

up implementing it. That is not what the people in Minnesota are asking. That is not what people in the country are asking.

Mr. REID. Mr. President, will my friend yield?

Mr. WELLSTONE. Yes.

Mr. REID. Mr. President, I ask unanimous consent that the time until 2:30 today be for debate on the pending amendments, with the time equally divided and controlled between Senators DORGAN and GREGG or their designees; that no intervening amendment be in order prior to the disposition of amendment No. 4300; that a vote on or in relation to amendment No. 4300 occur at 2:30 this afternoon, without further intervening action or debate; provided further, upon disposition of that amendment, Senator COCHRAN be recognized to offer an amendment on the issue of drug reimportation.

The PRESIDING OFFICER (Mrs. CARNAHAN). Is there objection?

Without objection, it is so ordered.

The PRESIDING OFFICER. Under the previous order, the Senator from Minnesota is recognized.

Mr. WELLSTONE. Madam President, I will take 1 more minute. Other Senators want to speak. Senator STABENOW has been a leader on this legislation for a long time and has been coordinating the effort of all Democrats.

Let me just conclude this way: I know Senators do not want to be seen as opposing an amendment that would enable all of our seniors and all of our citizens to be able to get a reasonable price for prescription drugs. My fear is that we will have an amendment out here with fine-sounding language which will create a huge loophole and will basically kill this amendment by giving any Secretary of Health and Human Services the ability to stop this legislation before it is ever implemented. That is unacceptable. That is unacceptable. We cannot let the pharmaceutical industry kill this bill and kill this amendment.

I believe that people in Minnesota, people in Michigan, and people around the country look at this as simple. I have said it before. I will conclude it this way. I think this is a test case of whether we have a system of democracy for the few or a democracy for the many. If it is a democracy for the many, we will support this provision. If is democracy for a few of the pharmaceutical companies, the devil is in the details. They will be able to create a huge loophole, which will mean this will never be implemented and they will be able to kill it.

I urge all colleagues to support this Dorgan, Wellstone, Stabenow, et al, amendment and to resist any amendment to essentially gut this amendment and stop this piece of legislation from being implemented.

I yield the floor.

APPOINTMENT OF CONFEREES— H.R. 3763

The PRESIDING OFFICER. Under the authority of the order of July 15, the Chair appoints the following conferees on the part of the Senate on H.R. 3763.

The Presiding Officer appointed Mr. SARBANES, Mr. DODD, Mr. JOHNSON, Mr. REED of Rhode Island, Mr. LEAHY, Mr. GRAMM of Texas, Mr. SHELBY, Mr. BENNETT, and Mr. ENZI conferees on the part of the Senate.

GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2001—Continued

The PRESIDING OFFICER. Who yields time?

The Senator from Michigan.

Mrs. STABENOW. I thank the Chair, I yield myself up to 15 minutes under the agreement.

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

Ms. STABENOW. Madam President, this is a very important second-degree amendment that not only will help our seniors be able to lower the prices they pay for prescription drugs, as my colleagues have said. I thank the Senator from Minnesota for his ongoing leadership on this issue and, of course, the Senator from North Dakota for his sponsorship and ongoing leadership and advocacy, as well as my other colleagues who are cosponsoring this amendment.

This not only affects our seniors, this affects everyone. It affects the president of Michigan State University, who called me about his health clinics and his college of medicine looking for ways to be able to lower prices so that he does not have to deal with possibly laying off more staff, which he had to do this year as a result of the dramatic increases in the health care costs at the university.

It addresses the big three automakers, small businesses, families, and everyone who is paying exorbitant prices for prescription drugs.

I want to start by quoting our President, President Bush, when he was a candidate for President. He indicated that he thought this idea was a good idea. He said:

Allowing the new bill that was passed in the Congress made sense to allow for, you know, drugs that were sold overseas to come back and other countries to come back into the United States.

That was what then-candidate George W. Bush and now President Bush said makes sense. It does make sense. It made sense before. The problem before was that there was an amendment added which basically killed our ability to be able to do this. We know that same amendment which is supported by the pharmaceutical industry will be offered later. There will be an attempt to kill it again.

But we are hopeful that our colleagues will join with us in what is a very reasonable proposal that address-

es any legitimate issues regarding safety and health and allow us to open the border to Canada and be able to provide the kind of competition we need to lower prices.

I think it is important also to reiterate that at a September 5, 2001, hearing before the Senate Commerce Committee's Subcommittee on Consumer Affairs, William Hubbard, FDA Senior Associate Commissioner, testified:

I think as a potential patient, were I to be ill and purchase a drug from Canada, I would have a relatively high degree of confidence in Canadian drugs.

We know the Canadian system is similar to ours as it relates to the regulatory and safety system.

We feel very confident that this modest proposal of simply opening the border to Canada—and we know that Canada right now exchanges goods and services with us every single day. We have the largest port of entry in Detroit, MI, which I am proud to represent, with over \$1 billion in goods going across. We trade every day with them.

We believe this proposal will allow one thing to be traded which is desperately needed by our citizens and is not now allowed to go back and forth across that port of entry. It makes sense. This is a reasonable, modest proposal.

Instead of opening all of our borders, some would argue that this does not go far enough; that we should open to Mexico, Europe, or other places around the world. But we are taking a modest step to begin to show that this kind of approach can work.

We want to simply start with Canada with a very modest approach that will allow us to be able to share with our neighbors to the north the ability to bring back to our citizens American-made prescription drugs which are sold in Canada.

I think this is an issue of fairness as well because we are talking about prescription drugs on which we helped to underwrite research. As I have said so many times, \$23.5 billion this year alone was given by the taxpayers of this country. And I support that strongly. I support having that be a higher number. I think basic research into new potential treatments is absolutely critical and is a good investment. But we are making those investments. We are then giving that information to the drug companies, that pick up the information and then proceed to do their own research and development.

We allow tax writeoffs for that research and development, tax credits, and tax reductions. We subsidize them further. We allow up to 20-year patents so they can recover their costs because we know it costs a lot to research and develop new drugs. So we let them be able to recover those costs without competition for their name brand. So we highly subsidize—highly subsidize—this area; the most profitable industry in the world, highly subsidized by American taxpayers.

Then what do we get at the end of that process? The highest prices in the world. One of the reasons is we close the borders to competition. And we are subsidizing heavily all of the research and development of new medications that the Canadians enjoy, that people around the world enjoy, while we in fact pay the highest prices in the world.

I have had an opportunity to take a number of bus trips to Canada; the latest was on June 10 of this year. I will just share with you some of the differences. My colleagues have talked about that as well. But it is shocking to take a mere 5-minute bus trip across a bridge or through a tunnel and see the dramatic differences in prices.

I might add, I am not interested in continuing to put people on buses or in cars to have to go over to Canada to get those lower priced medications. What we want is the ability to bring them back, so that the neighborhood pharmacy can offer these same kinds of prices. That is what this is all about, to bring them back and place them in the local pharmacy.

But it is shocking when we look at the differences. Zoloft is an antidepressant drug. In Michigan, it costs \$220.65 for a monthly supply; in Canada, \$129.05. So it is \$220 versus \$129. That difference can buy food, pay the electric bill, pay the rent, it can be the difference between someone having a quality of life that makes sense and one that involves struggling every day to pay for their medications.

We also know one of the most dramatic differences is tamoxifen, which I have spoken about here before. Tamoxifen is a breast cancer treatment drug. When we went to Canada, we were able to get it for \$15. And back in Michigan it is \$136.50.

If you have breast cancer and you are struggling to pay for your medications to get the treatments you need to deal with all of the other issues in your life as well, the difference between \$15 and \$136 a month is a big deal. That is why this amendment is a big deal. I hope our colleagues will join overwhelmingly in our amendment—which is, in fact, a bipartisan amendment, a tripartisan amendment—to say: Yes, it is time to be fair to Americans.

This is about fairness for Americans. It is about competition. It is about opening the border in a way that maintains safety for our citizens.

I would like to speak to a couple of the arguments that I know we will hear from colleagues who are opposing this amendment and what the drug companies have said.

The drug companies have said that bringing those prescription drugs back from Canada is not safe. For the record, drugs are already frequently imported into this country, but predominantly by the companies themselves, by manufacturers.

I also note that individual consumers now are allowed to bring back up to a 90-day supply. Because of the concerns

that have been raised, they have looked the other way at the FDA and allow people, for personal use, to bring back up to a 90-day supply.

In fact, according to the International Trade Commission, \$14.7 billion in drugs were imported into the United States in the year 2000, and \$2.2 billion in drugs sold in Canada were originally made in the United States.

So it is ironic that the drug makers are saying that drugs cannot safely move between the borders of the two countries. They do already. The issue is price. The issue is who controls them moving back and forth. When the companies want to move them back and forth, they think it is fine. When the pharmacists want to move them back and forth or individuals want to move them back and forth and get a lower price, it is not fine. They are the same medications. It is a question of who controls them.

In fact, in recent years the FDA has allowed thousands of American consumers to import from Canada medications for their personal use every year. The FDA Senior Associate Commissioner, as I said before, indicated that as a consumer he would have a relatively high degree of confidence in drugs purchased from Canada. So these arguments do not make sense. The arguments we will hear about safety do not make sense.

We will hear that safety standards in Canada are more lax than here in the United States. There was a September 2001 report by the nonpartisan Congressional Research Service—which we all use—which confirms that the United States and Canadian systems for drug approval, manufacturing, labeling, and distribution are similarly strong in all respects. Both countries have similar requirements and processing for reviewing and improving pharmaceuticals, including ensuring compliance with good manufacturing practices.

Both countries also maintain “closed drug distribution systems” under which wholesalers and pharmacists are licensed and inspected by Federal and/or local governments. All prescription drugs shipped in Canada must, by law, include the name and address of each company involved along with the chain of distribution.

Let me finally address one of the other myths I am sure we will hear more about today, and that is that somehow our bill will allow Canada to become a conduit for counterfeit or contaminated drugs into the United States.

On the contrary, this bill provides for safe protections, many of which are not in current law. We go beyond current law, which we all know needs to be done now as we look at so many areas of homeland security.

We have gone beyond what is currently in place. If implemented, this bill would have the potential to decrease, more than today, the possibility of allowing counterfeit drugs into the United States.

We would provide there be strict FDA oversight, proof of FDA approval of imported medicines. There must be a paper chain of custody, which is important. Only licensed pharmacists and wholesalers would be able to import medications for resale. They would have to meet requirements for handling as strict as those in place by the manufacturers—equally strict as what the manufacturers do today.

There will be lab testing to screen out counterfeits, registration with Canadian pharmacists and wholesalers by HHS. There will be lab testing to ensure purity, potency, and safety of medications.

We also say that the Secretary of Health and Human Services can immediately suspend this provision, immediately suspend the importation of prescription medicines that appear to be counterfeit or otherwise violate the law.

We have made it very clear that they can immediately suspend “on discovery of a pattern of importation of the prescription drugs or by the importer that it is counterfeit or in violation of any requirement under this section or poses an additional risk to the public health”—they can immediately suspend.

This is a responsible provision. It is a moderate provision. It opens the border to a country that we trade with every day, whose system is similar to ours. It allows actions if in fact anything is found to create a threat to Americans in terms of our health and safety. It allows immediate action and suspension of this new provision.

I believe we have put into place something that is reasonable. It is logical. It is long overdue. I am hopeful that we will have a strong bipartisan vote.

If we want to lower the prices immediately, without much, if any, expenditure of taxpayers’ dollars—if we want to do it immediately—all we have to do is drop the barrier at the border to Canada.

I urge my colleagues to join us.

The PRESIDING OFFICER. The Senator from Michigan.

Mr. LEVIN. Madam President, I yield myself 5 minutes.

The Dorgan amendment before the Senate has enormous potential to make more prescription drugs more affordable for more people. The amendment is particularly important for our seniors, most of whom live on fixed incomes and constantly have to decide whether they can afford to fill those prescriptions.

We have a bizarre situation. We manufacture drugs in America, but they are sold at cheaper prices in other countries. Just a few examples: Brand name drugs cost an average of 31 percent less in the United Kingdom than they do in the United States; 35 percent less in Germany; 38 percent less in Canada; 45 percent less in France; 48 percent less in Italy. The General Accounting Office has studied 121 drugs

and found that on average prescription drugs in the United States are priced 34 percent higher than the exact same products in Canada.

I travel around Michigan, and I listen to the stories of citizens who are trying to pay for expensive prescriptions and wonder why their neighbors in Canada, just a few miles away, are able to buy the exact same drug, manufactured in America, often for half the price.

We conducted a survey this last February of two of the most commonly prescribed prescription drugs. In every case, the prescription in Canada cost significantly less than the same drug in Michigan. For example, we looked at a number of pharmacies on both sides of the border. A 1-month supply of Prilosec, a gastrointestinal drug, costs about \$126 in Michigan but only \$71 in Canada. Similarly, a 1-month supply of Lipitor, a cholesterol-lowering drug, costs \$74 in Michigan but \$41 in Canada.

As a result of these enormous price disparities, we have the spectacle of American citizens, mostly seniors, going into Canada by the busload to buy American-made prescription drugs at a fraction of what they have to pay here. It is absurd. It is unconscionable that we give pharmaceutical manufacturers tax breaks and direct grants to bring new drugs to the market, and then those drugs cost more in America, where they are made, than they do in other countries. We subsidize the drug costs for the rest of the planet, and that has to change.

The Dorgan amendment fixes this problem in two fundamental ways: First, the amendment allows U.S. licensed pharmacists and drug wholesalers to import FDA-approved medications from Canada. Second, the amendment would allow individuals to import prescription drugs from Canada as long as the medicine is for their own personal use, as evidenced by a prescription, and is a 90-day supply or less.

These provisions will allow American citizens, through the appropriate channels, to take advantage of lower prescription drug prices in Canada.

According to a Boston University School of Public Health study, drug reimportation, just from Canada, could have saved consumers \$38 billion in the year 2001, an enormous sum.

In the year 2000, the Senate approved strikingly similar legislation by a strong bipartisan vote of 74 to 21. Unfortunately, a technical amendment blocked implementation of the legislation. Now the Senate can act again to bring lower priced prescription drugs to people who desperately need them. We can act to bring in some competition. We can act to bring in some free trade. American scientific know-how has led to the development of hundreds of lifesaving and life-enhancing prescription drugs.

Some of the newer prescription drugs are modern-day medical miracles which help millions of Americans lead healthy lives well into their golden years.

These drugs won't do any good if people can't afford them. It is that simple and that demanding.

I hope our colleagues will support the Dorgan amendment and allow for the reimportation of prescription drugs.

I yield the floor.

The PRESIDING OFFICER. Who yields time? The Senator from Tennessee.

Mr. FRIST. Madam President, I yield myself 20 minutes to speak in opposition to the amendment.

The PRESIDING OFFICER. From whose time?

Mr. COCHRAN. The time should be charged to that under the control of Senator GREGG. He has asked me, as his designee, to yield.

The PRESIDING OFFICER. The Senator is recognized.

Mr. FRIST. Madam President, I rise to address the issue introduced in the last hour and a half; that is, the issue of reimportation of drugs, especially as it affects the safety of the American people. They have been introduced by the proponents of this legislation as myths. By calling them myths, it is as if in some way we should say they are myths. They are not real, therefore, let's proceed down this path.

I want to give a little bit of historical perspective to these so-called myths and explain to my colleagues why I believe they are not myths but reality. The potential of such reality can result in direct harm as we look at public health and safety.

I look forward to the afternoon because the debate will continue. The debate ultimately will start with cost and buses running back and forth to Canada. Then Senators will say that this idea is appealing and critically important to pass so we can lower the cost of prescription drugs. We are all for lowering prescription drugs costs. Prescription drugs cost too much; they are out of reach today for too many people.

The focus is on cost. It is motivating and a driving force because it is something on which we all agree. Prescription drugs costs too much today—the rate of increase is too much. But to focus on cost without focusing on public health and safety is wrong and irresponsible.

If we look at the legislative history of the consideration of reimportation of drugs and pharmaceutical agents from other parts of the world outside of the borders of the United States to this country, we have a lot to learn. It is a rich history in terms of lessons learned.

I will not focus on the cost issue, but let me just dismiss the cost issue in terms of my comments now by saying there is no evidence that this amendment will guarantee price savings. For seniors, individuals with disabilities, or the American people who are listening today, there is no evidence to indicate this. It is pretty dramatic, holding up two bottles and saying one comes from another country and one from the here.

The assumption is that it will reduce the cost of prescription drugs in the United States, however, that evidence is not there.

What I want to focus on—and I think it is even worse than not being able to make that assurance to the American people—is my concern with health.

From July 1985 to June 1987, nine hearings were held and three investigative reports issued regarding the issue of reimportation of pharmaceuticals. These efforts, over that time, led to the enactment of the Prescription Drug Marketing Act of 1987. That law was specifically designed to protect America's health and safety against the risks of drugs that in some way may have been altered or counterfeit imported medicines.

The act, a product of the debate at that time, found among other things, "a significant volume of pharmaceuticals are being reimported. These goods present a health and safety risk to American consumers because they may become subpotent or adulterated during foreign handling and shipping."

The overall purpose of the Prescription Drug Marketing Act of 1987 was to "to decrease the risk of counterfeit, adulterated, misbranded, subpotent or expired prescription drugs reaching the American public."

In the Committee report which accompanied the Prescription Drug Marketing Act, the Commerce Committee concluded:

Reimported pharmaceuticals threaten the American public health in two ways. First, foreign counterfeits, falsely described as reimported U.S.-produced drugs, have entered the distribution system. Second, proper storage and handling of legitimate pharmaceuticals cannot be guaranteed by U.S. law once the drugs have left the boundaries of the United States.

I mentioned the history because it is incumbent upon us—as we look at this legislation and change, modify, defeat, pass, improve, strengthen this legislation—that we have to address the issues that were so prominently raised at that time. That was from 1985 to 1987. At that time, we did not have nearly as many cost concerns as we do today.

In 2000, as was mentioned on the floor, Congress revisited the issue and passed at that time the Medicine Equity and Drug Safety Act. This act allowed reimportation of prescription drugs if the Secretary of Health and Human Services could guarantee the safety and certify that cost savings would result. Safety and cost savings, again, are two issues that remain current today. We want to bring down the cost of prescription drugs, but we certainly do not want to do it if it is going to hurt the American people.

Since that time, two Secretaries of Health and Human Services—of two administrations—have stated that the Food and Drug Administration cannot guarantee the safety of reimported prescription drugs.

In fact, then-Secretary Shalala called it "impossible . . . to demonstrate that [reimportation] is safe

and cost effective." Let us jump to the next administration.

Secretary Thompson also concluded that reimportation would "pose a greater public health risk than we face today and a loss of confidence by Americans in the safety of our drug supply."

Those were Secretaries of Health and Human Services and their overall approach in reimportation.

Let us now turn to the Commissioners of the FDA. When FDA Deputy Commissioner Lester Crawford was asked to comment on "whether reimportation (from Canada) now raises greater challenges than it did previously"—meaning prior to September 11—and "what is your view as it relates to safety as it relates to drugs for the consuming Americans," Deputy Commissioner Lester Crawford replied, "The problem would be if it becomes apparent to the rest of the world, including the world of terrorists that we are not interdicting shipments of drugs that come from Canada. . . . I think this is a signal to a would-be terrorist that this might be a way to enter the United States. . . . It also would be a signal to a community that it is not as dangerous as terrorists obviously, but to the transshippers and these would-be people in various countries that may not have a regulatory system or may not have a regulatory system for exported drugs. . . .

I think the important issue is that we are in a new world, compared even to 2 years ago, and that it is incumbent upon us to address this whole idea of having drugs produced or imported or reimported from outside our boundaries at the same time we are trying to strengthen our boundaries in terms of what comes into this country. How careful can we be, how assured can we be that a product is not counterfeit, has not been adulterated, or is not the product of somebody who has ill intent against America. At the same time, we are working to make the borders less porous and tightly overseen, we want to make our borders more porous when it comes to chemical and pharmaceutical agents.

Former FDA Commissioner, Dr. Jane Henney, expressed severe reservations regarding the importation of drugs. This is from a different administration than the current one. Dr. Henney said:

The trackability of a drug is more than in question. Where did the bulk product come from? How is it manufactured? You're just putting yourself at increased risk when you don't know all of these things.

Let us go back to another FDA Commissioner. Remember, the FDA Commissioners are those people who we have, as a nation, given the responsibility of overseeing the public's health and safety of food and drugs. Dr. David Kessler, former head of FDA, stated:

In my view, the dangers of allowing reimportation of prescription drugs may be even greater today than they were in 1986. For example, with the rise of Internet pharmacies, the opportunities of illicit distribu-

tion of adulterated and counterfeit products have grown well beyond those available in prior years.

That is David Kessler, former head of FDA. He continues:

Repealing the prohibition on reimportation of drugs would remove one of the principal statutory tools for dealing with this growing issue.

Let us look back to an FDA Commissioner from the Carter administration, Dr. Jere Goyan, who said it best. This is FDA Commissioner Goyan:

I respect the motivation of the Members of Congress who support this legislation. They are reading, as I am, stories about the high prescription drug prices and people which are unable to pay for the drugs they need. But the solution to this problem lies in better insurance coverage for people who need prescription drugs, not in threatening the quality of medicines for us all.

It is important because, again, in our urge to bring down the cost of prescription drugs and restrain that skyrocketing of costs, we do not want to put drugs out of the reach of the American people. We do not want to do that unintentionally.

Given the statements of the FDA Commissioners and the Secretaries of Health and Human Services, we do not want to open the door and increase the risk to the public health.

Last fall the FDA affirmed its concern about the safety of reimported drugs—even those from Canada, and I understand the underlying amendment is focusing on one country—stating they could not even provide safety assurances for those drugs entering the Nation over our northern border. The FDA further noted that reimported drugs "pose considerable risks to consumers because they may be counterfeit, expired, superpotent, subpotent, simply tainted, or mislabeled."

I point this out early in the debate and want to turn to other people and to the other side, who say: Yes, our amendments are written with more safeguards in the pieces of legislation that come forward. I think that needs to be debated. Ultimately, the safety issue is the key issue in addressing this legislation as we shape it and vote for or against it.

I fear that, in spite of the proponents' attempts in the underlying amendment to establish a mechanism to assure safety—and it is fairly elaborate—a lack of success, lack of assurance of having these safety mechanisms, at the end of the day, puts at risk the American people. This is all in the interest of bringing down the cost of prescription drugs, which is something that we agree with, but there are better and more direct mechanisms to deal with that issue of cost.

We see an elaborate set of safety mechanisms that I think are impossible to implement, which wholesalers and pharmacists are not equipped to handle and, more importantly, mechanisms that only ultimately add—and nobody talks about it—to the cost of prescription drugs. Regardless of whether a pharmaceutical is originally

manufactured here in the United States, once a drug leaves this country and crosses borders, I believe it is impossible to ensure that it is properly handled. It is out of our reach and our vision. We can sort of pass the laws and pass regulations, but in truth, we are not going to see it.

It is impossible to guarantee how it is handled, stored, at what temperature it is stored, and whether it is safe for eventual use.

Most people know—we have talked about this in the Chamber of this body—it is very important how drugs are stored, at what temperature, and their potency. In fact, certain drugs that are used in a routine way, if improperly handled, can become lethal if mishandled in being brought back into this country.

Even more hazardous to the health of Americans is counterfeit medicines. I mentioned terrorism, and I do not want to overstate that, but again, we are currently working very hard to fight issues such as bioterrorism. We are working hard to make sure we are able to track and regulate contents of agents that can be used against us. I do not think we should be moving in the direction of opening those borders broadly when I contend it is impossible, or next to impossible, to guarantee their safety.

There is one interesting example. Gentamicin sulfate is a prescription medicine to treat people with resistant infections, abdominal infections, and people who are very ill. Several years ago, FDA reported that this drug resulted in 17 deaths and 202 serious reactions. This drug is a very powerful drug, a very good drug, and one of the best antibiotics out there when used in a targeted, specific way.

Ultimately, it was no surprise to later find that the medicines causing these 17 deaths were being imported from another country. It was not Canada. It happened to be China. Both the current and former leaders of the FDA have made it ultimately clear, really crystal clear, that they will have a tough time establishing mechanisms that are sufficiently elaborate, complex, and detailed enough to ensure pharmaceuticals coming into this country from foreign manufacturers are safe to use.

The underlying amendment purports to address drug safety by only allowing U.S.-approved drugs to be reimported and incorporating a drug testing requirement. Again, it sounds very good, but let me state up-front—and we can debate it as the day goes on—end product testing, after a drug has traveled and handled in certain ways, simply is not adequate. End product testing is not adequate to demonstrate that a drug was manufactured in accordance with U.S.-approved standard and quality requirements.

Also, testing at the moment of import, at the time it actually comes into the country, does not ensure the integrity of the drug throughout its shelf

life once it arrives here. Drugs are fluid agents. They are agents that can be adulterated. They can be changed, and, as I mentioned, their storage is critically important.

I will close mentioning this whole danger of counterfeiting drugs because, again, in this environment post-September 11, it is one we need to look at. We need to address this issue up-front. It is the new environment in which we are working. In that regard, I am hopeful we can address this amendment to make absolutely sure we have safe drugs for the American people. We need to make sure that we have not opened the door at the same time we are putting interest in lowering costs and reducing costs over time, opened the door, opened our borders, or made them more porous in a way that ultimately will hurt the American people.

I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. How much time remains on each side?

The PRESIDING OFFICER. The Senator from North Dakota controls 21 minutes; and the Senator from Mississippi controls 25 minutes.

Mr. DORGAN. Madam President, I yield 8 minutes to the Senator from Massachusetts.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Madam President, I thank the Senator from North Dakota for bringing this matter to the attention of the Senate. I am very hopeful it will be accepted in the Senate in a short time. There are some interesting underlying facts. What we are finding now has been referenced during the course of this debate. The United States and its taxpayers are subsidizing the world in terms of prescription drugs. That happens to be a fact.

The research for brand and generic drugs is basically now conducted in the United States. They have moved dramatically from Europe over the recent years. With the doubling of the NIH budget, much of that is funding basic research which is essential for the development of drugs. So the taxpayer is paying for the funding of the NIH and then paying the additional costs at home. Furthermore, these drugs are a good deal cheaper outside the United States.

We are doing for the rest of the world in the area of prescription drugs what we are doing for our national security. We keep the Straits of Malacca open, the Suez Canal open, and the Panama Canal open. The great choke points of the world are free because of the U.S. Navy and that is the way it is. We wish that it could be better. There are things that could be done and should be done in this area. Nonetheless, that is the case. That is one issue, if we are able to have prices that are reasonable for the American consumer, but we do not have that. One of the principal efforts of what we are discussing in the Senate is taking steps to assure those

families who are in need of prescription drugs that they are going to have access to them.

We have an underlying bill that will make a very important difference. The Dorgan amendment, cosponsored by our Democrat and Republican colleagues, can make an important contribution to that as well, and we will have follow-on amendments.

Rightfully, it has been identified that safety is a key issue. However, we are talking about drugs that are FDA approved and produced in plants that have FDA inspections. Many of the safety issues raised in Secretary Shalala's letter some years ago in criticism of a much broader amendment by the Senator from North Dakota have been addressed in this legislation. The safety issues that have been addressed included the counterfeiting, the proliferation of handling, and a wide range of other issues. They have been addressed in a very serious and responsible way.

We are doing this against a background where we are free, thank goodness, of examples or incidents where there has been contamination of drugs imported from Canada. That has not been true in terms of Mexico and other countries, but it certainly has been true with Canada.

This is a very modest program, but it is an important one. It is a vital program certainly for millions of our citizens who live in or around the northern tier States. It has caught on because of the frustration of our fellow citizens. And it is a legitimate frustration because of the fact that we in the Congress have not taken steps to assure that the generic drugs or that brand-name drugs are going to be sold at a more reasonable cost. It is out of frustration for that.

I do not hear those supporting this proposal saying they are in strong support of the underlying proposal that will make the availability of drugs less expensive for the consumer, or other means as well. It is a question of the cumulative effect. This is targeted to Canada, where we have high regard and respect for their system of handling these ingredients.

I think the issues which have been outlined and detailed expressing reservations about this proposal, certainly with regard to Secretary Shalala, and to a significant extent Secretary Thompson, have been addressed by the Dorgan amendment. This will be a measured but very constructive and important step in assuring that some of our citizens get vitally needed drugs.

As the Senator from North Dakota has pointed out, the fact is that if people are not able to get drugs at all because they cannot afford them, they are willing to take some risks to be able to get them. That is what this is about. We cannot make the excellent the enemy of the good.

The opportunity for getting good quality drugs at reasonable prices will

make a difference, as the Senator has pointed out with his examples of individuals with cancer who otherwise would not be able to afford any of the higher-priced drugs. So with all the inevitable health hazards that they are facing, it is either these drugs or no drugs.

This is a measured step. It is one that is eminently worthwhile. I commend my colleague for offering it, and hopefully it will be accepted.

The PRESIDING OFFICER. Who yields time?

Mr. DORGAN. Madam President, how much time remains?

The PRESIDING OFFICER. The Senator from North Dakota has 14½ minutes.

Mr. DORGAN. Do we know with respect to those who are yielding time to the opponents of this legislation, or at least yielding time on behalf of Senator GREGG, whether they will be using their time at this point?

The PRESIDING OFFICER. The Senator from Mississippi has 25 minutes.

Mr. COCHRAN. Madam President, we are happy to abide by the unanimous consent agreement which calls for a vote at 2:30. We have an indication that there are Senators who want to talk. I will speak on the subject. We already have had remarks by Senator FRIST on this subject.

Mr. DORGAN. Madam President, as the Senator who offered the amendment, I reserve some time to close debate.

I yield 5 minutes to the Senator from Michigan.

The PRESIDING OFFICER. The Senator from Michigan.

Ms. STABENOW. Madam President, I thank my colleague from North Dakota, who has worked so hard on this legislation and has done such a wonderful job of crafting what is a very reasonable and modest approach.

I did want to respond to comments that had been made a little while ago to emphasize again that this is a different proposal than was brought before the Congress before it was passed. It is limited to Canada where we know there is a very similar safety regulatory structure. We are trading back and forth. Our manufacturers of prescription drugs go back and forth across the border all the time. The only difference is they control the prices, as opposed to giving consumers the ability to have lower prices. So this is a different system. This is a system that sets up a number of protections, in fact more protections than we have in current law.

So this is actually strengthening, and given the current times that we are in, that makes sense. It makes sense to limit this to Canada as a way to begin this process and see how it works, and it makes sense to add all the safety provisions that are put in. It also makes sense to allow the Secretary of Health and Human Services to have the power to immediately stop reimportation if, in fact, there is a

problem. If there is a safety problem, if there is a health problem, if there is a concern at all about counterfeit drugs, then the Secretary has the ability, based on the evidence, to be able to stop this process.

So I believe we have built in a number of provisions that are very important, that are very responsible, and I believe this plan should go forward.

My colleague from Tennessee also said that there is no evidence we will see prices lowered or that we will see the lower prices passed on. First, I would absolutely say what we do know. There is great evidence that in fact our seniors—in fact everyone—are going to be paying higher prescription drug prices every year. We do know that. We do know in the last year, the brand name companies raised the prices over three times the rate of inflation. We do know that. We do know there is an explosion in advertising, two and a half times more in advertising, than research. We know there is in fact an explosion in prices going on in this country. We do know that our families are desperate, that our seniors are desperate, and many have drug bills that are higher than their incomes; families struggling to help mom and dad, grandma and grandpa.

We do know our small businesses are struggling to provide health care for themselves and their employees. We do know too many workers find themselves in a situation where their employer says: We have to have a pay freeze in order to be able to afford your health care benefits.

We know that is predominately because of the rising prices of prescription drugs.

So even if one thinks this is not the best proposal in the world, it is better than what is occurring today for American consumers, for American families, American seniors. I am very confident, in talking to pharmacists, community pharmacists, those who are on the front lines around this country, that they would welcome the ability to have a lower cost product brought into their pharmacies so they can offer it to American citizens.

They are on the front lines. They see the senior that walks up, gives the prescription for a 30-day supply of a drug, and then looks at the bill and comes back and says: Can I get one week's supply or I cannot get this at all. Or they take it home and they cut the pills in half. I have known couples who both needed the same heart medicine. They buy one and share it. We all know the stories.

I know that pharmacists in our neighborhood pharmacies are very much in support of efforts to bring in lower priced prescription drugs. One way to do that is by opening the border to Canada.

So I would simply rise to, again, voice strong support and my pleasure at being a cosponsor of this amendment, having worked on this issue for a number of years. I urge my colleagues

to get beyond the scare tactics and to support us in this reasonable, moderate effort to add competition and lower prices for our citizens.

I yield the floor.

The PRESIDING OFFICER. The Senator from Mississippi.

Mr. COCHRAN. Madam President, as the designee of Senator GREGG, I yield myself such time as I may consume.

To refresh the memory of Senators on this subject and the fact that we have had this issue before the Senate on an earlier occasion, 2 years ago during the consideration of the annual appropriations bill for the Department of Agriculture and the Food and Drug Administration and related agencies, the Senator from Vermont, Mr. JEFFORDS, offered a similar amendment to allow drug reimportation. These were prescription drug reimportation rights.

Senator KOHL, who was the ranking Democrat at the time on the appropriations subcommittee, and I, serving as chairman, offered an amendment to that amendment which required a finding by the Secretary of Health and Human Services that the implementation of that amendment would not increase risk to public health and safety and that it would result in a reduction in the cost of products to consumers.

This language was modified slightly in conference with the House. The word "demonstrate" was substituted for the word "certified," but in all other respects the amendment survived conference and was a part of the law.

Subsequent to that, Secretary Shalala, who was serving as the Secretary of Health and Human Services in the Clinton administration, wrote a letter to President Clinton describing her views about whether the Department could demonstrate, as required by the law, that the reimportation rights would not cause any failure of safety standards and that it would reduce the costs of prescription drugs to those who reimported them.

Her letter suggested that she could not make such a demonstration; she could not meet the requirements of the law and certify that.

Then at some point Senator KOHL became chairman of the subcommittee, and we thought we would be confronted in the next Congress with the same amendment. So we had a meeting in his office with FDA officials, Department of HHS officials, and others, to discuss the views of the administration on this subject. We had a new administration come to town. Secretary Thompson was in the meeting.

I was impressed and surprised at how much counterfeiting of drugs goes on; that countries manufacture and label and package drugs all over the world to look exactly like the drugs, some of which are off-the-shelf medications in our drugstores throughout our country; others are prescription drugs you can buy only if you have a prescription from a physician. They showed us parcel after parcel, illustration after illustration, of how much of this is going on

around the world. They cautioned we should be very careful about accepting any language that would make it easier for the counterfeiters and for those who would want to do harm and bring such drugs into the country because there is no guarantee of their safety or efficacy, or that the strength stated on the package is really what is on the inside.

By looking at the drugs or the medical devices, one could not tell the difference. I could not tell the difference. No one could tell the difference to decide whether this was safe or without a chemical analysis.

The point of the story was, we were prepared to insist upon the same language in the appropriations bill that we had gotten the Senate to approve unanimously the year before, 96 to 0. They voted on the language that would make sure we would not be doing anything that would affect safety and that we really would be doing something to help reduce the cost of prescription drugs to America. But no amendment was offered.

I say that now by way of background and also to suggest to the Senate, after we vote on the Dorgan amendment, which says if you are going to permit reimportation and you find there is counterfeiting going on, you can suspend it. That is what this amendment says. OK, that is harmless enough. Let's approve that when we vote at 2:30 on a regular vote. We agreed to accept this amendment by voice vote, but there will be a recorded vote. I will vote for it. Sure, they ought to be able to suspend reimportation if they find it to be counterfeit. But guess what. There is counterfeiting and they will find it. It is no big secret.

This amendment is meaningless. What we will need to do after we adopt the Dorgan amendment at 2:30, under the agreement I will offer the same amendment. We will say that the Secretary of Health and Human Services must be able to certify that this will not adversely affect safety or be a threat to U.S. consumers, and it will result in cost savings. I want the Senator to know we will have an opportunity at that time to consider another amendment to this proposal which I hope the Senate will also adopt, as it has in the past, by unanimous vote.

I yield to the distinguished Senator from Utah.

Mr. HATCH. I thank my colleague.

Almost 2 years ago today, we visited the issue of whether to allow importation of prescription drugs from other countries. The Senate has before it today The Prescription Drug Price Parity for Americans Act, designed to permit the commercial importation of prescription drugs from Canada and to permit personal importation of prescription drugs from any country.

S. 2244 is intended to modify the Medicine Equity and Drug Safety Act of 2000, MEDSA, attempts both to address the safety concerns voiced by FDA, DEA, U.S. Customs, Secretary of HHS,

and others and also expand the personal importation exemption contained in current law.

As I will explain, reimportation was not a good idea then, and it is an absolutely terrible idea today, especially after 9/11.

The high cost of pharmaceuticals is indeed one of the most difficult matters facing our society today. We face a harsh reality: At a time when scientists are able to offer an unbelievable new array of medication, diagnostics, and vaccines, many Americans are encountering difficulties in affording these state-of-the-art and often cost therapeutics.

We have all heard stories of Americans going across the borders to Mexico and Canada to purchase cheaper drugs. This type of activity is also increasing over the Internet.

It may appear that the solution is simply to allow the importation of prescription drugs into our country. While I do not question the good intentions of those who believe this is the correct solution, we all must be aware of the disturbing, lasting unintended and negative consequences this proposal would have.

It is not possible to assure safety of reimported pharmaceuticals 2 years ago. Sadly, it is even more difficult to do so today.

We are facing an unprecedented time in history. I need not point out to my colleagues the challenges this country is already facing in our war on terrorism. Allowing drug reimportation is only going to further threaten our safety and inundate our law enforcement and regulatory agencies.

As always, there are many issues at play in this debate. But, the number one fundamental issue at stake here is the safety of the American people.

Assuring the American public that these imported drugs are safe and effective and unadulterated is next to impossible, especially now, in the midst of a war on terror. I worry that a day will come when either an under-potent or over-potent or adulterated, either intentionally or unintentionally, batch of imported drugs will cause injury and even death.

Yes, we can have certifications and regulations and foreign inspections and every other policing mechanism you can think of, but the fact remains we cannot police everyone around the world.

With this bill, we are opening a door that Congress prudently closed in 1988 when it enacted the Prescription Drug Marketing Act.

Let me give you a little background regarding the history of drug importation law.

During the 1980s, the House Energy and Commerce Committee conducted a lengthy investigation into the foreign drug market that ultimately led to enactment of the Prescription Drug Marketing Act legislation—PDMA.

This bill was enacted after our nation experienced a series of serious adverse

events due to improperly stored, handled, and transported imported drugs. There were serious threats to public health and safety. That investigation discovered, among other things, that permitting reimportation of American drugs “prevents effective control or even routine knowledge of the true sources of merchandise in a significant number of cases.” As a result, the House Committee found that “pharmaceuticals which have been mislabeled, misbranded, improperly stored or shipped, have exceeded their expiration dates, or are bald counterfeits, are injected into the national distribution system for ultimate sale to consumers”. It was determined that we could not prevent the introduction of substandard, ineffective, or even counterfeit pharmaceuticals.

The PDMA was necessary to eliminate health and safety problems before serious injury to consumers could occur. The Committee report was clear on why the PDMA was needed:

“[R]eimported pharmaceuticals threaten the public health in two ways. First, foreign counterfeits, falsely described as reimported U.S. produced drugs, have entered the distribution system. Second, proper storage and handling of legitimate pharmaceuticals cannot be guaranteed by U.S. law once the drugs have left the boundaries of the United States.”

Now we place a high premium on our citizens receiving safe and effective products, free from adulteration and misbranding. The Dorgan bill, could unravel the protection that the PDMA provides us.

Dating from the 1906 Pure Food and Drugs Act, through the 1938 Federal Food, Drug and Cosmetic Act, the 1962 efficacy amendments written by the Senate Judiciary committee, and the 1988 Prescription Drug Marketing Act, our Nation has devised a regulatory system that painstakingly ensures drug products will be carefully controlled and monitored all the way from the manufacturer to the patient's bedside.

Under the current Federal Food, Drug, and Cosmetic Act, FDCA, it is unlawful for anyone to introduce into interstate commerce a new drug that is not covered by an approved New Drug Application, NDA, or Abbreviated New Drug Application, ANDA. When a product is introduced into interstate commerce that does not comply with an approved application, it is considered an unapproved new drug in violation of section 505 of the FDCA. It is also misbranded under section 502. These basic rules cover importations, since importing is a form of introducing a drug into interstate commerce. Under FDCA, a drug that is manufactured in the US pursuant to an approved NDA and shipped to another country may not be reimported into the US by anyone other than the original manufacturer.

The provision restricting the right to reimport US drugs to the original manufacturer was designed to ensure that

only the party that can truly vouch for the purity of the drug is allowed to bring that medicine back into the country. The prohibition on reimportation of products previously manufactured in the US and exported abroad was added to the law in 1988 to guard against the entry of counterfeit and adulterated products into this country.

On the issue of importing drugs for personal use, FDA has had a “personal importation” policy since the mid 1980s, which permits the importation of an unapproved new drug for personal use, meaning the individual may import no more than a 90 day supply, in certain situations.

It was intended solely to allow unapproved medications into the US for compassionate use. But over the years, there has been a tremendous increase in volume and FDA has recently taken the position that the personal importation policy has outgrown its usefulness and now presents a threat to public health.

In a letter to Congress, FDA reported that the personal importation policy “is difficult to implement . . . due in part to the enormous volume of drugs being imported for personal use and the difficulty faced by FDA inspectors, or even health practitioners, in identifying a medicine by its appearance”. FDA lacks the ability to adequately monitor the enormous volume of mail-order pharmaceuticals.

The FDA has therefore proposed to the Department of Health and Human Services that it eliminate its personal use policy for mail imports. The Dorgan bill proposes to expand personal importation at a time when the FDA is telling us that it can't handle this and wants us to stop this policy.

In 2002, Medicine Equity and Drug Safety Act—MEDSA—included a provision that allowed an importer or wholesaler—in addition to the original manufacturer—to reimport US-manufactured drugs into the United States. But this provision would become effective only if the Secretary of HHS demonstrated to Congress that its implementation would impose no additional risk to the public's health and safety and that it would result in a significant reduction to the cost of covered products to the American consumer.

In December 2000, HHS Secretary Donna Shalala said she could not make this determination, citing flaws in the legislation that could “undermine the potential for cost savings associate with” prescription drug reimportation and that prescription drug reimportation “could pose unnecessary public health risks”.

In July 2001, HHS Secretary Tommy Thompson also declined to make this demonstration on the premise that the safety of prescription drugs could not be adequately guaranteed if reimportation were permitted under its provisions.

So we have certifications by the top health officials of both the Clinton and

Bush administrations that reimportation is inherently unsafe. Are we willing to say, that it is safer today to import drugs by mail and other avenues and that we can do a better job ensuring the safety of these imported drugs? Especially after the tragic events we have been through?

The Dorgan bill, S. 2244, is a modified version of MEDSA. A review of S. 2244 will show that the new language is not significantly different from the MEDSA provisions that Secretary Shalala and Secretary Thompson rejected. Senator DORGAN, the sponsor of the bill, has stated that it is very similar to MEDSA.

Although the modifications in S. 2244 are intended to address original concerns inherent in MEDSA, they fall short of providing these safeguards—safeguards which are nearly impossible to implement. The new bill suffers from the same flaws as did MEDSA.

For example, S. 2244 is limited ostensibly to drugs imported from Canada. In fact, however, a drug could be imported from anywhere in the world under this bill, as long as it entered the U.S. through Canada.

There is no effective way under this bill to prevent the transshipment of drugs—legitimate or not—from other countries into Canada and then into the U.S. This would permit the entry of drugs that have been manufactured, stored, shipped, and handled anywhere in the world—in unsanitary conditions, unregulated conditions—and drugs that have become adulterated and even toxic.

At a September 2001 hearing before the Senate Consumer Affairs, Foreign Commerce, and Tourism Subcommittee, FDA's Senior Associate Commissioner for Policy, Planning, and Legislation, Bill Hubbard, warned of this very risk. Mr. Hubbard stated, "Even if the Canadian system is every bit as good as ours, and I don't know whether it is or not . . . the Canadian system is open to vulnerabilities by people who will try to enter the U.S. market again because that's where the money is."

To give another example, S. 2244 differs from MEDSA insofar as it would require manufacturers to allow importers to use their FDA-approved U.S. labeling free of charge. This could lead to an influx of misbranded products into the U.S., as importers paste FDA-approved labeling onto products from other parts of the world.

These drugs would be seen as an FDA-approved product manufactured and sold by a U.S. manufacturer—but could easily be a different product—a drug that could have deteriorated, or been contained, subpotent, or toxic. The products would be indistinguishable to a consumer in a local pharmacy, to a health professional, and even to the FDA. Consumers would be deceived by this practice, thinking the U.S. manufacturer had vouched for the purity, safety, and effectiveness of the product when in fact the manufacturer could not and had not.

Our top health care financing official has concerns as well. In March 2002, the Administrator of the Centers for Medicare and Medicaid Services—CMS—told the Senate Finance Committee that CMS opposes the reimportation of prescription drugs into the U.S. "We have opposed it," he stated. "There is no way for FDA to monitor and regulate drugs coming in from Canada, Mexico, or other countries."

The Dorgan bill also permits a significantly lower standard for personally imported drugs than applies to domestic drugs. The Dorgan bill could also open up a loophole in the FDCA for unscrupulous commercial importers. It permits FDA to issue regulations permitting individuals to reimport prescriptions not only in their personal luggage but also through the mail or other delivery services.

We all know there is no way for FDA to limit mail order shipments to personal use. A commercial importer could simply divide its shipments into 90-day quantities and mail them separately, taking advantage of the personal use policy to introduce counterfeit products into the stream of U.S. commerce. This would overwhelm the ability of FDA and Customs to process the millions of incoming packages. Many of the criticisms of MEDSA—voiced by FDA, DEA, and others—apply equally to the new Dorgan Bill.

Many senior officials in various agencies, including FDA, U.S. Customs Service, the DEA, the Secretary of HHS warned of the difficulty in ensuring the purity and safety of reimported drugs.

Let's hear again what the experts have to say about reimportation.

William Hubbard, FDA Senior Associate Commissioner for Policy, Planning and Legislation, June 7, 2001:

We are very concerned that a system, if designed to be a different system than the current system, poses risks and we cannot be assured that we could successfully implement such a system and bring in safe drugs because we do not have the same level of confidence about where it was manufactured, and how it was manufactured, and by whom it was manufactured, that we have under the current system.

Elizabeth Durant, Executive Director, Trade Programs, U.S. Customs Service, June 7, 2001:

You can see the kinds of drugs that come through the mail. They are not even in bottles many times, just loose in paper. We have counterfeit drugs. We have gray-market drugs. We have prohibited drugs and we have unapproved drugs. And this is a situation that is pretty much replicated around the country.

We live in a very different world now after 9/11—a more dangerous, less certain world. We must question the safety of reimportation of prescription drugs even more than ever.

As Secretary Thompson cautioned on June 9, 2002:

Opening our borders to reimported drugs potentially could increase the flow of counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired and contaminated

drugs, and drugs stored under inappropriate and unsafe conditions. In light of the anthrax attacks of last fall, that's a risk we simply cannot take.

That's the Secretary of Health and Human Services warning us.

Here's another quote from William Hubbard, FDA Senior Associate Commissioner for Policy, Planning and Legislation, July 9, 2002:

The cheaper drugs are there. We just have no way to say to a given consumer, "You have gotten a product that will help—will save your life," and we fear that many people will get a bad product that will hurt them.

We invest lots of money and resources in the United States to ensure that medications and other therapeutics are made and distributed at the highest quality and standards. Our agencies, while not perfect, have a remarkable record of protecting the public from contaminated, ineffective, and unsafe drugs.

We cannot guarantee an acceptable level of quality and safety with reimported drugs. We can't sacrifice quality and safety in the hopes of getting cheaper medications. What's the use of cheap drugs if they can potentially do a great deal of harm and threaten the public's safety?

Reestablishing a system where wholesalers and pharmacists may import prescription pharmaceuticals through Canada to the U.S. would recreate the public health risk of counterfeit, unsafe, and adulterated drugs that Congress sought to eliminate in the late 1980s with the Prescription Drug Marketing Act.

Even if we put aside these very real safety concerns, the idea that the Dorgan bill can achieve the goal of bringing cheaper drug products to US consumers is unlikely.

This bill requires drug manufacturers to disseminate their drug formulations to potentially thousands of pharmacies and wholesalers. This information, currently protected under patent laws, could be worth millions of dollars per drug, on the black market. Unscrupulous individuals could obtain drug formulations and learn how to make their fake drugs look real and survive chemical analysis.

Allowing individuals to pirate the hard work and innovation of American drug companies to produce so called "gray market" products, counterfeit products, is no way to ensure that Americans have access to the latest pharmaceuticals in the long-run because they simply will not exist if we do not protect the work of our private sector companies.

While there is a clear and obvious health danger in a contaminated, pirated product, there is also great detriment to the American public if the unscrupulous are allowed to reimport America's inventions back into America without compensating the inventor. Few will be willing to invest the up-front capital—hundreds of millions of dollars—to develop a drug if another

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

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

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

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

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

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

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

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

We would also incur far more costs policing this endeavor. The cost of im-

plementing the Dorgan bill would require very substantial resources at a time when we are stretching our funding to HHS and other federal departments to prevent future terrorist incidents.

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

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

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

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

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

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

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

UNANIMOUS-CONSENT AGREEMENT

Mr. REID. Mr. President, I ask unanimous consent that at a time to be determined by the majority leader, following consultation with the Republican leader, the Senate may proceed to the consideration of Calendar No. 486, H.R. 5011, the Military Construction Appropriations bill; and that it be considered under the following limitations; that immediately after the bill is reported all after the enacting clause be stricken and the text of Calendar No. 479, S. 2709, the Senate committee-reported bill be inserted in lieu thereof; that debate time on the bill and substitute amendment be limited to a total of 45 minutes; with an additional 20 minutes under the control of Senator MCCAIN; that the only other amendment in order be an amendment offered by Senators FEINSTEIN-HUTCHISON, which is at the desk; with debate limited to 10 minutes on the Feinstein-Hutchison amendment; that upon the use or yielding back of time on the amendment, without further intervening action or debate, the Senate proceed to vote on adoption of the amendment; that all debate time, not

already identified in this agreement, be equally divided and controlled between the chair and ranking member of the subcommittee or their designee; that upon disposition of the Feinstein-Hutchison amendment, and the use or yielding back of all time, the substitute amendment, as amended, be agreed to; the bill, as amended, be read three times, that Section 303 of the Congressional Budget Act be considered waived; and the Senate then vote on passage of the bill; that upon passage of the bill; the Senate insist on its amendment, request a conference with the House on the disagreeing votes of the two Houses; and that the chair be authorized to appoint conferees on the part of the Senate, without further intervening action or debate.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2001—Continued

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

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

The PRESIDING OFFICER. The Senator from Louisiana is recognized.

Mr. BREAU. Thank you very much.

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

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

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

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