marketing than for research and development.

Let me get back to the thrust of what this debate is all about, and let me be very clear. As I mentioned a little while ago, the Cochran amendment is a poison pill. If anyone is serious about prescription drug reimportation, if people are serious about lowering the cost of prescription drugs from 25 to 50 percent, if people are serious about standing up for consumers in this country, they will vote against the Cochran amendment.

So that no Senator has any doubt about what is going on, Mr. President, I ask unanimous consent to have printed in the RECORD a Statement of Administration Policy, dated May 1, 2007, from the President's office, and I will quote from the bottom of page 2, where there it is in black and white. This is a two-page letter. It says:

As a result, if any such importation provision were included in the final version of the bill presented to the President, the President's senior advisers would recommend that he veto the bill.

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

EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF MANAGEMENT AND BUDGET,

Washington, DC, May 1, 2007.

STATEMENT OF ADMINISTRATION POLICY

S. 1082—FOOD AND DRUG ADMINISTRATION REVITALIZATION ACT

(Sen. Kennedy (D) MA)

The Administration strongly supports reauthorization of the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA). These two programs account for nearly one quarter of the Food and Drug Administration's (FDA) annual budget and support more than two thousand Agency employees who work diligently to ensure the safety and efficacy of the medical products on which the American people rely. Reauthorizing PDUFA and MDUFMA will enhance FDA's ability to more efficiently and effectively regulate drugs, biological products, and medical devices, a critical component of the Agency's public health mission. Additionally, the Administration is committed to reauthorizing the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA), which have provided invaluable information to the Agency about medical products' interaction with pediatric populations.

The Administration shares the goal of S. 1082 to provide FDA with the appropriate tools and resources to enhance the safety and efficacy of the products the agency regulates. However, the Administration has serious concerns with S. 1082 in its current form and will work with Congress to address them as the legislative process moves forward.

The Administration appreciates that portions of S. 1082 are consistent with the Administration's recommendations for reauthorization, which strengthen FDA's ability to ensure the safety and availability of new drugs and medical devices, create a new program for review of television advertisements, and strengthen post-market review. These user fee programs expire at the end of the current fiscal year, and their timely reauthorization is critical to the ability of FDA to continue to carefully and expeditiously review and approve new drugs and devices to benefit the health of the American people.

The Administration is committed to further improving drug safety through better tools for surveillance of drug events, improved scientific tools for evaluating drug safety problems, and better means of communicating drug safety problems to providers and patients. However, the Administration is concerned that the bill, as written, would require significant resources to implement burdensome process changes that will not contribute meaningfully to improving drug safety. For example, the prescriptive timeframes to develop and process Risk Evaluation and Mitigation Strategies are particularly burdensome and are not likely to contribute to improving drug safety. Additionally, the Administration is concerned about the provision in S. 1082 that would use increased user fees to fund certain additional drug safety activities that were not agreed to during the statutorily required Agency-industry negotiations. This provision reopens and is inconsistent with the Administration PDUFA proposal that was developed through extensive consultation.

There are other provisions in S. 1082 that also raise serious concerns. Specifically, the bill would make changes to the BPCA and PREA to reduce the incentives to conduct clinical trials for children, thus reducing the effectiveness of the program. It also would impose administrative burdens that would make the programs inefficient and in many ways unworkable. These provisions would reduce the flexibility the agency needs to conduct these programs, require an inefficient duplication of scientific expertise, and cause delays in the review of pediatric assessments. Both BPCA and PREA have been very successful in providing the necessary incentives for drug companies to conduct pediatric clinical trials to improve our understanding of how drugs work in children, thus enhancing the quality of their medical care. BPCA and PREA should be extended without modification.

Potential Amendments: Follow-on Protein Products and Importation of Prescription Drugs

The Administration supports the goal of making safe and effective drugs available and affordable for American consumers. While some in Congress may be interested in attaching legislation related to follow-on protein products to this bill, the Administration believes that these complex issues should be considered thoroughly through a robust scientific, regulatory, and legal discussion. Sufficient discussion has not yet occurred and should not be abbreviated for the convenience of a particular legislative vehicle. Any legislative proposal considered to authorize a regulatory pathway for follow-on protein products must, as a first priority, ensure the safety and efficacy of the resulting products, thus protecting patient safety. Furthermore, it should also include adequate intellectual property protections for innovators, in order to maintain the research enterprise that has generated life-saving medications. The Administration believes further discussion must take place before addressing these issues in legislation. The Administration strongly opposes the inclusion in this bill of any provision related to follow-on protein products.

The Administration would also strongly oppose any provision that might be added on the Senate Floor regarding the importation of prescription drugs that does not address the serious safety concerns identified in the December 2004 Department of Health and Human Services Task Force Report on Prescription Drug Importation. The Administration believes that allowing importation of drugs outside the current safety system established by the FDA without addressing these serious safety concerns would threaten public health and result in unsafe, unapproved, and counterfeit drugs being imported into the United States. As a result, if any such importation provision were included in the final version of the bill presented to the President, the President's senior advisors would recommend that he veto the bill.

The Administration strongly opposes the inclusion of any unrelated provisions that would disrupt the timely reauthorization of the user fee program. The Administration looks forward to working with Congress to reauthorize PDUFA and MDUFMA expeditiously to avoid any disruptions to these successful programs.

Mr. SANDERS If you are voting for the Cochran amendment, which says, well, we want the Secretary to certify we can go forward, what you are voting for is to kill reimportation. The White House was honest enough to make that very clear. So it would seem to me that for those people who want reimportation, you have to vote ''no.'' If you don't want reimportation, then you can vote for it. But that is the simple reality.

There is another issue which I understand was raised a little while ago—I was not on the floor at that moment—and that dealing with the Clinton administration's attitude toward reimportation. I must say when I was a Member of the House, I was very involved in this issue. I was one of the leaders in the House in fighting for prescription drug reimportation. Back in the year 2000, we worked very closely with the Clinton administration and with then Secretary of Health and Human Services Donna Shalala to craft and pass reimportation legislation. During that process, the Clinton administration came to support reimportation over a period of time.

Unfortunately, as many in this Chamber remember, it was during that debate on reimportation that the Senator from Mississippi first offered the certification language he is putting forward today. So he has been doing this for quite a while. It is true Secretary Shalala refused to implement the reimportation legislation passed in 2000 as a result of this certification. I know opponents of reimportation like to characterize Secretary Shalala's refusal to implement reimportation because she believed reimportation was impossible to make safe. That is the argument we hear over and over again: Hey, it is not us. Even the Clinton administration said reimportation could not be made safe. But what I must say,

as straightforwardly as I can, is that argument is not accurate. It is not right.

In her December 26, 2000, letter to President Clinton dealing with this issue, Secretary Shalala outlined several ''flaws and loopholes'' that would prevent the legislation from being effective. As someone who was active in the debate of 2000, let me also say it is a fact that these ''flaws and loopholes'' were identified prior to the passage of that legislation, but opponents of reimportation refused to address them because they knew those flaws and loopholes would be fatal.

The legislation being offered today by Senator DORGAN addresses each and every one of those flaws and loopholes identified by Secretary Shalala. So let me say this again. If anyone comes to the floor of the Senate and says the Clinton administration thought reimportation should not go forward because there were flaws in it that could not be dealt with, that is simply inaccurate. What Secretary Shalala said is, there are concerns I have, and these concerns have got to be addressed. Well, guess what. Senator DORGAN's legislation does just that.

Let us take a look at her letter. Mr. President, I ask unanimous consent that the letter I am referring to be printed in the RECORD.

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

DECEMBER 26, 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. SANDERS. Mr. President, the first flaw Secretary Shalala identified was the lack of any requirement that the drug manufacturers give importers permission to use the FDA-approved labeling for imported medicines.

The Dorgan amendment addresses that concern.

The second flaw identified by Secretary Shalala was the lack of any ban on drug companies discriminating against foreign companies that export medicines to the United States.

The Dorgan amendment addresses that concern.

The third flaw identified by Secretary Shalala was the 5-year sunset in that version of the bill. That sunset would limit the public benefit from the investment the public would be making to put a safe reimportation system in place. In other words, she was saying, why should we go through all this effort if we are to only have a 5-year process.

The Dorgan amendment addresses that concern.

Finally, the Secretary noted the absence of a long-term income stream to fund enforcement of the reimportation system.

The Dorgan amendment addresses that concern.

In short, to characterize Secretary Shalala's letter as one that says reimportation is unsafe is to mischaracterize the essence of that letter. What Secretary Shalala was critical of was poison pills, what she called ''flaws and loopholes'' that were put in, or allowed to remain in the bill at the bidding of the pharmaceutical industry so they could defeat reimportation.

I have been involved in this issue for a long time, and that is what the drug companies do. Every day there is another reason why we can't go forward to lower the cost of prescription drugs. Every day there is another reason why we have to pay the highest prices in the world for prescription drugs. We have 1,200 lobbyists, no doubt many of them running around right now knocking on doors, to make sure our people continue to pay the highest prices in the world.

Secretary Shalala wrote in her letter that she, in fact, hoped Congress would fix the flaws and close the loopholes in that 2000 legislation of 7 years ago, and this is what she wrote to President Clinton:

> Mr. President, the changes to the reimportation legislation that we have proposed can and should be enacted by the Congress next year.

In other words, in 2001. Let me repeat that. Secretary Shalala wrote to President Clinton:

> Mr. President, the changes to the reimportation legislation that we have proposed can and should be enacted by the Congress next year.

Unfortunately, it has taken 7 years of work to bring us to where we are today. This should have been done years ago. Under the Republican leadership, there was no question we could not get to first base on reimportation. I hope things have changed now.

Let me conclude by saying that anyone who comes up here and says they are for reimportation but they are voting for the Cochran amendment is in fact not for reimportation. Anybody who comes up here and says, well, even the Clinton administration said we could not do that, I am afraid also that is not accurate and I think they are quoting Secretary Shalala, who was then Secretary of Health and Human Services, out of context.

As I have mentioned before, I have been through these battles with the

drug companies before. There is nothing the pharmaceutical industry will not do—nothing—in order to make sure they remain one of the most profitable industries in America. They will say anything, do anything, and put any kind of pressure they can on Members of the Senate or Members of the House.

Today, we have an opportunity to do something important. For many years there was growing concern in this country about a do-nothing Congress, about a Congress that was worried far more about the wealthy and the powerful than the needs of ordinary Americans. The elections in November have changed that. We have new leadership here. I hope very much that under this new leadership we will all summon up the courage to stand up to the drug companies, the most powerful, the most greedy lobby and industry right here on Capitol Hill, and that we will go forward and we will pass this legislation to lower the cost of prescription drugs for all Americans.

Mr. President, I yield the floor, and I suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. NELSON of Nebraska). The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

Mr. BURR. Mr. President, we are at a lull in the movement of the drug safety bill, a bill to assure American consumers, American patients, that there is more than just the acknowledgment by the Food and Drug Administration that a drug is safe and effective; that there is a mechanism post-approval as Americans across the country begin to take those medications; that we are watching for potentially any adverse reactions to a drug that a new population, an increased number of Americans that may be taking the drug. It is in an effort to make sure that if we see the signals of that unintended consequence, that we look more thoroughly at the benefits of that drug being on the market.

When I left the floor earlier today, the sponsor of the importation amendment suggested that Vioxx was not beneficial to anybody. The fact is, I do not think it is the role of Members of the Senate—unless you are Dr. COBURN—to suggest that you practice medicine. There are physicians who found the advantages of Vioxx, while it was on the market, they found it was advantageous to thousands, if not hundreds of thousands, of patients.

I am sure those patients are back on ibuprofen, Naprosyn, or other products that might cause significant gastro challenges for them, and that is why their doctors switched them originally. They needed relief from pain.

Well, a lot of things have been said, and the Senator from North Dakota said we should stay focused on the facts. I have come to the floor for a few minutes just to talk about some of the facts.

Many of us have suggested that, two years ago, when we created Medicare Part D—which is a prescription drug benefit for individuals in this country who are Medicare eligible—we lessened the problem that many seniors had expressed; and that is, their inability to buy pharmaceutical products.

Just recently, an analysis published by AARP, the American Association of Retired Persons, showed the new Medicare drug benefit saves seniors more money than buying pharmaceuticals from Canada. Now there is a new one. For those who are on border States, the AARP—the authority because they certainly had a loud voice before Part D was created—said drugs from Canada are actually more expensive than what Part D has been able to negotiate.

Let me say in every State we have multiple choices. Seniors make their choice. They participate in a plan. It is a private sector plan. But there are basically four large benefit managers, and they negotiate prices. What they have done is, they have been able to negotiate a price that has even exceeded what Canada could sell drugs for at retail.

This AARP bulletin found that many who choose the least expensive plan that meets their prescription drug needs—this is under Part D—will still pay less for those drugs than they would purchasing them from Canada. So it is not the ''Cadillac'' plan that seniors would have to choose to get less expensive drugs in the United States than from Canada. In fact, with the least expensive plan, AARP evaluated they would get a cheaper price on their pharmaceuticals by having Part D, accessing it at a U.S. pharmacy where they can feel fairly confident, if not totally confident, the product is, in fact, what they thought it was.

Just recently, in Detroit, MI, an indictment charging 19 individuals with operating a global racketeering conspiracy, was unsealed. The Federal court announced—the U.S. attorney for the Eastern District of Michigan—the indictment alleges that portions of the profits made from illegal enterprises were, in fact, funding Hezbollah. This is a foreign terrorist organization, by the way. Nine of the individuals were arrested. The indictment charged that between 1996 and 2004, this group worked together in a criminal enterprise to traffic in contraband cigarettes, counterfeit Zig-Zag rolling papers, and counterfeit Viagra.

So as to the claims we have made on the Senate floor—I believe the Senator from North Dakota when he says: We have done everything we can in this bill to assure the public of the safety and integrity of the product—though there is nothing in the bill that forbids anybody who wants to circumvent the law, in other words, make counterfeit drugs, make drugs that have no active ingredient, make drugs that look just like those drugs that are approved by the FDA, whether they are Viagra or Zocor, and to find a way for those to come to the marketplace.

It is not something the FDA today, or any FDA prior, has said they can police. For those Members who have been intricately involved since September 11, 2001, at understanding what our ability is to have a full knowledge of what comes into this country, some of us have actually gone to Washington Dulles Airport. We have seen the Customs officials go through the bags and bags of pharmaceutical products that come into this country. It is impossible, without a chemical test, to determine whether one tablet is authentic or the next one is counterfeit, whether one has an active ingredient or whether one is minus all active ingredients.

There have been several operations conducted in this country that deal with the cyber-trafficking of pharmaceutical products.

Fictitious pharmacies: These are companies that prey on individuals who are solely looking for low-priced pharmaceuticals. They think they are dealing with reputable pharmacies around the world. Yet there is no pharmacy. At the other end of the Internet are crooks. They prey on people who look for pricing. In fact, as some of those groups have been rolled up by our law enforcement, what we find is the products that were coming in had substantial deficiencies in things such as active ingredients.

What happens when a patient takes a product where the active ingredient does not exist? The illness they have is not affected. For an individual who might have high cholesterol who has been put on a drug that will lower that cholesterol because they are susceptible to heart problems, to have no active ingredient means they have a cholesterol buildup in their veins, and without intervention the likelihood is they might have a heart attack. They might die. Unfortunately, when they take a drug they think is real, but it has no active ingredient, unfortunately, they do not know until they have a medical incident.

So let me make this point to all my colleagues: If the purpose is to lower the cost of health care, then we are taking a mighty big risk because, in fact, what we may be doing is we may be raising the cost of health care in America, and with a disregard for the lives of the individuals who might be affected.

When I came to the floor earlier today, I mentioned that last year alone 1.7 million tablets of counterfeit Viagra were uncovered, 1 million tablets of Lipitor. This is according to the Wall Street Journal. I think that is surpassed, though, by the fact that last year—as we were in the heat of this new potential pandemic flu, H5N1, the bird flu; and we aggressively in this country then and still today are trying to come up with a vaccine and with

other countermeasures that might be able to defeat or minimize the impact of the bird flu—companies around the world started to look for Tamiflu as a successful countermeasure.

Individuals in this country searched outside of the country because the supply was so limited. Well, Customs agents have intercepted more than 50 shipments of counterfeit Tamiflu. It is an antiviral drug that is specifically designed to be stockpiled for the pandemic flu.

You see, my point is this: Counterfeiting, the trafficking of pharmaceuticals exists today. Anything that loosens the regulations on access to these pharmaceuticals invites more people to participate in gaming the U.S. consumer and, for that matter, the global patient. This is not something that is limited to the United States.

Clearly, the adulterated product is usually a product that is manufactured somewhere outside of this country. Not only can they make a handbag look like a designer bag, they can make a ''Viagra'' pill look like Viagra. Now, unfortunately, you will know real quick whether there is an active ingredient in that. But you will not know if it is, in fact, a cholesterol-lowering drug or one of the things that really does affect the long-term health of the American people.

A study published in the medical journal Science found when a cholesterol-lowering drug manufactured in the United States was compared just to generic copies bought over the Internet from Mexico, Thailand, India, and Brazil, there were differences in the blend, the uniformity of the blend—an error that could dilute their effect on patients. The authors concluded that clinically this would have significance for a patient who was prescribed a half a tablet per day, which is not an uncommon practice.

So for that senior at home, who has suggested an increase in the amount of milligrams of active ingredients so they can cut their pills—take half one day and half the next day because there are ways to maximize—what this report found, published in the medical journal Science, was that an adulterated product that does not reach the correct consistency throughout the pill might on one side provide the active ingredient and might on the other side not provide any active ingredient whatsoever. It could affect the dissolving rate, which could affect the onset of effect, or bioavailability.

These are stories that come right out of medical journals. This is not about pharmaceutical companies and how powerful they are in Washington. This is about whether the focus of the Senate is on the safety and the well-being of the American people. This is about whether, in fact, we are going to maintain the gold standard of the Food and Drug Administration or whether we are going to accept the standards of other countries in the world where their bar is not quite as high, where they are willing to accept less in innovation, just to receive less in price.

I am not sure that is a good tradeoff for the country. Clearly, the Senator from North Dakota has the votes potentially to win this. I do not find that too comforting, myself. I spent 2 years of my life actively involved in the 1997 modernization of the Food and Drug Administration. I worked with people on the right, the left, and the middle. I worked with people who wanted to do things at the FDA that today we still have not done, thank goodness, but there are still people who want to do it. But we all came together to uphold one thing in that process—not to lower the bar, not to lower the standard that we asked companies to reach with their products for us to put that FDA stamp of approval, ''safe and effective,'' on it.

There are products sold outside the United States that could never pass the application process in this country. I know the Senator from North Dakota does not, in his bill, allow those products to come in. He limits it to FDA-approved products. So my focus is solely on the product that is FDA-approved in this country, but that has been manufactured in a way that either provides little active ingredient or no active ingredient, and with potentially harmful components found in that pill, or whatever the dosage might be.

It is my hope we will continue to talk about this issue. But when I left the floor I thought it was important to go look at some of the articles to see if this is still a real problem. It is a problem today. It will be a problem tomorrow, and if we pass this, I think it will be a bigger problem in the future. It is a problem that is involved in funding terrorism around the world. It is a problem that will not go away, but at least today, we are able to control it. We are able to control it in a way that has a smaller effect on the quality of life of the people in this country. I think that is why they have us here. But we will continue the debate and we will see where we end. I think it is important enough that we spend days, if it takes days, to debate this legislation and to make sure everybody in this country understands what is at stake.

I yield the floor.

The PRESIDING OFFICER (Mrs. McCASKILL). The Senator from North Dakota is recognized.

Mr. DORGAN. Madam President, I would like to offer a few comments about this subject. My colleague has spoken on it several times. As I have indicated, we all want to deal from the same set of facts. This is not—let me emphasize again—it is not importing the standards of other countries with respect to the safety of prescription drugs. It does not do that. I want to make sure everybody understands what the facts are. Everyone is entitled to their own opinion; everyone is not entitled to their own set of facts. This does not import the standards of some other country into this country with respect to the safety of prescription drugs. This is simply the question of whether we want to continue to have FDA-approved drugs made in FDA-approved plants; that is, a plant inspected by our Food and Drug Administration, producing medicine and put into a bottle that is approved by our Food and Drug Administration and sold in this country and the same medicine, in the same bottles, sold in France, sold in Italy, sold in Germany, sold in Canada, sold in England, to have the U.S. consumer pay the highest prices of all of those countries. Is that fair to the U.S. consumer? The answer is no.

We have a lot of issues that are being raised on the issue of safety. All the things I have heard discussed on the floor of the Senate apply to today—now—when we don't have importation. We are not able to import safely. I should say we are not able to import, rather, prescription drugs because there is a prohibition against it. The only entity that can import a prescription drug is the manufacturer. Lipitor. I held up two bottles of Lipitor on the floor today. Lipitor is made in Ireland. They send it all around the world. They send it to Canada and they send it to the United States. The bottle looks the same, the pill looks the same because it is the same, and it is sold under the same chain of custody—Canada and the United States. There is only one difference. The U.S. consumer is treated to double the price when they purchase their Lipitor. Is that fair? Should we pay twice the price for an FDA-approved drug? I don't think so.

My colleagues have said there are counterfeiting issues. Well, all of the stories that have been recounted about counterfeiting issues are occurring under today's schematic of prescription drug sales in America. This has nothing to do with importing. In fact, the legislation I have offered is legislation that would make the supply of prescription drugs in this country and the supply that would come into this country under reimportation much safer. They would be safer because we have put in place safety procedures that have previously been blocked in the Congress, establishing serial numbers on the supply of prescription drugs, samples of the supply of prescription drugs to be held back by those who are manufacturing and moving the prescription drugs, establishing a pedigree for all of these drugs and the bottles in which they travel. It is much safer. It will be much safer for the domestic supply in addition to the supply of imported prescription drugs. That is the point we make.

I suppose people will be tired of hearing me say that I respect those who have a different opinion, but I would prefer if they would stand up and say: You know something. Here is my situation. I think the American people ought to pay twice the cost for Lipitor because I believe that. That is a pricing strategy that works for my constituents.

I don't hear anybody saying that, of course. They stand up and say there will be big safety issues, or my colleague who in an earlier speech this

morning said this amendment would allow drugs to be imported into this country from all over the world. I am sorry. That is not right. That is not debating the bill that exists. We are not letting drugs in from all over the world; only from countries that would qualify, that meet the safety standards. These would only be FDA-approved drugs, and they would only be drugs that are retained under a chain of custody, with a pedigree attached to the drug. There are no safety issues, unless one thinks it is unsafe for the pharmaceutical industry not to make the profits they currently make. They perhaps would see some smaller amount of profit if they passed part of the lower cost along to the consumers.

Maybe perhaps the industry could do a little less advertising, just a little less advertising. When you turn on the television at night and you sit down at the end of a long day and you see somebody driving in a convertible with beautiful people and they park under a tree someplace and the Sun is setting, it is a beautiful appearance, and they say: These people are feeling good because of medicine they are taking. You should be asking your doctor whether you might want to take some of that. Get some of this pill. Get some of this medicine. The Sun shines, you get to ride in convertibles, feel better, hang around beautiful people. That is the way advertising works, I guess. I have talked about the purple pill. They say: Ask your doctor, is the purple pill right for you? I don't know what the purple pill is, but I almost feel like asking the doctor, is the purple pill right for me? All of this promotion and advertising, maybe they could back off a little bit of that and reduce the prices to the American consumer. But that is not the strategy.

The strategy in pricing prescription drugs is that almost every country has some kind of limitation on what can be priced with respect to prescription drugs, except the United States of America, and here it is Katie bar the door. Whatever they want. We do have price controls in America. Not imposed by the Government; price controls by the pharmaceutical industry.

Now, this is a fine industry. They have men and women working, trying to unlock the mystery of diseases, trying to find ways to produce medicines that will manage diseases. I admire all of that. I say congratulations to them. But I have a serious disagreement with them on pricing strategy. They are wrong to believe they have to charge the highest prices to American consumers. That is a fact. They are wrong about that. They say: Well, it is the only way we can do research and development. That is not true at all. That is not true. A substantial portion of research and development is done by the taxpayer through the National Institutes of Health and others, and the product of that is turned over to the pharmaceutical manufacturers in terms of intellectual property that is developed and they manufacture drugs. Good for them. I know they also do substantial research on their own and I appreciate that. I don't appreciate the pricing strategy because I think it is unfair to the American consumer.

I don't know how many people I have talked to over the years who have come up to me and told me of their problems: I am 80 years old. I have heart disease. I have diabetes. I take all kinds of medicines, they say, but I can't afford them. The doctor says in Dickinson, ND, one night: I have this welfare woman, and this patient has a pretty aggressive form of breast cancer. He says: You have to be taking this medicine to prevent a reoccurrence when you have surgery. You have to take this medicine to prevent a reoccurrence of breast cancer. She says: What does it cost? He tells her. She says: I can't possibly do that. I can't possibly take that. I don't have the money to do that. I can't buy that medicine. Does this matter? It sure matters to the person whose life is at stake. So price is an issue. It is a big issue.

We have all these anecdotal stories. We know the data. The amendment I have offered will save $50 billion over the next 10 years—$50 billion—most of it to consumers, through lower drug prices. That is a fact. It is not going to, in any way, injure the safety of our prescription drug supply. It will, in fact, enhance it dramatically by establishing pedigrees with respect to the movement of prescription drugs in this country and into this country. That is a fact as well.

I said this morning I hate to lose debates I am not having, and it happens all the time on the floor of the Senate because someone is debating a bill I didn't introduce. They are welcome to do that. If it is attractive, maybe I will introduce it someday, but I am not interested in having a debate with somebody who wants to reformulate the legislation I have introduced. This addresses safety, all of the issues that Donna Shalala, the former Secretary of Health and Human Services raised, so we have incorporated into the bill, Senator SNOWE and I and others have incorporated that right into the legislation. So you can't, it seems to me, make a strong case that there are valid safety issues. Again, I don't have problems with those who come to the floor saying let's continue the current system, but I think the current system is wrong. They have a right to advocate for the current system, but the current system is unfair to the American consumer, in my judgment.

I want us to have the opportunity to have good health care and opportunities to be able to access miracle drugs, the opportunity to use those miracle drugs to manage diseases so you can stay out of an acute care bed, which is the most costly health care in our country. But I think it becomes almost a health care rationing in our country when we say we will ignore the situation that exists in this global economy in which the American consumer pays one price and consumers in virtually every other country pay a lower price for their prescription drugs. That, I think, is a horrible disadvantage to consumers in our country.

Some will say: Well, you know now we have a Part D in Medicare which offers prescription drug benefits to senior citizens. Yes, that is true. It does. It has what has been defined around here only in the lexicon of politics as a doughnut hole. Only in the political system could we use those kinds of descriptions, but it has a kind of a circumstance where you reach a certain level and then there is no drug coverage on up from that level. Obviously, the prescription drug Part D for Medicare is helpful to senior citizens; there is no question about that. But it certainly isn't perfect because there is a substantial portion of it in which prescription drugs are not covered. At that point, senior citizens who are reaching the declining years of their lives are finding it very difficult to purchase their prescription drugs.

There is much to say about this issue. I know there are some who worry that offering this amendment on prescription drug pricing to this underlying bill, the FDA Reauthorization Act, injures the underlying bill. I support the underlying bill. I think my colleagues, Senator KENNEDY and Senator ENZI, have done some good work. I support that work. Let me say—and I know they know this—it is perfectly appropriate to offer this amendment on this bill because this is where it belongs. This is exactly where you would offer an amendment of this type. No one should express surprise about that.

So we offer the amendment and then we file cloture so we can actually get to a vote on it, and all of a sudden it is like the circus left town. They pull up the tent stakes, fold up the tent, everybody is gone. All of a sudden we can't vote anymore. Why? I guess they are upset that my amendment is now in order to be voted on, and they say: You know, I don't know. We can't do that.

As I have indicated before, I would be willing to offer this amendment in a different form—the same amendment but in a circumstance where I had an agreement to be able to bring it up. Four hours of debate, for example, a couple of amendments that would be offered by the other side, I would have the right to offer second-degree amendments, we would go to a vote and decide whether the Senate will pass a proposition that would give us an opportunity to reimport FDA-approved drugs from other countries that are identical to the other drugs we now purchase, except at a lower price. I would be happy to agree with others who would give us that time and that circumstance so that we could have this vote. I don't need to have the vote today or Monday or Tuesday, if I have an agreement that we will be able to get the vote at some moment.

This vote has been stalled a long while. Senator Frist, when he was the majority leader, standing right back here at the end of this aisle at about 1 o'clock in the morning, in exchange for my releasing a hold on the nomination of Dr. McClellan, indicated to me and then put into the CONGRESSIONAL RECORD, in the Senate RECORD, that we were going to have action on this kind of legislation. It turns out it never happened. Senator Frist, of course, is now gone. For whatever reason, it never happened. I spoke at great length to him about these issues, but it didn't happen.

So this is an opportunity for us to advance this legislation, and it is the right place at the right time. This has 33 cosponsors. JOHN MCCAIN is a cosponsor, TED KENNEDY is a cosponsor, CHUCK GRASSLEY is a cosponsor, DEBBIE STABENOW is a cosponsor, and OLYMPIA SNOWE is the major cosponsor with me. It is the Dorgan-Snowe bill.

Thirty-three Republicans and Democrats are cosponsors of this legislation. This is exactly where it should have been offered, and it was. Now, all of a sudden, apparently there is some kind of gastric distress because we had a cloture vote and we prevailed in the vote that we say, all right, let's have votes on this amendment. So my hope is that, first, while we might form opinions on this amendment, we could coalesce on a central set of facts that represents what the amendment does and says; and, second, that we can begin, on behalf of the American people, to make some movement here and to begin to have votes.

I also hope that, as I listen to further debate on the floor, we can stick to what the amendment is. It is not to reimport lower priced FDA-approved prescription drugs from everywhere. It limits it to those areas where we have safe and effective supplies of prescription drugs.

I hope we can get all of the facts straight. This amendment has a lot of support. I believe the American people, by 75 to 80 percent, support this. I have seen poll after poll where the American people believe it is wrong and unfair for them to be charged the highest prices in the world for prescription drugs. Why on Earth should they drive 10 miles between two drugstores—one on the Canadian side and one on the American side of the border—only to find that the same medicine, put in the same bottle, made by the same company, FDA approved, has only one difference—the American consumer gets a chance to pay double. How do you justify that? You don't. We ought to change it.

I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER (Ms. KLOBUCHAR). The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

U.S. POLICY IN IRAQ

Mr. BYRD. Madam President, President Bush marked the fourth anniversary of his announcement that major combat operations in Iraq have ended by vetoing war funding legislation because he claimed it limited his ability to prosecute a war unconditionally and indefinitely. Our Armed Forces are now well into their fifth year of combat operations—longer than the U.S. was involved in World War II—and the time is overdue to examine and update U.S. policy in Iraq.

The legislation, which President Bush vetoed, would have set a responsible, new course for the war that was a balanced and fair proposal that I was pleased to support. Sadly, the President continues to believe peace and stability can be forced on the Iraqi people at the point of a gun. He was wrong in 2002 when he sought authorization to go to war, and he is wrong today.

However, now that the President has insisted on continuing down this failed path, it is our responsibility to discuss alternatives that can become law. The Congress is not an ATM, spitting out billions whenever the President requests it. It is a policy arm of the Government, as well as its banker. The Constitution says the Congress shall have power to provide for the common defense. It is the Congress—yes, it is the Congress—that is given the sole power to declare war. The Congress is sworn to raise and support armies. The Congress and the people of the United States have a right to expect clarity in our mission and a foreseeable end to this conflict.

The situation in Iraq, in 2007, is very different from what it was in 2002, when the Congress authorized the use of military force in Iraq. The President himself said this:

> This is not the war we entered in Iraq, but it is the war we are in.

It is time to rethink, reset our goals, and consider a new authorization which outlines the mission as the President now sees it. The October 11, 2002, authorization for the President to use force in Iraq was very specific. After expressing support for diplomatic efforts to resolve the causes of conflict with Iraq, the authorization allowed the use of force for two purposes. The first was to defend the national security of the United States against the continuing threat posed by Iraq. The second reason was to enforce all relevant United Nations Security Council resolutions against Iraq.

In 2002, and early 2003, President Bush made his case to Congress and to the American people for the invasion of Iraq. His stated goals included the elimination of the weapons of mass destruction programs that Iraq was thought to possess, and the overthrow of Saddam Hussein's regime. By that yardstick, the U.S. military has achieved brilliant success. No weapons of mass destruction were found in Iraq—not just weapons that could threaten the national security of the United States but also no weapons of mass destruction of any description. Saddam Hussein and his Government are gone. The Iraqi people have elected a new government. The U.S. military has achieved success in Iraq, and that success has come at a high price, both in dollars and in lives. Thus far, over 3,350 American men and women have been killed, and many more have been wounded. Including the funding in the emergency supplemental vetoed by the President, over $450 billion has been provided by Congress to execute this war.

The October 11, 2002, authorization to use force has run its course. It is time—past time—to decommission this authorization and retire it to the archives. If the President has more that he wants to do in Iraq, then he needs to make that case to Congress and to the American public. Our continuing presence in Iraq is not supported by the people or the Congress. The President must redefine the goals and submit his plan to achieve them to a thorough and open debate in the Congress and throughout the country. That is the American way. Success will elude us without the support of the people whose sons and daughters are being asked to die daily in the sands—yes, the sands—of Iraq.

I propose October 11, 2007, as the expiration date for the 2002 authorization and that the President seek a new authorization from the elected representatives of the people in Congress. The President must be clear about what he now hopes to accomplish in Iraq and how he intends to achieve it. President Bush must build support for his plan. Without the support of the public and the Congress, we should no longer be in this fight. It is now an Iraqi fight for national reconciliation, not a war to ensure U.S. national security. If the President sees a further role for U.S. troops, he should articulate it and seek consensus for a changed mission. I hope my colleagues on both sides of this important debate and on both sides of the aisle can agree that the 2002 authorization has run its course. It is no longer viable, and it should be set aside.

What I propose does not mandate redeployment on any date certain. It simply calls on the President to make the case for the new situation in which we find ourselves. My proposal does not set limits on troop levels, nor prevent them from doing what is necessary to protect themselves and U.S. personnel. It also does not prevent us from pursuing terrorists who may have set their sights on the United States. What it does is stop our troops from fighting endlessly in an Iraqi civil war after October 11, 2007, unless the President—our President—receives a mandate from the American public and the U.S. Congress.

Let us try to give the President a chance to refocus his vision on the changed circumstances in Iraq, free

from the shackles of a shamelessly outdated grant of authority. I deplore the political gamesmanship which has polarized our Nation. I regret the harsh partisanship which rages while our brave troops fight and die.

A fresh start could help to change the dynamic in this country. A concerted effort by the White House to reassess its goals and opportunities in Iraq could point a path to progress. A new debate in Congress could resolve confusion and contention about continuing a strategy for Iraq that no longer addresses the exigencies of today. We need a new mission which makes clear the changed role of our troops. We need a diplomatic component to the plan which might encourage the national reconciliation so badly needed to quell the violence in Iraq. We need a plan to reach out to other countries in the area which share our interest in seeking stability in Iraq. But first we need to clear the cobwebs and the confusion caused by a grant of authority that no longer has any relevance to the present conditions of Iraq.

I ask other Senators to consider my proposal, whether this proposal is considered on the supplemental, on the Defense authorization bill, or on the Defense appropriations bill. I ask cooler heads to see the possibilities of beginning a new assessment of where we are and where we are going. I ask for a cease-fire in the political war in Washington for the sake of our troops and for the sake of our country.

Madam President, I yield the floor, and I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mrs. CLINTON. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

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

Mrs. CLINTON. Madam President, I rise to join my colleague and friend, Senator BYRD, to announce our intention to introduce legislation which proposes October 11, 2007—the 5-year anniversary of the original resolution authorizing the use of force in Iraq—as the expiration date for that resolution.

As Senator BYRD pointed out, the October 11, 2002, authorization to use force has run its course, and it is time to reverse the failed policies of President Bush and to end this war as soon as possible.

Earlier this week, President Bush vetoed legislation reflecting the will of the Congress and the American people that would have provided needed funding for our troops while also changing course in Iraq and beginning to bring our troops home.

I believe this fall is the time to review the Iraq war authorization and to have a full national debate so people can be heard. I supported the Byrd amendment on October 10, 2002, which would have limited the original authorization to 1 year, and I believe a full reconsideration of the terms and conditions of that authorization is overdue. This bill would require the President to do just that.

The American people have called for change, the facts on the ground demand change, and the Congress has passed legislation to require change. It is time to sunset the authorization for the war in Iraq. If the President will not bring himself to accept reality, it is time for Congress to bring reality to him.

I urge my colleagues to join Senator BYRD and me in supporting this effort to require a new authorization resolution or to refuse to do so for these new times and these new conditions that we and our troops are facing every single day.

Madam President, I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Madam President, what we are actually on, of course, is the 30 hours of debate postcloture on the drug importation amendment, and I do want to make some comments on that. I perhaps should have done more extensive debate before, rather than agreeing for a time specific for a vote on it, but that option has passed at the moment. I congratulate Senator DORGAN for his tremendous victory.

I am hoping there will be some changes yet. Perhaps there will not be. We took a 300-page bill that dealt with drug safety in the United States and we then added a 140-page bill that deals with bringing in drugs from other countries. It is a limited number of countries, to start with, but it is bringing in drugs from other countries. I suggest if they are as safe as what we have been told, parts of this bill would not exist.

For instance, page 48, on bioequivalence. It was my understanding what would be brought into the United States would be drugs from companies from the United States that went to Canada, or went to some other place, and could be brought back into this country. These would be FDA-approved drugs. These would be the ones we rely on the FDA for. If they are exactly the same drugs, by exactly the same company, why would there be a section on bioequivalence?

It says:

> . . . if the Secretary determines that the qualifying drug is not bioequivalent . . . the Secretary shall . . . include in the labeling provided under paragraph (3) prominent advisory that the qualifying drug is safe and effective.

Well, let me see. We didn't ask them to review it, we didn't ask that it go through the same procedure, but we want the Secretary to provide labeling that says it is safe and effective. I don't know why we would expect the FDA to say anything that is bioequivalent should have their endorsement of being safe and effective. If we do, it expands their job dramatically and there ought to be resources that go with it to be sure that what we are promising will be done gets done.

There are a lot of pages here, a lot of different things. I am definitely not going to hit on all of them, but I am going to mention a few that people probably ought to be a little concerned about.

Here again, on page 56, I thought it was going to be U.S. drugs, or at least drugs from U.S. companies that are already FDA approved that we were going to make sure there was an absolute chain of making sure they got back into the United States so that you could trust what came from U.S. companies. Yet on page 56 we see:

> Notice; drug difference not requiring approval.

What?

> . . . supplemental application would not be required for the difference to be made to the U.S. label drug, or that states that there is no difference.

And then a whole bunch of requirements again for the Secretary, which goes down the line to the FDA. So I think we can conclude we are not just going to bring in U.S. drugs. If there is anything you would like to have, you can.

Then there is a section called ''Importation by Individual.'' This covers the portion where each person can get on the Internet or telephone or whatever way and order drugs. There are requirements in this bill for exporters, which are the people who are sending drugs to other countries; there are requirements in here for importers, which are companies receiving drugs—and those could be pharmacies, probably would be pharmacies, although there could be some wholesale—but there is also this section about importation by the individual.

I hope everybody takes a little look at that, because in the United States I have been working a lot on financial literacy, trying to get people to understand finances and how they can stay financially sound and hopefully financially secure, and it is a huge job. With regard to the No Child Left Behind Act and in Education, we keep talking about plain old literacy; just being able to have people read, and read at grade level, and hopefully read well enough to have a good job and to protect themselves. They better be literate, because look on page 62 and read what the importing individual is responsible for. Because if they are not responsible for this, they could easily be getting something that is not an approved drug or that is not from the source they think it is. It could be a counterfeit drug, and particularly as this opens up on the front end. How many people doing counterfeit drugs now are going to want to jump into the breach and catch people before they understand any of this? I suspect there will be a huge escalation of companies getting into the counterfeit business. There are a few dollars in it—quite a few dollars.

I would encourage people to look on page 62. There are things scattered

throughout the bill an individual would have to know to be sure what they were getting was safe, if they ordered individually. But that is kind of the point of the bill, because most of them probably will be ordered individually.

On page 64, Request for Copy of Special Labeling and Ingredient List. I think that probably would be handy.

Then, on page 65, it goes into the question of adulteration, where it says a qualifying drug that is imported or offered for import shall be considered to be in compliance if the drug is in compliance with all these other sections.

There is also a section titled Standards for Refusing Admission. There are quite a few ways it can be denied, but in order for these adulterated drugs to be denied, to be refused admission, somebody has to find them. So what kind of force are we going to add to the FDA to make sure these things can be found?

I am particularly fascinated with item (F), which gives the Secretary some extra capability if the drug is counterfeit or if the drug may have been prepared, packed, or held under insanitary conditions. Now, the fact that they mention it has to make you believe there is a possibility—maybe a probability, the way it is put in here—that they will be prepared, packed, or held under insanitary conditions.

The United States has a little different level of sanitation than a lot of the countries around the world. Of course, all of these aren't going to come from all around the world to begin with, or will they?

Let's see. They do not have to be bioequivalent. There are a whole bunch of things the individual has to watch out for themselves. It doesn't have to be the same drug that was manufactured in the United States or from a United States company, and if it gets into the EU, it can come to us. That is EU now; EU later. The EU is expanding. We ought to take a look at some of the countries that are being brought into consideration, particularly if you might be worried about them being packed, held, or prepared under insanitary conditions.

Then we get to page 71. Again, there are a lot of things I would like to mention in between, but this is all boring detail stuff, anyway, so I will highlight a few of these things and let people think about them a little bit.

On page 71, we give the Secretary some more responsibilities. They have to:

> . . . enter into an agreement with the government of the country to receive information about recalls and withdrawals of qualifying drugs in the country; to monitor recalls and withdrawals of qualifying drugs in the country using any information that is available to the public in any media.

There are requirements for notice and changes in the labeling, packaging, and that sort of thing.

That is all additional. We are asking them to do some more things in the United States to make what we have here and are relatively certain about even safer. That is the purpose of the bill. Now we are adding these additional sections, 140 pages, which bring the problem from other countries to our country. I grant it, a lot of those are made in the United States or by companies from the United States.

Page 72, again, has a whole bunch of requirements for what kinds of things ought to be included with the drug. You need to know those because if they are not, you maybe ought to suspect there may be a problem. You have to be able to check the packaging and note whether it has the proper seals and whether there could have been any damage to them. It is your problem—unless, of course, the consumer consents to waive the requirements after being informed the packaging does not comply. There is fascinating stuff in here.

Here is one of the parts that really ought to interest us. When we get to page 76, page 76 says you have to play the game: You can't win, you can't lose, and you can't get out. Here is how that works.

Canada has price fixing. There is no doubt about it. That is how they get some of the lower prices on some of the drugs. You can't buy all of the drugs in Canada at lower prices. In fact, I have a friend in Afton, WY, who is a pharmacist. He had a fellow come in who was from Canada but he could not get back to Canada and his prescription had run out, so he relied on an American pharmacy to get his prescription refilled. All the time they were filling the thing, he is complaining about how this darned prescription is going to cost him an arm and a leg because it is in the United States and the cheap drugs are in Canada. The pharmacist gave it to him, told him what the price was, and he said: But that is cheaper than I get it in Canada.

That is a little bit of financial literacy. Just because you heard everything is cheaper in Canada doesn't mean it is.

You should particularly pay attention if there are generics because U.S. generics do not translate to Canada nearly as quickly, if at all. The companies had to go through this bidding process. The bid doesn't take into consideration the change, and that is part of the deal, that you get a little bit of exclusivity with your pill.

I was interested in Zocor. It is a big drug in the United States and a big drug in Canada, although Canada has one-tenth the population of the United States. The Health Minister called me and said: You cannot be considering this import thing. We do not have the capability to supply the United States with their drugs. We will be inundated with prescriptions, and we do not have that big of a supply because we have a tenth of the people the United States has.

Getting back to my Zocor story, that has gone generic. In Canada, you still have to get Zocor, and it is $33.64 for 30 pills. That is a 1-month supply of 10-milligram pills. That would not, of course, include the cost of shipping and handling.

In the United States, there is a generic Zocor, simvastatin. The statins are all designed so that part of the label talks about doing similar things. But the generic Zocor in the United States costs $29.99 for 30. So that is $3.50 less. It is not a lot, depending on what you consider a lot to be, but it is less. But if you are willing to use provostatin or lovastatin, we are talking about $4 a month—$4 a month as opposed to $33.64 a month.

People need to be aware that just because we say Canada is cheaper, it is not always cheaper. But for those drugs which are cheaper, page 75 has a little provision.

I need to explain how Canada gets this price fix. It is called negotiated price. How do you negotiate a price if there is a sole supplier? You really do not have much luck negotiating if it is a sole supplier, so you have to take similars. I use the example that if there are five heart medicines, you make those five bid against each other. That is your leverage. If you make them bid against each other, you have to drop somebody to get the price down, and probably several to get the price down, so maybe you have one or two heart drugs instead of five. But you tell your doctors—who in Canada work for the state—that is their choice, and they make it.

But in the United States, we are used to having our doctor make the decision. And because of television advertising, we are able to make some of our own decisions on what we think would be the best one and tell our doctor what he better do for us. Sometimes that is another little problem.

At any rate, that is how Canada gets lower prices. We can probably do that in the United States, too, but people in the United States really expect to be able to get the drug their doctor says they ought to have. I think we would have a large-scale revolution if we started suggesting that the Government could figure out which drugs they could have so we could get lower prices.

Page 75, section (b), that is where they say if a company has a drug that is in Canada, it has to be sold in the United States at the same price. So you really do not have to go through Canada. That will just move Canada's price fixing down to the United States.

I have to mention a little thing on pricing when the Government gets into that business. Back in 1975, I got married, and my wife and I started a shoe store in Gillette, WY. You will recall at that time that the Government decided they would put some prices in there. This really shows that it was 1975. We always made sure there were several styles of men's shoes that were under $10. I don't know if you can get the laces for $10—yes, you can. But you

cannot buy $10 leather shoes, leather lined, particularly not made in America. That has disappeared, too.

But they decided, for a whole range of products in the United States, that the Government would set the price to keep down inflation. The companies, as soon as they heard about that, said: This will really affect our profitability, and we are not going to be allowed to raise them except at set particular times and for set amounts. So what they did was raise their prices right away. A $10 shoe became a $15 shoe overnight. Then the price setting went into effect and they were allowed to raise it again, and they raised it again to the maximum there. And every time they were allowed to raise it, they raised it. It made a huge difference in the price of shoes, as it did with everything that was being attempted to be controlled. People wound up paying a lot more than if there had been no Government pricing.

How will that work here, if you are a pharmaceutical company and they say that you are not going to be able:

. . . to discriminate by denying, restricting or delaying supplies of a prescription drug to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section. . . .

And you can't:

discriminate by publicly, privately, or otherwise refusing to do business with a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section . . .

And so on. I am reading from the bill here. What it says is that if you are selling it to them now, you can't change at all.

If I am the company that is about to find out that the price I have in this deal with Canada, which is just a small part of the deal, and I am doing it—I am the only accountant in the Senate. For accounting purposes, sometimes these companies will sell to another entity a ways away—in this case, another country—for a lower price because they cover the costs and make a profit on what they are doing. But by picking up peripheral sales, there is less cost involved in them, so there is still the same amount of profit. Granted, that is kind of an accounting technique, but it is the way a lot of businesses have to pick it up. That is why they keep going for additional sales and looking for ways to get additional sales. They have gotten additional sales in Canada by going through this bidding process which fixes the price.

But what we are saying on page 75 of this bill is that if you sell to Canada, you have to keep selling, you have to keep selling at the same price, and you cannot get out of the game unless—and here is the ''unless'' that I bet you kicks in—unless you are not selling to them. So unless there is some kind of ironclad contract that requires them to continue to do that, Canada is just about to lose its drug supply because they are not going to continue to sell up there at a rate that is below cost—if you are doing it at U.S. costs—if you can jerk that drug.

That is why Canada is a little bit concerned about what we are doing here. First of all, they don't have enough drugs in the pharmacy and enough pharmacies to supply 10 times their population, for the people in the United States, and second, they are worried because their supply will be cut off before this bill goes into effect, so it really doesn't go into effect. That would be the effect of it, that this would be 140 pages of wasted trees.

You have to believe, unless there is an ironclad contract, that is what a business would do. It is a terrible thing to have happen to Canada or the other countries. But that is what happens when you fix prices.

I would mention that on page 115, it begins a section on Internet sales of prescription drugs. I will give them credit for giving it a try. I will not give them credit for having a very complete or safe job on it, but it is a try. It is important for them to try because most of the people in the United States will be ordering their drugs, probably, through the Internet—perhaps over the telephone but not in person.

The examples we have heard of everything working fine have been of people going across the border in a car and buying at a pharmacy. That makes sure the trail of concern and safety is more likely to be there. But the Internet is a little bit more universal. Things can go around the world in a matter of minutes. They can go from one server to another server to another server—you are now covering three countries—and it looks as if it came out of the last country, perhaps, if you want it to look like that. There are a lot of things that can be done. I know the kids would probably understand that more than I would because they are able to do a lot more things on the Internet than I am able to do on it.

I know there are some difficulties with the Internet because the FDA has already intercepted problems and been able to confiscate some drugs that were tremendous problems. They are pretty sure some got into the country and didn't wind up in a situation of death, but they did find out they wound up in a situation where the person was not getting what they thought they were getting and it wouldn't digest and problems such as that. But they have also confiscated a huge amount of drugs which have been sold over the Internet which came into this country and which have a lot of problems.

I had a display up here on the desk. The Senator from North Dakota likes to hold up two pill bottles and say: What is the difference between these two pill bottles? One is the United States and one is Canada. What is the difference in price? And he goes through the pricing difference. But one of the things he ought to go through at the same time is: Can you tell which was made in the United States and which was not? Can you be sure the one you say was made in Canada was made in Canada? I will tell you, there are some absolutely marvelous counterfeits out there.

The box I have here has a couple of examples of confiscated drugs from the FDA. You cannot tell by the box, you cannot tell by the packaging, you cannot tell by the pill. I am even told that if you grind it up, you will wind up with the same components; they are just not put together right, so they don't work. But as long as it is not a lifesaving drug for you, you can get along with it, anyway, you just will not be getting the benefits from the drug. Something to think about.

There is a possibility of improving that section, because one of the amendments that has already been filed is by the Senator from New Hampshire, Mr. GREGG, who has been working this Internet problem for a long time. He has an amendment that is a vast improvement over this section and might be able to greatly enhance and perhaps correct some of the problems that can happen there.

I would mention one more. Page 131, a restricted transaction. See if you have the pharmaceutical literacy to know exactly what is happening here. A restricted transaction means a transaction or transmittal on behalf of an individual who places an unlawful drug importation request to any person engaged in the operation of a registered foreign pharmacy.

Now we have got to know who the registered and unregistered ones are and whether it is lawful or unlawful drugs. Again, there is so much literacy that has to go into this, as opposed to what you get in the United States, that you know it was from the United States.

We probably do pay a premium for our safety. Most people want to be sure they are safe. There is also a little bit of a problem with the bill the way it is written and being able to tell about the wholesale licensure and the pedigrees that go with that licensure. There will be another amendment that will be submitted that hopefully can clear up some of those problems. I hope people will work with us.

As you can see, one of the things we are trying to do is to make a problem better. I think it would have been a lot better if we could have gone ahead and had the drug safety taken care of today, which we were on a track to do, because Senator KENNEDY and I had already worked through all of the amendments that had been turned in, with the exception of the importation one. We had been able to resolve or have them withdrawn for almost everything and could have wrapped it up with a few more votes. But it will take us a little longer now. We are hoping there are opportunities to improve the bill. I know under the procedure of the Senate there are ways to keep people from being able to have votes.

I mentioned a number of times the success Senator KENNEDY and I have

had with the Health, Education, Labor, and Pension Committee, a big bite of the apple, the success we have had in the previous 2 years. Some was because we did not follow an exact procedure of going to a markup and arguing until things were polarized. We took what we could and worked with people through the process, and they trusted us enough to work through the process, so by the time it came to the floor, we had a managers' amendment that covered a lot of the difficulties people had with the bill.

When you put in an amendment, technically the amendment is one way or the other. Oh, yes, there are ways to do second-degree amendments, but you will not see many of those around here, because that is putting in another very concise set of words that is accepted or rejected. They can change the original bill a little, or perhaps a lot. Some of them can be complete substitutes. But they are polarizing, and they do not take care of the technicalities. The advantage of running the bill through this sized body, then through the other end of the building with 435 people, is to get 535 opinions of what ought to be done. Out of 535 opinions, we can usually come up with a pretty good bill. But when an amendment is put in and there is no way to do any correcting, or the only way you can do correcting is another take-it-or-leave-it bill correction to it, it is a very difficult way to get any legislation done.

Our success over the last 2 years of getting legislation done was because we worked this process of continually working until we got to a final product, which meant cleared through conference committee.

But evidently we are not going to do that this year with this piece. It was a significant victory for someone who has worked very hard on it. Senator DORGAN has worked hard on it for a long time. He did an outstanding job of presenting it. Now I am hoping he will work to see that it gets perfected a little bit more. It cannot be perfected in the way we normally perfect it, but a little bit more as we go through the process, and perhaps by about next Thursday we can finish with the bill. It is an extra week of work, but I think this could have been brought up in a separate bill, handled individually, and had some of the same mechanisms for improving it we would normally have in a bill. But that is behind us now. So we continue to work on the bill, and we hope by a week from today we can have this concluded.

Mr. President, I yield the floor, and suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. WHITEHOUSE). The clerk will call the roll.

The legislative clerk proceeded to call the roll.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

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

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

Mr. KENNEDY. Mr. President, to review where we are in this debate and discussion, we will be meeting again on Monday next, making critical choices and decisions about the way we are going to proceed. We have made good progress over the course of this week. Some of us were hopeful that we would be able to move toward the completion of this legislation. But this legislation is enormously complex and enormously important.

We have made, as I say, good progress. We have a number of different areas we have worked through over the period of these past days. We will propose a managers' package and we will make the final judgments about the determination of this legislation on Monday next.

Again, we thank all of our colleagues who have worked with us on the legislation. Very quickly, to say again why this legislation is important, and that is because, as we know, the FDA effectively protects the prescription drug supply and our pharmaceutical supplies, medical devices, vaccines, food supply and cosmetics; about 25, almost 30 percent of all of the consumer products. So, it is enormously important that we have the FDA be the gold standard to protect American families, particularly with regard to prescription drugs and with regard to food and other items as well.

So very quickly, and finally, to review exactly what this legislation does and why it is so important, why it is so urgent, why it is so necessary—and this legislation falls in that category—that is why we are urging that we reach conclusion on Monday next.

One of the notorious recent examples of fear that took place in many households this past year, over the period of the last year, was the Vioxx scare, the whole issue and question about those whose lives may very well have been shortened because of Vioxx.

The best way to illustrate what we are talking about in terms of patient safety is how this legislation would deal with a future kind of a Vioxx that might endanger the health of our fellow citizens.

First, can the FDA quickly detect a safety problem with a drug? With the Vioxx situation, the answer was no. Now we have a completely new system, a sort of an information technology system with regard to post-marketing surveillance. We draw on all of the public as well as private systems—the Mayo system, the veterans system, the myriad different systems that will be collecting information. It will be collected in one central place—the FDA—so the Food and Drug Administration can demonstrate that there is a safety problem. There will be notice for the Agency.

Can the FDA require the label changes to warn of safety problems? Under the existing circumstances, there was a negotiation for some 14 months before they were able to resolve that issue. Finally, the drug was withdrawn by the company. If the company doesn't deal with the Agency, the Food and Drug Administration has the authority and power to withdraw the approval and effectively repeal the drug. But that has very important safety considerations because there may be certain populations where this particular drug may be suitable. That is probably true with Vioxx. It is not suitable for the general population but suitable for a particular population. What this does is give the FDA the kind of opportunity for labeling changes to warn of safety problems. It has other alternatives which I will refer to lower in the chart.

Are companies stopped from hiding safety problems? It is extremely difficult because we include the publication of clinical trials so they will be available to the public. This transparency included in this legislation is enormously important. The value of clinical trials is not only important from a safety point of view but also for individuals who are affected by disease and illness. They may make a judgment that they want to enroll in a particular clinical trial and try to remedy their particular health challenge. There will be the registry and the opportunity for them to do that. That has not existed in the way we have done this. That opens up enormous kinds of opportunities for many people who have many of the illnesses and sicknesses we know affect so many of our families. So, we have the safety provision and also the opportunity for people who have those illnesses and diseases to take advantage of this program.

Does the FDA have flexible tools to enforce safety decisions? The answer is yes. This was described well by my friend from Wyoming, Senator ENZI. He talked about the toolbox available to the FDA. It can be included in labeling. It can be included in terms of training of various personnel to administer the drug. It can be included in terms of specialized targeting, particularly groups in the medical profession who have the skills to dispense those drugs. There are a variety of different tools that are in there that do not exist today.

Finally, is the FDA the gold standard for protecting the public health and assuring access? We believe the answer is yes. These are practical examples of how we protect families.

We have another chart which makes this point as well. We had an excellent study done by the Institute of Medicine, an extraordinary group of individuals who reviewed the powers of the FDA and made recommendations. This chart shows we have incorporated in this legislation, by and large, the recommendations made by the Institute of Medicine, with respect to drug safety. We built in the epidemiology and the informatics capacity to improve post-

marketing assessment, using information technology; to make public the results of the post-clinical trial; to regularly analyze post-market study results; to give FDA clear authority to require post-marketing risk assessment and management. If there are additional kinds of requirements in terms of the drug itself, the FDA will have that authority and give better enforcement tools. We also include some civil penalties to make sure this is going to be enforced—that is important—and conduct regular evaluation of a new drug's safety profile. We will continue with post-marketing surveillance. This will be a continuing process to protect the American consumer. It is an enormously important concept to implement this. We will also increase drug safety resources available to the FDA. We have done all of these in this legislation.

We have enhanced the Office of Science, and we have improved significantly the conflict of interest and other provisions.

This gives you some idea. We have an excellent statement from groups who represent 30 million patients: This legislation gives the FDA the ability to continue to study the safety of drugs after approval, flexible enforcement tools necessary to ensure compliance with these new safety protections, and additional funding to support these new activities. Allowing the Agency to act on clear safety signals could actually allow the FDA to approve drugs more quickly, knowing it will have the ability to respond on behalf of patients if safety concerns appear post-market.

That is important. With breakthroughs in the life sciences and different opportunities that are now available, the Agency will feel more comfortable in approving drugs which they may have a speck of doubt about, but they will know that with the kind of review processes we have insisted on in this legislation, they can get on the market quicker and that it can improve the quality of health and safe lives. This is very important: ''knowing it will have the ability to respond on behalf of patients if safety concerns appear post-market.''

This is from the Alliance for Drug Safety that represents 30 million patients, a very solid endorsement of what this legislation is all about.

We have done a similar protocol with regard to food safety as well, of the importance of surveillance. As we would with some bioterrorist threat, it is enormously important that we understand what is happening in a number of these countries around the world, early survey labs, and the follow-on provisions that we have included.

A final point, we have had a debate with regard to the differential that has taken place in the different countries. The presentation has been made. There has now been the pending Dorgan amendment which recognizes this disparity to make some adjustments on this issue in terms of the medicines.

We will move ahead on this. We have other items which have been proposed by our colleagues and on which we are prepared to make some recommendations. We have worked very closely during the evening, early morning with Senator ENZI and our colleagues. We are hopeful we will be able to see a conclusion of this legislation, which is so vitally important to the American people during the early part of next week.

Again, we are enormously thankful to all and extremely grateful to my friend and colleague, Senator ENZI. We look forward to a good discussion and debate and continued progress on this very important bill at the beginning of the week.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

PEACE IN SUDAN

Mr. DURBIN. Mr. President, I rise today to once again address the ongoing violence in Darfur, Sudan.

Hundreds of thousands of people have been killed in that terrible genocide, and millions have been driven from their homes.

This week, the International Criminal Court has issued its first arrest warrants for these murderous crimes. The ICC issued warrants for the arrest of Sudan's so-called Humanitarian Affairs Minister Ahmed Haroun and against a jingaweit militia leader known as Ali Kushayb. Sudan says there is no need for such a trial and that its own courts are capable of prosecution. This is the very same Government that has helped orchestrate this campaign of violence, a government wheree courts are more likely to prosecute rape victims than the men who attack them. That is why we need international action in response to these crimes against humanity.

Mr. Haroun, who today serves as Sudan's Minister for Humanitarian Affairs, was in charge of Darfur in 2003 and 2004, at the height of the killing.

The jingaweit commander, who is the second man named in the warrant, commanded thousands of militia members and is accused of promoting rape and torture as part of his war strategy. The Sudanese Government claims he is in custody, but witnesses have told reporters that in reality he has been traveling in Darfur under police protection.

These arrest warrants are a significant, if small, step toward justice, but there is so much more the world must do to bring peace, justice, and security to the people of Darfur.

Recently, President Bush delivered a speech at the Holocaust Museum, promising that unless Sudan agreed to a full-scale peacekeeping mission and took other steps, then the United States would expand unilateral sanctions against the Sudanese—in the President's words—''within a short period of time.'' The President also stated he would press for multilateral sanctions through the United Nations. Both are important steps. I wish they had been taken far earlier, but they are still welcome steps.

Deputy Secretary of State John Negroponte recently returned from Sudan. The report on his trip was not encouraging. He told us that Sudan's President Bashir continues to stand in the way of a full-scale U.N. mission. He also said Bashir is not taking steps to disarm the militia that have terrorized villages in Darfur, with the Khartoum Government's tacit, if not open, support.

I know President Bush had planned to announce new sanctions at his speech at the Holocaust Museum. He agreed to delay implementing further measures in response to a strong personal request from the Secretary General of the United Nations.

We cannot solve Darfur alone. It will take many nations. I understand why President Bush felt compelled to give the United Nations an opportunity. But the world cannot wait long, and the people in Darfur certainly cannot be asked to wait any longer. The violence there is entering its fifth year.

A new report by the International Crisis Group, a nongovernmental organization working to prevent conflict across the world, spells out the urgency. This report states that combat in Darfur is rising, and the Sudanese Government continues to rely on aerial bombardment and raids by the jingaweit militia as its tactics of choice against its own people.

The Crisis Group report also spells out the complexity of what is happening there. The report states:

> Darfur is the epicenter of three overlapping circles of conflict.
>
> First and foremost, there is the four-year-old war between the Darfur rebel movements and the government, which is part of the breakdown between Sudan's centre—the National Congress Party in Khartoum, which controls wealth and political power—and the marginalized peripheries.
>
> Secondly, the Darfur conflict has triggered a proxy war that Chad and Sudan are fighting by hosting and supporting the other's rebel groups.
>
> Finally, there are localized conflicts, primarily centered on land tensions between sedentary and nomadic tribes.
>
> The regime has manipulated these to win Arab support for its war against the mostly non-Arab rebels.
>
> International interests, not least the priority the U.S. has placed on regime assistance in its ''war on terrorism'' and China's investment in Sudan's oil sector, have added to the difficulty in resolving the conflict.

This report calls for implementation of a full-scale peacekeeping mission and the need to revitalize the peace process itself. Peacekeeping troops can help keep civilians protected. International mediators from the African

Union and the United Nations must also help the rebel groups and the Sudanese Government reach a more broad-based peace agreement. The first requirement, however, is getting peacekeepers into Darfur. Conflict is rising. The humanitarian space is shrinking. It is becoming harder and harder for many relief groups to reach those in need.

In testimony before the Senate Foreign Relations Committee on April 11, Special Envoy to Sudan Andrew Natsios stated that Secretary General Ban Ki-moon had requested a 2- to 4-week window in order to pursue diplomatic negotiations with Khartoum before any additional measures were taken. May 11, just a few days away, will mark a full month since Mr. Natsios's testimony. On that date, if Khartoum has not acted to take the necessary steps toward peace, I hope President Bush will launch expanded, hard-hitting U.S. sanctions and seek to pass a United Nations Security Council resolution with meaningful multilateral sanctions.

We need to strike out economically where it will hurt—against Sudan's oil industry. And I hope that China, which sits as a permanent member of the Security Council and represents Sudan's biggest oil customer, will join in our efforts. China buys 70 percent of Sudan's oil, and reportedly the Khartoum Government spends 60 to 80 percent of its oil revenue on its military. The Sudanese Government uses that military against its own people, especially in Darfur.

As a rising power, as the host of the next Olympics, and as a member of the Security Council, it really is China's responsibility to use its influence to convince Sudan to accept the full-scale peacekeeping mission that is really needed. China has helped convince Sudan to say it will accept 3,000 U.N. peacekeepers, but far more than that is needed, and Beijing can play a pivotal role in bringing peace to Darfur. The statement made by the Chinese Government a few days ago was encouraging, but it was a very modest statement when you consider the magnitude of this genocide.

Today, there are fewer than 7,000 underequipped African Union peacekeepers spread across Darfur—an area the size of Texas but Texas without roads or infrastructure.

The cause of Darfur has captured the hearts of millions of Americans. This past weekend, in Chicago and in cities across the Nation and around the world, thousands of people gathered in support of the people of Darfur and in support of efforts to divest from companies that invest in Sudan.

I should also mention that this same weekend, at Soldier Field in Chicago, thousands of young people gathered in support of the ''Invisible Children'' of Uganda. These children have also been victimized by years of war, and indeed the conflicts in Northen Uganda and Sudan are intertwined.

For years, the Sudanese Government has supported and assisted the Lord's Resistance Army, which has terrorized northern Uganda.

One of the focal points of the Sudan rally last weekend was to support legislation introduced by my friend, State Senator Jackie Collins of Chicago. She is a wonderful leader on this issue. She has shown such persistence and courage, pushing for divestment so that Illinois, my home State, can have maximum impact to end this genocide. Her bill would divest State pension funds and other investments that add to the coffers of the Sudan Government.

At the rally, participants also supported efforts here in Congress, which Senator JOHN CORNYN and I have introduced, to express Federal support for States, universities, and others that choose to divest.

This movement is expanding, not just here at home but abroad as well. Rolls-Royce has announced it is withdrawing from Sudan. According to media accounts, including the Associated Press, the Ford Motor Company, which produces Land Rovers, will no longer sell Land Rovers in Sudan. According to these press accounts, Ford made this decision after the Securities and Exchange Commission sent the company an inquiry asking about reports that some Land Rovers may have been used by military or paramilitary organizations.

This Saturday, Berkshire Hathaway, one of the largest and most respected investment firms in the country, will convene a shareholder meeting. Warren Buffett, who runs Berkshire Hathaway, has agreed to put the divestment question on the agenda.

The divestment movement was launched on college campuses. It is now reaching the boardrooms of major corporations and the agenda of shareholder meetings. Divestment is one tool among many, along with U.S. and U.N. sanctions, increased penalties for violations of U.S. law, stepped up engagement by China, and a commitment to reengage the peace process itself.

I have made these points before, but we must not let the Sudanese Government think that the often limited American attention span will wander away from Darfur. We will not blind ourselves to genocide, and we will not grow fatigued by more news stories of suffering in this distant place. We must do, in every way possible, what we can do as individuals, as Members of Congress, and as Americans who care, Americans who have said when it comes to a genocide: Never again.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Ohio is recognized.

Mr. BROWN. Mr. President, I appreciate very much Senator DURBIN's words on Darfur and how he continues to keep that issue in front of the American public, and how important it is that the assistant majority leader do that.

I rise to speak on behalf of the Dorgan amendment, the reimportation amendment, which will mean major cost savings to Americans when they buy prescription drugs. Several times over the last decade as a Member of the House of Representatives from a district in northeast Ohio, including Lorraine, Akron, and Medina, I took busloads of senior citizens to Windsor, Ontario to buy prescription drugs—a rather peculiar thing perhaps for a Federal official to do, to take people to another country to buy a consumer good. But what all of us know in this Chamber and most of the American people who have paid attention to this and understand, is that the same drug, the same dosage, the same manufacturer, often the same packaging—that those prescription drugs cost one-half, one-third, and sometimes as little as one-fourth in Canada what they cost in the United States. So we would take busloads of mostly seniors across I90 on the turnpike, up through Toledo, into Windsor, Ontario to buy prescription drugs and save seniors several hundred dollars, sometimes several thousand dollars a trip for each of them.

The opponents of the Dorgan amendment, the opponents of reimportation, for years—and when I was in the House they used these same arguments—have continued to use the issue of safety, as if the drugs you buy at Hunter's Pharmacy in Windsor, Ontario are any less safe than the drugs you buy 3 miles away across the bridge in Detroit, MI, or 50 miles down the road or 60 miles down the road in Toledo, OH. The fact is that issue is a smokescreen. We know that drugs sold in Canada often are drugs that are made in the United States. Lipitor is a drug made in Ireland. It is sent to Canada or it is sent to Steubenville, OH. It is the same drug, the same packaging, the same dosage, the same manufacturer, and it is every bit as safe in Steubenville, OH, as it is in Windsor, Canada, or just as safe in Windsor as it is in Steubenville.

Let me talk for a moment about the whole issue of the safety of these drugs. Importation, I believe, as Senator DORGAN does and as do so many in this Chamber, as do I believe 62 Senators who voted for cloture, importation is safe for drugs and for other sensitive commodities. In the year 2000, for example, the Pentagon imported Anthrax vaccine from Canada for U.S. troops. There was no question as to whether it was safe. Of course it was safe, and it mattered, and it protected our troops. The U.S. imports guns and explosive chemicals, uranium, food, pacemakers, heart valves, and other medical devices safely. Again, we are able to make sure these drugs are safe.

If the Federal Government can put a man on the Moon, they can certainly ensure the safety of imported prescription drugs. The Federal Government that says it can build a nationwide missile shield with thousands of precisely coordinated weapons and sensors can ensure the safety of imported prescription drugs. The Federal Government that says it can develop hydrogen-powered cars within 15 years can

surely ensure the safety of imported prescription drugs. A Federal Government that says it can safely ship and store thousands of tons of nuclear waste can surely ensure the safety of imported prescription drugs.

What is the real safety issue? The real safety issue is not whether a consumer from Ohio, from Ashtabula, driving up to Canada, driving through Erie, PA, into Buffalo and across the river into Ontario, can't buy the same safe drug with the same safe drug regimen in Ontario as that consumer does in Ashtabula. The issue about drug safety is that, frankly, unaffordable drug prices are what compromise the safety of these drugs.

Let me give a couple of examples. The drug companies' pricing policies compromise the health and safety of U.S. patients in this way: A study completed last year found that seniors who can't pay what the drug companies demand fill fewer of their prescriptions. That means the doctor is telling the patient that the patient should take this drug the doctor prescribed and the patient is not fully filling the prescription, so the patient is compromising his or her safety. Another study found that thousands of seniors with serious health problems reported they skipped doses to make prescriptions last longer. My wife last year was in a Shaker Heights drugstore—a generally affluent suburb west of Cleveland—and standing in line behind a patient who was trying to negotiate the price with the pharmacist. The patient asked if there was any way she could get the drug less expensively. The pharmacist said: This is the only price I am able to charge. The elderly woman said: How about if I just skip today and take the drug every other day, and the pharmacist said: You can't do that. It would compromise your health. The lady said: How about if I cut the pill in half and take a half a pill every day, and the pharmacist cautioned against that. When she walked away, my wife said: Does that happen often? The pharmacist said that happens every day, all day.

A 2001 study determined that patients were choosing less effective alternative medicines instead—pill-splitting, for instance. Patients will sometimes buy doses larger than appropriate for their condition in order to save money, and then divide the pills with a knife. That kind of pill-splitting is on the rise. Some health insurers actually require their enrollees to do it. The VA encourages it. Florida's Medicaid Program requires its beneficiaries to split their antidepressant medication that way. This controversial practice raises important safety concerns, all because of cost. It is why Medicaid, why the VA, and why health insurers require their enrollees to do it. The American Medical Association, the American Pharmaceutical Association, the American Society of Consultant Pharmacists, all oppose this pill-splitting.

The Miami Herald last year reported that a recent study of 11 commonly split tablets found that eight of them, after splitting, no longer met industry guidelines.

A spokesman for the drugmaker Pfizer told the Washington Post:

> We don't recommend it for patients. Splitting can lead patients to receive too much or too little medicine.

All of this happens because of the pricing of prescription drugs.

So when the opponents of the Dorgan amendment say we can't guarantee the safety of these prescriptions we get from Canada, that Drug Mart or CVS might buy wholesale from Canada, that these can't be guaranteed safe—they can be guaranteed safe just as well as CVS or Drug Mart going to an American wholesaler the FDA has approved. The real safety issues are when patients cannot afford the high cost of these drugs and either don't fill the prescription or take the drug every other day or cut the pill in half so their prescription lasts twice as long for the same costs. Those are the real problems.

Only the Dorgan amendment will save money. When you think about what has happened with drug costs in this country, the Alliance for Retired Americans issued a comparison this year of United States and Canadian retail prices for 20 popular medicines. Compared to Canadian citizens, United States customers pay 20 percent more, for instance, for their high blood pressure medicine Norvasc, 60 percent more for their cholesterol medicine Pravachol, 100 percent more, twice as much, for the heartburn drug Prilosec, 200 percent more, 3 times as much, for the heart medicine Toprol XL, and 750 percent more for the breast cancer medicine Tamoxifen—750 percent more.

Many of these drugs were developed by U.S. taxpayers through National Institutes of Health grants. Yet the drug companies thank American taxpayers for doing all this research by charging Americans 750 percent more for Tamoxifen that will save the lives of women who have breast cancer, and by charging 3 times more for heart medicine, and by charging 3 times more for another drug or 60 percent more for cholesterol medicine. The fact is, again, that safety is compromised because of the high price of these drugs.

In 2001, U.S. consumers filled 24 million prescriptions for the arthritis medicine Celebrex and another 23 million prescriptions for the arthritis medicine Vioxx. Using the ARA price differential of about $41 for Celebrex and $46 for Vioxx, U.S. consumers spent almost $1 billion more for Celebrex in 2001 than Canadian consumers, and over $1 billion more for Vioxx than did Canadian consumers.

No wonder so much is at stake in the Dorgan amendment. It saves consumers billions—$50 billion is I think the number he used on the floor yesterday—$50 billion. This saves American consumers billions of dollars. That means individual seniors out of pocket, it means insurance companies, it means taxpayers, it means the VA, it means all of us would save significant amounts of money. But we know what is at stake because the drug companies are going to make that much more money as a result.

That is what this is all about. It is all about drug companies protecting their profits, increasing their profits. We all know the drug industry—and this amendment is not against the drug industry. It is for consumers. It is for taxpayers. It is for small businesses. It is for insurers. It is for the payers, people who are paying for these expensive drugs. But we know that in this institution, in the Senate and down the hall in the House of Representatives, it is all about drug company lobbyists, hundreds and hundreds and hundreds of drug company lobbyists fighting to keep their profits, to expand their profits. It is an industry that over the last 20 years has been the most profitable industry in America, year in and year out, exceeded only a couple of years by the oil industry. But typically, in a normal year, the drug industry's return on investment, return on equity, return on sales is far and away the most profitable industry in this country.

The U.S. market accounted for 60 cents of every dollar in revenue for the 10 biggest drugmakers. The 10 biggest drugmakers in 2001, for instance, their revenue was $217 billion more than the gross domestic product of Austria. They had profits of $37 billion—more than the Government spent on VA health care, more than the entire budget that year for the U.S. Department of Housing and Urban Development; profit margins of over 18 percent, 3 times the average of other Fortune 500 companies. These companies charge too much. They get much of their research done by the U.S. Government, and then they are charging these kinds of prices, which compromises the safety of seniors who struggle to pay for these prescriptions that their doctors have ordered.

In addition, when you think about what these skyrocketing drug prices mean—health care overall, and especially skyrocketing drug prices—just for American families, not just for seniors but for taxpayers and for small businesses—prescription drug costs increased almost 19 percent in 2002. Medicaid prescription drug costs increased a similar amount in 2001. Private health insurance premiums grew 15 percent and are projected to grow another 14 percent this year. Small employers saw HMO premiums increase 25 percent. This is consistently, 25 percent, 15 percent, 10 percent, year to year to year. What that means is because of the high cost of drugs, it is not just compromising the safety of our seniors, it is also hurting our small businesses. It also means that in too many cases, American companies simply have difficulty internationally competing with other countries, because they want to take care of their

own employees and provide prescription drug coverage for them.

The Dorgan amendment makes sense for small business. It makes sense for taxpayers. It makes sense especially for seniors who are taking these prescription drugs. Pure and simple, it makes sense for our country. If we care about the safety of seniors and the safety of drugs, don't buy the argument that these drugs are contaminated or adulterated or not safe. The fact is we know the drugs that are sold in pharmacies in Canada or Great Britain or by pharmacists in those countries or pharmacies in Japan or Israel and Germany are safe. They have a regimen like FDA to protect the safety of their drugs. The issue here is whose side are you on? Are you on the side of seniors, on the side of taxpayers, on the side of small business, or are you going to side with the drug companies? It is pretty clear where people line up in this institution.

I ask my colleagues in the Senate to support the Dorgan amendment when it comes to a vote next week.

Mr. President, I yield the floor, and I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

Mr. NELSON of Florida. Mr. President, I rise to support the Dorgan amendment of which I am a cosponsor. Senior citizens in Florida in the year 2007 should not be in a position, as some are, of having to make a choice between buying groceries or buying their medicine. Unfortunately, there are some seniors who have to make that choice. Ultimately, once we get the Medicare prescription drug law changed that will ultimately bring down the cost of those prescriptions, that will solve the problem.

I might say that the private marketplace is starting to have an effect. It was some several months ago that Wal-Mart announced it was going to start selling, for $4 per prescription for a 30-day supply, generic drugs from a compendium of over some 200 drugs. That program has been successful. And, of course, others, such as Target, have picked up and started that program as well. So we are seeing that the marketplace is starting to have some say in this.

But with regard to the delivery of these drugs, senior citizens are having difficulty, even under what is supplied by Medicare right now. Until we have, eventually, the ability of Medicare to use its bulk purchasing power in order to negotiate prices of drugs—something the Veterans' Administration has been doing for years—until that occurs, along with the effects of the marketplace, along with the entry of generic drugs—until all of that happens, we are not going to see the cost of these drugs brought down to where in America today we do not have a senior citizen making a choice between buying groceries or buying their prescription medicines. In the meantime, there is something we can do about it; that is, we can allow senior citizens to purchase drugs from Canada, where often the price is one-half of what they get those drugs retail here.

This Senator has been involved in this because, naturally, my State has the highest percentage of the population that is 65 and older. Naturally, when their shipments of drugs coming from Canada are interdicted, as they have been by Customs over the last several years, guess who they are going to call. I get involved in this, and then I have to get ahold of the Customs Department to find out why they are doing this. I have to get ahold of the FDA, and I get conflicting messages.

A couple years ago, I spoke to the acting head of the FDA. He said that, as a policy, we do not have any objection to a limited supply—and he named that as 90 days or less—for personal use. Naturally, the FDA has to be concerned about the safety of large quantities of counterfeit drugs. That is what we want to protect. That is what we want Customs to be going after.

He pointed out that all of the counterfeits we have to go after—it is not the individual senior citizen wanting a limited supply, 90 days or less, for personal use coming from a Canadian pharmacy; that is not a threat to the health of our people.

Last year on the floor, Senator VITTER of Louisiana and I coauthored and offered an amendment, and it passed. It would have allowed what I just described. That bill went to the House in a conference committee and, because of the power of the pharmaceutical industry, they watered it down so that instead of the senior citizen being able to order by mail, by Internet, or by telephone, what became law was that they could bring it personally across the border. Well, that may do somebody good in Michigan or in North Dakota, but it is obviously not going to do senior citizens in other parts of the country, including Florida, any good.

Thus, until we can get this equilibrium of the marketplace by bulk purchases, by additional generics—all the time—and there is an interest, I agree, of the pharmaceutical industry, protecting them with those patents so they can recoup research and development costs but not to keep extending that patent after the life of the patent so that the generic can never get to the marketplace—until we can get all of those things straightened out, we simply have to bring some relief to our people. Albeit this is just one small way of doing it, it is an important step to allow the purchase from Canadian pharmacies. It is the same drug, made in the same pharmaceutical facility, that we get here. Indeed, it is even the same packaging, except it is sold through a Canadian pharmacy at half the price.

I am as reasonable as any Senator in trying to work out an accommodation with certain interests that want to protect their turf, but this has simply gone too far. As the Senator from Ohio has just given a number of examples his wife was observing at the counter of the pharmacy, so too have I witnessed this among seniors.

A lot of the seniors today came out of the ''greatest generation.'' We have an obligation to them, and no senior citizen should not be able, either through a Government program such as Medicare or a Government-subsidized program, through Medicaid—if they don't get their pharmaceuticals from one of those, they simply should not be in a position where they have to cut those pills in half or take them every other day or not be able to take those pills at all.

When Medicare was set up back in the mid sixties, we didn't have the miracles of modern-day drugs; there wasn't a Medicare prescription drug benefit back then. Now, thanks to—kudos ought to go to the pharmaceutical industry, and the money we vote here for the research that goes through a lot of our scientific and medical institutions, federally funded money that goes to that research, the commendations ought to be all the way around the block, including the pharmaceutical companies. But we have to take the view that we cannot keep looking out for our own selfish interests all the time. We have to look to the greater good. When there is a part of America that is hurting, we have to address it.

It is for those reasons that I am a cosponsor of this amendment. I was quite heartened when, earlier today, we got the necessary 60 votes in order to break the filibuster and proceed with the amendment. I hope that once we pass it here in this Chamber, it will not be stripped off when it gets to the other Chamber.

Mr. President, I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative 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 (Mr. NELSON of Florida). Without objection, it is so ordered.

CLOTURE MOTION

Mr. REID. Mr. President, I send a cloture motion to the desk.

The PRESIDING OFFICER. The cloture motion having been presented under rule XXII, the Chair directs the clerk to read the motion.

Mr. REID. Mr. President, this is regarding the substitute amendment to S. 1082.

The legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, hereby move to bring to a close debate on the committee substitute amendment, as modified, to S. 1082, the FDA Revitalization bill.

Ted Kennedy, Dick Durbin, Byron L. Dorgan, B.A. Mikulski, Patty Murray, Claire McCaskill, Amy Klobuchar, Sherrod Brown, Jack Reed, Herb Kohl, Charles Schumer, Christopher Dodd, Barbara Boxer, Bill Nelson, Jeff Bingaman, Debbie Stabenow.

CLOTURE MOTION

Mr. REID. Mr. President, I send a cloture motion to the desk.

The PRESIDING OFFICER. The cloture motion having been presented under rule XXII, the Chair directs the clerk to read the motion.

Mr. REID. Mr. President, this is calendar No. 120, S. 1082.

The legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, do hereby move to bring to a close debate on Calendar No. 120, S. 1082, the FDA Revitalization Act.

Harry Reid, Jeff Bingaman, Patrick Leahy, Russell D. Feingold, H.R. Clinton, Patty Murray, Bernard Sanders, Frank R. Lautenberg, Christopher Dodd, Dianne Feinstein, Ted Kennedy, Benjamin L. Cardin, Benjamin Nelson, Bryon L. Dorgan, Kent Conrad, Dick Durbin, Jack Reed.

Mr. DURBIN. Mr. President, I rise today to discuss two amendments that I have filed to this bill, Nos. 1027 and 1023. I do not intend to offer them at this time, but they raise important issues that I would like to highlight.

I want to begin by thanking the chairman, Senator KENNEDY, and ranking member, Senator ENZI, for their hard work on this bill. Together, we made significant progress yesterday by adopting an ambitious amendment to improve our food safety system for both humans and pets.

I also want to thank Senators KENNEDY and ENZI for agreeing to work on a comprehensive food safety package. That commitment is not taken lightly, and I look forward to working with them on this comprehensive package.

Although we took great strides yesterday with respect to food safety, there are two important areas where the FDA is limited in its ability to protect our food supply. These weaknesses have been exposed in recent recalls: the E. coli spinach contamination; the peanut butter recall; and, most recently, the expanding pet food recall that has entered, or at least come very close to entering, the human food supply.

The first weakness is that the FDA lacks the authority to issue a recall or pull defective products from shelves to protect consumers.

This is surprising to many people, but here is a quote from the FDA website, summarizing its recall authorities:

The manufacturers or distributors of the product carry out most recalls of products regulated by FDA voluntarily. In some instances, a company discovers that one of its products is defective and recalls it entirely on its own. In others, FDA informs a company of findings that one of its products is defective and suggests or requests a recall. Usually, the company will comply.

This is true. Most often, companies comply, and there are penalties for failing to recall.

However, sometimes companies recognize that they have a problem but choose not to recall a product because they are afraid of upsetting consumer confidence or losing market share. The FDA has reported multiple instances of firms failing to recall or recall in a timely fashion.

In the pet food recall, companies have time and time again expanded their recalls, and the process has lasted more than 6 weeks. Just yesterday Menu Foods, the first company to recall on March 16, 2007, expanded its recall yet again. This recall was for products made during the same period of time as the other recalled products announced on March 16. Menu Foods has also announced an expanding date range of contaminated product.

This same weakness was on display in 2002 in the ConAgra beef recall.

Unfortunately, without the power of mandatory recall, the FDA is in a weaker position to force companies to announce recalls quickly or to thoroughly study the extent of a recall. The result is slow, uneven, voluntary recalls that leave consumers at risk.

The Consumer Protection Safety Commission, the EPA, and even the FDA with respect to infant formula have recall authority. Why, then, does the FDA not have that authority for the other foods it regulates?

This authority would expedite the speed and thoroughness of voluntary recalls, protect consumers, and protect industries against bad actions that threaten consumer confidence.

A revision of recall authority is very much overdue, and my amendment would provide that. I hope that this issue will be seriously considered in the broader package of food safety reform.

The second area I would like to raise is the lack of resources for the FDA's food safety efforts.

One of the most significant aspects of the pet food recall and other food contaminations we have observed in recent years is that the FDA is struggling with its increasing responsibilities and its current level of resources.

If we look at the increasing volume of food that the United States imports each year, it is clear why this is a problem. In 2003, the United States imported $45.6 billion of agricultural products. Today, that number is $64 billion. Agricultural imports from China alone have nearly doubled from $1.2 billion to $2.1 billion.

Much of the responsibility for overseeing and inspecting the safety of these imports rests with the FDA. However, due to fairly flat budgets, the overall number of inspectors looking at these shipments and at domestic food processors actually has decreased from 2003 to the present from a level of more than 3,000 inspectors to about 2,700 inspectors today.

Less than 1.5 percent of these imports are inspected by the FDA, and the FDA lacks the resources and authorities to certify the standards of our trading partners.

This situation presents an economic, public health, and bioterrorism risk to the United States. The CDC estimates that 76 million Americans become sick from food borne illnesses each year. More than 300,000 are hospitalized and 5,000 die each year.

We clearly need to review the FDA's funding to ensure it has the resources necessary to safeguard the 80 percent of our food supply that it is responsible for regulating.

The FDA office that is responsible for food imports, the Center for Food Safety and Nutrition, is also responsible for regulating $417 billion of domestic food and $59 billion of cosmetics. This includes points of entry into the United States, approximately 300,000 food establishments, and 3,500 cosmetic firms. President Bush has requested only $467 million for fiscal year 2008 for this department to regulate all of this activity, and only $312 million of that amount would be for inspectors.

Therefore, I am pursuing two tracks in this area. Last week, I sent a letter to Chairman KOHL and Senator BENNETT of the Agriculture Appropriations Subcommittee, which funds the FDA, asking for a significant increase in the level of funding for the FDA Foods Program. I hope my colleagues will join me in this effort.

Secondly, the amendment I have filed to this bill would direct the Secretary of Health and Human Services to study the feasibility of a user fee program for foods that would incorporate lessons learned from the prescription drug user fee program. This study would present various options on creating a user fee program for foods that could increase the resources and capabilities of the FDA in this area. Specifically, it calls for legislative recommendations that analyze the expected revenues for the FDA, as well as the costs to industry by sector.

For the sake of improving food safety, I think it is vital that we explore the various options for providing the FDA with adequate resources.

Again, I will not offer this amendment at this time, but I hope my colleagues will join me in supporting such a study in the future as Congress deals with broad food safety reform.

Mr. HATCH. Mr. President, a number of questions have been raised about how the Durbin amendment on food safety, adopted yesterday by a unanimous vote, would affect regulation of dietary supplements.

I wanted to take this opportunity to clarify the record.

First, let me indicate my support for the efforts of the Senator from Illinois, Mr. DURBIN. The recent misfortunes

with peanut butter, spinach, and pet food show me that our Nation's food safety policies are pitifully lacking. Therefore, I am supportive of Senator DURBIN's work and also the considerable work of Senator ENZI and his staff to resolve problems that were found with the draft amendment.

For the edification of my colleagues, section 201ff of the Federal Food, Drug and Cosmetic Act, FFDCA, contains the definition of dietary supplements. That definition includes a proviso that supplements are to be considered foods, except in the instance when a product makes a drug claim. In other words, by Federal law, dietary supplements are generally considered to be foods.

It is for this reason that the language of the original Durbin amendment establishing a new adulterated food registry could have been read to apply to dietary supplements.

This raised problems for me, and indeed for our colleague Senator HARKIN, since we had spent more than 2 years working with Senators DURBIN, KENNEDY, and ENZI to draft, pass and enact the Dietary Supplement and Nonprescription Drug Consumer Protection Act, Public Law 109–462. That law authorizes a new program so that reports of serious adverse events related to the use of a dietary supplement or over-the-counter drug would be reported to the Food and Drug Administration, FDA, on a priority basis.

As I said, the Durbin amendment contemplates a new adulterated food registry. Under the provisions establishing that registry, reports of adulterated foods would be made by many, if not all, of the same parties who are required to file reports of serious adverse events associated with the use of dietary supplements under Public Law 109–462. And so passage of the Durbin amendment could be seen to supersede the law we enacted last year for supplements, which I am relieved to hear was not the intent of our colleague, Senator DURBIN.

Consequently, the amendment we adopted yesterday contains language that Senator HARKIN and I suggested to make certain that dietary supplements would not be covered by the new food safety language and thus last year's law would not be superseded. To reassure those who are interested in the Dietary Supplement Health and Education Act, DSHEA, I wanted to take a moment to outline those changes.

First, there is new language in the section establishing the adulterated food registry to express the sense of the Senate that: (1) DSHEA has established the legal framework to ensure that dietary supplements are safe and properly labeled foods; (2) the Dietary Supplement and Nonprescription Drug Consumer Protection Act has established a mandatory reporting system of serious adverse events for nonprescription drugs and dietary supplements sold and consumed in the United States; and (3) the adverse events reporting system under that act will serve as the early warning system for any potential public health issues associated with the use of these food products.

In addition, language contained in the Durbin amendment modifies the definition of supplement contained in 201ff of the FFDCA so that supplements will not be considered foods for the purpose of the new adulterated foods registry. This in no way would alter the time-honored conclusion of the Congress that supplements are to be considered foods. On the contrary, all it would do is exempt supplements from the registry.

These changes, all contained in the amendment which was approved yesterday, make clear that there are no new dietary supplement requirements in the Food and Drug Administration Revitalization Act. It is my hope this will reassure the many who have expressed concern that Congress was inadvertently repealing Public Law 109–462.

Mr. KOHL. Mr. President, I rise to make a correction to the record. Earlier today, I erroneously named Senator LEAHY as a cosponsor of my amendment No. 991. Senator LEAHY is not a cosponsor of this amendment.

I thank the chair.

MORNING BUSINESS

Mr. REID. Mr. President, I ask unanimous consent that there now be a period for the transaction of morning business, with Senators allowed to speak therein for a period of up to 10 minutes each.

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

THE SYMBOLC TRANSFER OF THE HISTORIC WALDSEEMÜLLER MAP

Mrs. FEINSTEIN. Mr. President, as chairman of the Joint Committee on the Library, I want to take this opportunity to recognize the symbolic handover of the historic 1507 Martin Waldseemiller Map from German Chancellor Angela Merkel to the American people. This event took place Monday at the Library of Congress.

The map is often referred to as ''America's birth certificate.'' It was designed and printed by Martin Waldseemiller, a 16th century scholar and cartographer who worked in France. This mapmaker departed from accepted knowledge of the world at that time. He portrayed, in remarkably accurate fashion, the Western Hemisphere separating two huge and separate bodies of water, the Atlantic and Pacific Oceans.

There were 1,000 copies of the map printed from woodcuts, but only a single surviving copy exists today. The Library of Congress worked for decades to acquire this map from its owners. The map was housed for more than 350 years in the 16th century castle belonging to the family of Prince Johannes Waldburg-Wolfegg in southern Germany. The map was long thought lost, but it was rediscovered in storage in the castle in 1901.

In 1992, knowing of the Library's great interest in acquiring the map, Prince Waldburg-Wolfegg notified the Library that the German national government and the Baden-Württemberg state government had granted an export license. This license permitted the map, which is considered a German national treasure, to come to the Library of Congress.

The purchase of the map was accomplished through a combination of appropriated funds and matching private funds. Congress has played an important role in making this acquisition possible, as it has throughout the Library's history. Congress's first major purchase was Thomas Jefferson's library, which is the seed of the vast collections the Library holds today. Another once-in-a-lifetime purchase made possible by congressional support is the Gutenberg Bible, which is on display in the Jefferson Building.

The Library will begin displaying the map to the public in the Thomas Jefferson Building later this year. The map will be part of the Library's new visitor's experience. As an important acquisition to the Library's treasures, the map will be on view for limited periods of time as preservation standards permit.

AMERICA COMPETES ACT

Mr. DOMENICI. Mr. President, I would like to speak for a brief moment about recent Senate approval of the America COMPETES Act.

This legislation is the product of several years of work by many individuals here in the Senate and it was immensely gratifying to see this bill pass the Senate. For the last 3 years Senators from numerous committees, Republicans and Democrats, have worked together on this legislation. They saw America falling behind the rest of the world in math and science and realized the need to do something. Well I believe this bill is going to do that something. It will double spending on physical science research, provide money to recruit 10,000 new math and science teachers and retrain hundreds of thousands of our existing ones. This bill is a huge step in the right direction for our country, a step that could not have been taken by just one Senator or one party. In these often partisan times, the America COMPETES Act is a fine example of what this body can accomplish when it works together in a bipartisan manner.

I am very proud of the work my colleague from New Mexico Senator BINGAMAN, Senator ALEXANDER and I put into this legislation. I am proud that the members of our committee, Energy and Natural Resources, continue to work in this bipartisan way.

Additionally, I ask unanimous consent that two articles concerning the America COMPETES Act, one from the