

The objective of these al-Qaida attacks is to reignite the sectarian violence in Baghdad and breaking support for the war here at home. That was the goal of al-Zarqawi, whom we were fortunate to be able to take out of the fight, and that is the fight now of the remaining al-Qaida extremists in Iraq. General Petraeus explained it this way:

Iraq is, in fact, the central front of al-Qaida's global campaign.

It just boggles my mind, Mr. President, for some of us to stand here on the floor and say we ought to withdraw our troops from Iraq when, in fact, al-Qaida—the enemy that hit innocent Americans and killed 3,000 of them on September 11, 2001—considers Iraq to be the central front in their campaign against the West. Al-Qaida's role makes the conflict in Iraq far more complex than a simple fight between Iraqis. Many also belong to the same terrorist network, as I said, that attacked us on September 11, 2001. Were we to leave prematurely, were we to leave a power vacuum in Iraq, al-Qaida would no doubt, as they did in Afghanistan earlier, use that power vacuum as an opportunity to regroup, to plan, to train, to recruit, and then to export additional terrorist attacks against the United States here on this continent.

We need to give our troops all of the equipment and training and protection they need to prevail. Without a war funding bill, the military has to take money from some other account—notably, the Air Force or Navy—just in order to make sure the Army has the resources they need, so the troops can have the equipment they need, so they can rotate back on a timely basis and come home to the loving arms of their families, to repair existing equipment. And worst of all, in one sense, failing to send this money on a timely basis to the military hurts the military families who are waiting behind, anxious, as we all understand, for the welfare and safety of their loved ones. Our troops and their families deserve better.

So I hope that after the last 86 days, which have been characterized by political theater and gamesmanship, where some have been more focused on the 2008 election and trying to find ways to gain political advantage, I hope Republicans and Democrats, the legislative branch and executive branch, can come together and do what we should have done months ago—get the funds to the troops as soon as possible, without the surrender deadline, without tying the hands of our military commanders and making their opportunity for success impossible, and without the porkbarrel spending that demeans the noble sacrifice of these brave men and women.

Mr. President, I yield the floor and yield back our remaining time.

I suggest the absence of a quorum.

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

The assistant legislative clerk proceeded to call the roll.

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

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

Mr. KENNEDY. Mr. President, we yield back all morning business time.

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

The PRESIDING OFFICER. Under the previous order, the Senate will resume consideration of S. 1082, which the clerk will report.

The assistant legislative 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.

AMENDMENT NO. 1010 TO AMENDMENT NO. 990

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

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

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Mississippi [Mr. COCHRAN], for himself, Mr. CARPER, Mr. NELSON of Nebraska, Mr. HATCH, Mr. BENNETT, Mr. ENZI, Mr. BURR, and Mr. MENENDEZ, proposes an amendment numbered 1010 to amendment 990.

At the end of the amendment, add the following:

SEC. ____ PROTECTION OF HEALTH AND SAFETY.

This title, and the amendments made by this title, shall become effective only if the Secretary of Health and Human Services certifies to Congress that the implementation of this title (and amendments) will—

(1) pose no additional risk to the public's health and safety; and

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

The PRESIDING OFFICER. The Senator from Mississippi.

Mr. COCHRAN. Mr. President, I am offering this amendment for myself, as well as for these cosponsors: Mr. CARPER, Mr. NELSON of Nebraska, Mr. HATCH, Mr. BENNETT, Mr. ENZI, Mr. BURR, and Mr. MENENDEZ. This is an amendment to the amendment proposed by Mr. DORGAN.

Improving the health and quality of life for Americans is very important to all of us, and access to safe and effective prescription drugs is a major step

in accomplishing these goals. With recent scientific advances, a number of medical therapies have been made available to treat and, in some cases, to cure diseases. We want Americans to continue to have access to safe and effective drugs that are approved by the Food and Drug Administration.

But we must not create opportunities for potentially dangerous drug products from foreign countries to reach the American consumer. For example, counterfeit products, those that have been tampered with or those of unknown origin, should not be brought into this country. I am concerned that allowing the importation of prescription drugs would allow such risks to become more likely.

The amendment proposed by the Senator from North Dakota will put in jeopardy the process we now have to ensure the safety of prescription medications and protect the health of the American people.

I am offering this second-degree amendment to require the Secretary of Health and Human Services to certify that the importation of drug products will not pose additional risks to Americans and will, indeed, lower costs to consumers.

If, as some argue, a policy of importation is safe and will reduce costs, this amendment should not be a problem.

We have debated this issue before on several previous occasions. For example, during the consideration of annual appropriations bills for the Department of Agriculture, the Food and Drug Administration, and related agencies, when considering the Greater Access to Pharmaceuticals Act, and even during the debate and passage of the Medicare Modernization Act of 2003, a similar amendment to require the safety of imported drugs was considered and unanimously approved each time.

In all these instances, the Senate has adopted this amendment by a unanimous vote. The safety of the American consumer must be our No. 1 priority. These safeguards should also be applied to this proposal.

We should be certain that any change we make in the law does not result in less protection in terms of the safety of the drugs supplied to the American people and will, indeed, make prescription drugs more affordable. Liberalization of protections that are designed to keep unsafe drugs out of this country, especially considering the terrorist threats we face now, should occur only if the necessary safeguards are in place. This amendment will ensure that the concerns of the last two administrations regarding safety and cost-effectiveness are addressed prior to the implementation of this proposal.

Counterfeiting of drugs has become a more common practice throughout the world, and the transshipment of these counterfeit products through Canada is one of the most serious dangers we face. The Canadian Government itself has said that drug products shipped to

Canada for resale in other countries do not fall under the Canadian regulatory system, and they can provide no assurance as to the safety or authenticity of such drugs.

In fact, President Bush yesterday released a Statement of Administration Policy strongly opposing any provision that allows the importation of drug products outside the current safety system of the Food and Drug Administration. The statement declares that the President's senior advisers would recommend that he veto the bill if this provision is included.

Mr. President, I ask unanimous consent that a copy of the Statement of Administration Policy be printed in the RECORD.

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 2,000 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. COCHRAN. Mr. President, these conditions contained in this amendment are the same as those the Senate has previously adopted on other occasions on other bills. I urge the Senate to again support this language and approve this amendment.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I thank the Senator from Mississippi for his cooperation. For the information of our colleagues, if we get cloture on the Dorgan amendment tomorrow, sometime prior to the expiration of the 30 hours, we will vote on the Cochran amendment. That is a notice for Members about when we will address this issue. I thank the Senator.

The Senator from Colorado raised important issues during the markup, and he has a very significant amendment to offer to the Senate. I hope we will hear from him at this time.

The PRESIDING OFFICER. The Senator from Colorado.

AMENDMENT NO. 982

Mr. ALLARD. Mr. President, I ask unanimous consent to lay aside the pending amendment, and I call up amendment No. 982.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Colorado [Mr. ALLARD] proposes an amendment numbered 982.

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

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

The amendment is as follows:

(Purpose: To strike provisions related to market exclusivity)

Strike subparagraphs (D) and (E) of section 402(a)(6).

Mr. ALLARD. Mr. President, first, I thank the chairman, Senator KENNEDY, and the ranking Republican, Senator ENZI, for the bipartisan way in which they have worked in the committee, of which I am a new member. It is the HELP Committee, standing for Health, Education, Labor, and Pensions. I appreciate the opportunity to have offered this amendment in committee, as well the opportunity to offer it on the floor. It is a very important committee.

The bill, coming out of committee, can withstand some improvement. I know both Senator ENZI and Senator KENNEDY have sat down and made many changes that I think will help relieve some of the concerns we have about the bill. That is now in the form of a managers' amendment which is before the Senate.

The issue I remain concerned about is an issue that was in the original bill.

It remains in the bill, in the managers' amendment, and that is an amendment to the Best Pharmaceuticals for Children Act passed in 1997. This is an incentive program we put in place for the last decade that says to the pharmaceutical industry that if you would put some effort into getting children's medications, pediatric medications properly labeled for the market, then we will give you, in effect, an extension of 6 months on your patent rights. This has been an extremely successful program. For the life of me, I don't understand why the bill's sponsors feel it is important to put this provision in the bill.

This is a chart that reflects the drug studies that have been completed for kids, which equates to more drugs available for pediatricians to use in treating childhood diseases. As one can see, the red square on the chart is with no incentives, and very little effort was being made. But when the 6-month exclusivity provision was provided in the Best Pharmaceuticals for Children Act, we can see how dramatic the increase was and how the marketplace responded to this incentive.

In my view, we should not be removing or reducing the incentive for any pharmaceutical company to invest in children. Right now, with what the current managers' amendment has in it, it takes the 6-month exclusivity and reduces it to 3 months, and it has it applied to those that are referred to as the blockbuster drugs. In my view, I think we need to make sure everybody understands how very important this program is. If we go messing with it, we are going to reduce the incentives that are in it that have been working so well.

The Best Pharmaceuticals for Children Act allows the FDA to grant drug sponsors pediatric exclusivity. This is 6 months of additional market exclusivity—as I said, an extension basically of the patent rights—in exchange for conducting and submitting reports on pediatric drug studies. Current law is working. There is no reason I see to change significantly a program that is working.

The goal of the program is to develop additional health information on the use of such drugs in pediatric populations so they can be administered safely and effectively to children. This goal is reflected on this chart as being reached. Also, using pediatric research and development legislation to attack large pharmaceutical companies, in my view, is an abuse of power at the expense of kids. The data shows pediatric legislation has resulted in a substantial increase in pediatric prescribing information on the labels of those products, which have fulfilled the requirements necessary to be granted the pediatric exclusivity extension.

Here is what the GAO study on the Best Pharmaceuticals for Children Act has said about how the program has been working for the last decade. This study was issued on March 22 of 2007, so

it is a current evaluation, and here is what they say:

Prior to enactment of the Food and Drug Administration Modernization Act of 1997, which first established incentives for conducting pediatric drug studies in the form of additional market exclusivity, few drugs were studied for pediatric use.

Very few were done, as reflected on the chart.

As a result, there was a lack of information on optimal dosage, possible side effects, and the effectiveness of drugs for pediatric use. Almost all the drugs—about 87 percent—that have been granted pediatric exclusivity under the Best Pharmaceuticals for Children Act have had important labeling changes as a result of pediatric drug studies conducted under this Act.

As a result, exclusivity is working. In fact, it is working so well that, in my view, with increased exclusivity we may have even had more research and development in the area of pediatric pharmaceuticals. But that issue is for another day.

My amendment doesn't request an increase in what has been working. We merely ask that we return in this piece of legislation to that exclusivity-linked period, which is 6 months, which has been working so very well under current law.

Some Members want to try to damage the blockbuster drug companies by reducing the exclusivity for those businesses, but in reality the ones who are really being hurt are our kids because we take away the number of choices a pediatrician has in providing drug therapy for those kids who could be seriously ill.

I ask my colleagues to support me in my amendment and to return us to the 6-month exclusivity and away from the 3-month exclusivity period we currently have in the managers' amendment.

Mr. President, I yield the floor.

Mr. KENNEDY. Mr. President, in a few moments we will hear from Senator DODD, who was the architect for the whole undertaking in terms of testing for children, and also for the children's prescription drug program which has been immensely successful. He deserves great credit for it. I am sure he gets a great deal of satisfaction from it. It was bipartisan, with Senator DeWine, going back many years, and certainly Senator CLINTON has added an additional dimension to this whole proposal. But Senator DODD has studied this issue very carefully, and he really is the originator of the concept. He has followed it closely, and he will speak to the Senate on this matter in a very short time.

I see my friend from Ohio on the Senate floor, who also wishes to address it, but I will just say a brief word. I believe what we have in the legislation, which was earlier fashioned by the Senator from Connecticut, is the way to go, and I would hope the Allard amendment will not be accepted.

One of the major elements in the FDA bill is the program providing incentives for developing the new drugs,

and Senator DODD, Senator CLINTON, Senator ALEXANDER, and many others have been champions of this program, as was our former colleague, Senator DeWine. The reauthorization of an effective program is an opportunity to strengthen those aspects that work well and to improve those that need adjustment. Senator DODD took up this challenge and renewed the information about how the program has worked over the years since Congress last reviewed it.

He found that companies were sometimes rewarded with billions of dollars in additional sales in return for doing studies that cost them only a few million. Clearly, one must provide incentives to develop new drugs for children, but we must be responsible in doing so. That is why in this reauthorization, Senator DODD included a proposal to adjust the period of market exclusivity for drugs that generate over a billion dollars in sales. If they generate over a billion dollars in sales, these blockbuster drugs will receive only 3 months of exclusivity instead of 6 months, available to other drugs.

The Allard amendment would delete this sensible provision and give all drugs the full 6 months. That could be worth billions of dollars for a major medication. Those extra 6 months don't just apply to sales for use in children, they apply to all sales. That means a heart drug tested in children would get 6 months protection from competition, so it can wrack up big returns.

The amendment we face embodies a policy that has no proportionality. It gives the same broad protection to a drug such as Lipitor or Xanax as it does to a specialty drug that might be helpful in treating ear infections in children. Senator DODD's proposal has that sense of proportional reward, but the amendment overturns it. That is the wrong approach, and I hope the Senate will reject it.

Mr. President, I see my friend and colleague from Ohio wishes to address this issue, and I yield the floor.

Mr. BROWN. Mr. President, I thank Senator KENNEDY, and I want to join my colleagues, and I will precede Senator DODD and join him and Senator KENNEDY and others in urging a "no" vote on the amendment offered by the Senator from Colorado.

Drugmakers, as we know, have exclusive rights to market a prescription drug under a patent. That means no generic drugs are allowed on the market. There is no price competition and nothing to prevent drugmakers from charging top dollar for their products. Top dollar, as many of our constituents know all too well, for a prescription drug can be breathtaking. A 30-day supply of Nexium, the little purple pill, costs about \$193; a 30-day supply of Exelon, an Alzheimer's drug, is \$214; a 30-day supply of Pravachol, a statin drug, is \$168. Under current law—under current law—drugmakers are rewarded an additional 6 months of competition—

free time on the market when they agree to evaluate a prescription drug for use in children—6 months.

That is a tradeoff. It is a tradeoff the House and Senate agreed to, where adult consumers of this drug—adult consumers of the drug—are denied a less costly generic version of, for example, Prilosec, for an additional 6 months. This means their out-of-pocket health care costs—or their employer, or their insurance company, or the government—are significantly higher than they otherwise would be. That is the tradeoff.

At the same time, drugmakers agree to conduct pediatric testing they wouldn't have done voluntarily, sometimes for reasons all their own, and those tests provide invaluable information to pediatricians for the proper use and dose of medicines prescribed to children. That was the agreement—the 6-month exclusivity agreement. That incentive has worked to increase, we all agree, the number of pediatric tests drugmakers conduct. That is important. Pediatricians now have access to new information that has enabled them to make better use of prescription drugs to help our Nation's children.

My colleague, Senator DODD, championed the 6-month exclusivity law in his efforts in this area, as did my predecessor in the Senate, and so many others, and their work has improved the lives of children. Needless to say, the Senator from Connecticut would not arbitrarily or recklessly make changes to the pediatric exclusivity law. It was his idea and his work. He clearly isn't going to compromise it. But he is recommending one change, and this amendment, the Allard amendment, undoes that change, which is included in S. 1082.

He is recommending if a drug generates more than \$1 billion in revenues—that is, it is a blockbuster drug—if the drug generates more than \$1 billion in revenue, that drug should receive an additional 3 months of market exclusivity instead of 6 months. The reason is both simple and compelling.

It costs about \$13 million—think about these numbers—it costs about \$13 million to conduct pediatric testing on a new drug. If a drugmaker is taking in \$1 billion a year on that drug, \$13 million is about 1 percent of their revenues on that drug. Giving that drugmaker an additional 6 months of market exclusivity on a \$1 billion drug costs health care consumers and taxpayers—the taxpayers who cover the cost of public health programs such as Medicare, Medicaid, and the VA—it costs them millions of dollars each day.

This is not, as Senator ALLARD said, a provision to punish the drug companies. It is a provision to help people with their out-of-pocket drug costs. It is a provision to help taxpayers who fund Medicare, Medicaid, and the VA. It is a provision to help those businesses that are funding health care and drug plans for their employees.

The Federal Government could do it another way. The Federal Government could reimburse drugmakers for the cost of pediatric tests. It could reward them with a 600-percent profit on conducting those tests, and it would still cost appreciably less than rewarding them an additional 6 months of exclusivity. That is why we made the decision not to do it that way. But in light of the astounding imbalance between the cost of conducting a pediatric test—\$13 million—and the reward that 6 months of exclusivity provides when it comes to a \$1 billion drug, Senator DODD recommended we cut that in half. We provide 3 months of exclusivity for billion-dollar drugs instead.

It is still a breathtaking reward: A \$1 billion drug gets a 3-month exclusivity instead of a 6-month exclusivity for a \$13 million test—a breathtaking reward for one pediatric test, but it is measurably more justifiable than the 6-month moratorium on price competition.

Common sense, fiscal responsibility, and the fact that all of us in this Chamber report to U.S. taxpayers dictate that we support Senator DODD on this modest change in his own program. The Allard amendment gives \$1 billion drugs a 6-month exclusivity instead of 3. The logic is, if 6 months of market exclusivity is working to prompt drugmakers to conduct pediatric testing, we shouldn't change it. By that logic, we might as well give drugmakers 100 years of market exclusivity. I am sure that would work, too.

The point is, we have to draw the line to encourage pediatric testing, which this will, and to save money for our employers, for our taxpayers, and for senior citizens' out-of-pocket costs. When a drugmaker earns hundreds of millions of dollars, in many cases out of the pockets of U.S. taxpayers, for a pediatric test that costs about \$10 million, that is unnecessary, it is unjustifiable, and it is outright wrong.

Please vote for common sense, for protecting our children, for U.S. taxpayers, for consumers, and against the Allard amendment.

Mr. ALLARD. Mr. President, the Senator from Wyoming, who is managing the time, has granted permission for me to speak for 5 minutes.

Mr. President, I forgot to ask unanimous consent that the following individuals be added as cosponsors on my amendment: Senator BOND, Senator HATCH, and Senator ALEXANDER.

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

Mr. ALLARD. Mr. President, I would like to respond to this concern about drug companies investing relatively little and having huge returns. That doesn't apply to every drug.

Obviously, when you are developing a product for the market, there will be some that work out rather easily and the development costs may not be too much. But there are other drugs that require a substantial amount of work and analysis, and a considerable amount of thought has to go into the

labeling. When those costs get high and when you hit those, the profit margin is not so large. I hate to see us pick out a few companies that may have had a windfall and then punish our children and say we are going to take away an incentive that has resulted in 80 percent of the children's drugs that have come to the market being approved and getting the proper licensing they require.

In my view, we pick out a few outrageous circumstances and then we try and take away an incentive that has been working so well for us.

My point, again, is why mess with that incentive when it is working so very well? As I had indicated here on the charts, we had such tremendous results in getting children's pediatric drugs to the market. This allows the pediatrician more choice in selecting therapies for their patients. It means better medicine. I also believe that the more products you have on the market, the more competition you have, and the more competition you have, that then holds down the price of drugs. What we need to do is rely on the markets to control the price of drugs, to control supply. I hate to see the Government or this Congress try to apply any kind of artificial parameters that somehow or other would mean we would have fewer drugs for the treatment of our kids and their ailments.

I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Mr. President, I rise today in support of this amendment by Senator ALLARD which would strike a cap on pediatric research incentives for blockbuster drugs with more than \$1 billion in annual sales. That sounds like a lot. We are going to quibble here about whether they get 3 months of additional time or 6 months of additional time. They have had 6 months of additional time.

Incidentally, this is one time per drug. This is not every time they can come up with a child's use they can extend another 3 months or 6 months; this is one time on any drug, they can get an extension of 6 months.

Now we are going to decide that a company that comes up with a really great drug is only going to get 3 months versus 6 months because they make \$1 billion in annual sales? Three months' worth would be \$250 million in annual sales, and that sounds like a lot, but when you figure out what is profit out of that, it is a much smaller number.

I congratulate Senator DODD for originally coming up with this incentive. He came up with the idea for 6 months, and it worked. You have seen the chart that shows how dramatically there was an increase in the number of drugs that were studied for kids and how proper doses were derived for kids. The Allard amendment ensures that pediatric studies that are essential to our children's health and well-being will continue to take place, that they

will continue the same as they have with the same incentives and the same requirements. Under current law, in exchange for performing a pediatric study, a manufacturer can receive an additional 6 months of market exclusivity, one time per drug. This is a powerful incentive to ensure pediatric studies are completed. The substitute amendment we are debating today limits this exclusivity to just 3 months, and I am concerned that this will reduce or limit the number of pediatric studies. Senator ALLARD's amendment would revert back to current law. If we support and pass the amendment of Senator ALLARD, we go to current law, so manufacturers can receive the additional 6 months of market exclusivity.

Before incentives, there were very few pediatric studies. In the 7 years before Congress authorized incentives, only 11 pediatric studies were completed; 7 years, 11 studies—embarrassing. But at least 132 pediatric studies were completed, and more are ongoing. The current incentive system works.

This is not an abstract policy issue. Pediatric drug studies can mean the difference between life and death for our children. For example, initial research indicates that Viagra, which is a blockbuster drug, can work miracles for children with pulmonary fibrosis, a rare and potentially fatal lung disorder. Viagra seems to relax and expand blood vessels in afflicted children's lungs. Incentives spurred Pfizer to perform studies that are now underway and could save approximately 28,000 children who might otherwise die or suffer greatly. Without powerful incentives, such studies might not get done.

The Democratic witnesses at the HELP Committee's—the Health, Education, Labor, and Pension Committee—recent hearing agreed that caps are a risky experiment. The number—zero incentives, 11 studies; strong incentives, 132 studies—that speaks for itself. Reducing incentives will certainly reduce the number of pediatric studies. We should not undercut a system that is proven to help kids and then say we are improving the program. I don't think so.

I strongly agree we need to do everything we can to make health care more affordable and accessible, but harming a worthwhile program that saves kids' lives is the wrong way to do it. It is wrong to play the politics of drug pricing at the expense of our kids. We should protect these incentives which are proven to work.

Again, I congratulate Senator DODD for coming up with the idea of providing these incentives. I wish to note for the record it was at 6 months that we provided that. I ask that you support the Allard amendment.

I yield the floor.

The PRESIDING OFFICER (Mr. BROWN). The senior Senator from Connecticut is recognized.

Mr. DODD. Mr. President, let me first begin by thanking Senator KEN-

NEDY and Senator ENZI for including the Best Pharmaceuticals for Children Act and the Pediatric Medical Device Safety and Improvement Act in the bill before us. I congratulate them, particularly Senator KENNEDY for his efforts of putting all this together, this major legislation which is going to be so important for the health and well-being of all our citizenry. I am very grateful to him, and to Senator ENZI as well, for leading the minority on this issue and making it possible for us to be here today to discuss these issues.

My friend from Colorado and I worked together on this issue. I appreciate the comments about the effort we made over the past decade or more to try to do what this bill was designed to do and has done, and that is to increase the clinical trials and testing of products used in our younger Americans—children.

In too many cases, prescription drugs were being tested for adults, and there was an assumption that a smaller dosage of that product would be all that was necessary to take care of children. Obviously, that was not the case, as we heard in significant testimony over the years.

Countless hours have gone into the work on this legislation. The Presiding Officer has been a tremendous help. I thank him for his efforts, along with others on this committee helping us put this together.

It must be an Ohio tradition. As he has heard me say on occasion, Senator BROWN has been tremendously supportive, working on this issue. He was active on the issue when he served in the other body, and he brought his talents and knowledge to the issue when he arrived here recently. His predecessor, Senator DeWine, was my cosponsor on this bill for a decade, on a bipartisan basis putting the legislation together that has produced the results which have been identified by Senator ALLARD and Senator ENZI already this morning.

We find ourselves here having worked very carefully together on a bipartisan basis for more than a decade to craft legislation. None of us are claiming perfection here. The idea was to try to induce the industry to step forward and do something they had not done before—to test their products in children. We were not certain when we started out how this would actually work. Ten years ago, we saw a situation where the majority of drugs being used in children were not being tested for their use.

Children are not simply little adults. The results of drug studies conducted under the Best Pharmaceuticals for Children Act have shown they should not be treated as such. The initiative contained in the bill before us on pediatric medical devices is a similar effort to ensure children are not left behind as cutting-edge research and revolutionary technologies for medical devices advance.

Senator DeWine, as I mentioned, and I authored this bill more than a decade

ago, at a time when only 11 drugs on the market that were being used for children had actually been tested and studied for that use. Prior to the enactment of this legislation a decade ago, pediatricians were essentially flying blind because they lacked information regarding the safety and effectiveness of drugs they were prescribing. It was often the children who suffered the most.

What we have learned over this past decade after 10 years of experience is that children have been exposed to ineffective drugs, ineffective dosing, overdosing, or drug side effects that were previously unknown. In 10 years, nearly 800 studies involving more than 45,000 children in clinical trials have been completed as a result of this legislation. Useful new pediatric information is now part of product labeling for more than 119 drugs.

In sum, there has been a 20-fold increase in drugs studied in infants, children, and adolescents as a result of the legislation I authored 10 years ago. Children with a wide range of diseases such as HIV/AIDS, cancer, allergies, asthma, neurological and psychological disorders, and obesity can now lead healthier and more productive lives as a result of new information about the safety and efficacy of drugs they use to treat and manage their diseases when previously there was none. This successful program for children will expire on the 30th of September unless we reauthorize it.

I have spent months crafting a proposal to reauthorize this legislation, which is now reflected in the underlying bill. It had been my hope that this initiative would continue in that bipartisan tradition that began more than a decade ago. Fashioning legislation when there are 100 of us here, trying to come up with ideas, and yet balance disparate views and opinions. There are some, frankly, who would have no periods of exclusivity and believe the industry ought to be doing this as a matter of obligation to one out of four Americans. You have heard from others who think we ought to provide extended periods of exclusivity, longer than 6 months. It is not easy to fashion these compromises here, where you can put something together that does what we want to do, all the while ensuring that the program can continue to generate more benefits than were originally contemplated. There has to be some limitation in terms of how we deal with all this.

I thank Senators KENNEDY, HARKIN, BINGAMAN, MURRAY, REED, CLINTON, and BROWN, who all cosponsored the legislation I introduced which, as I previously mentioned, has been incorporated on this bill.

Mr. President, I will ask unanimous consent that these letters be printed in the RECORD so my colleagues will know the bill we are considering is not something we threw together haphazardly. This was major, extensive work with major organizations in this country

that spend every waking hour working on children's diseases and issues that affect their health. I am grateful to the AIDS Alliance for Children, Youth & Families; the American Academy of Child and Adolescent Psychiatry; American Academy of Pediatrics; the American Brain Coalition; American Pediatric Society; the American Psychiatric Association; the American Thoracic Society; the Arthritis Foundation; the Association of Medical School Pediatric Department Chairs; Children's Cause for Cancer Advocacy; Elizabeth Glaser Pediatric AIDS Foundation; National Association of Children's Hospitals; National Organization for Rare Disorders; Society for Pediatric Research—the list goes on.

I ask unanimous consent to have printed in the RECORD two letters from this myriad of organizations which every day are involved with children's health and are strong advocates of what we are doing here and respectfully disagree with the amendment offered by Senator ALLARD today.

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

APRIL 17, 2007.

Hon. EDWARD KENNEDY,
Hon. CHRISTOPHER J. DODD,
Hon. MICHAEL B. ENZI,
Hon. HILLARY RODHAM CLINTON,
U.S. Senate,
Washington, DC.

DEAR SENATORS KENNEDY, ENZI, DODD AND CLINTON: As organizations working to ensure better health care for the nation's children, we write to thank you for your longstanding commitment to children's health and to express our support for legislation to reauthorize the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) and to improve children's access to safe medical devices. We are very pleased that BPCA and PREA reauthorization language and S. 830, the Pediatric Medical Device Safety and Improvement Act, have been included in the Chairman's mark of S. 1082, the "Food and Drug Administration Revitalization Act," for consideration by the Senate Health, Education, Labor and Pensions Committee tomorrow.

Over the past decade, Congress has enacted bipartisan legislation that has dramatically increased the number of drugs tested and labeled for children. The results from BPCA are extraordinary—over 336 requests have been generated for over 780 pediatric studies, resulting in over 115 new drug labels for children. Sen. Dodd's BPCA reauthorization language strengthens this very successful existing program in several important ways, including ensuring prompt label changes, requiring that all study protocols and results be made public, improving adverse events reporting for children, and identifying and addressing important gaps in treatments for children's diseases. In addition, the BPCA language includes a reasoned approach to address the small percentage of drugs for which the exclusivity provision has far exceeded the incentive it was intended to provide pharmaceutical companies.

S. 993, the Pediatric Research Improvement Act (PRIA), introduced by Sen. Clinton and included in the Chairman's mark, reauthorizes the Pediatric Research Equity Act of 2003 (PREA), which requires drug manufacturers to test their products for use in children. This law ensures that children are not a therapeutic afterthought and has gen-

erated impressive and invaluable safety and dosing information for children. Since the 2003 passage of PREA, 55 drugs have new or improved pediatric labeling. These drugs range from treatment of ear infections to the prevention of rejection of organ transplants. S. 993 places children on equal therapeutic footing with adults by creating the presumption that medicines coming onto the market for illnesses and conditions that occur in children will be labeled for pediatric use and be available in formulations (e.g., liquids, chewable tablets) that children can take.

The Pediatric Medical Device Safety and Improvement Act of 2007 provides a comprehensive approach to ensuring that children are not left behind as cutting-edge research and revolutionary technologies for medical devices advance. Like drugs, where for too long children were treated like small adults, many essential medical devices used extensively by pediatricians are not designed or sized for children. According to pediatricians, the development of new medical devices suitable for children's smaller and growing bodies can lag 5-10 years behind those for adults. S. 830 improves incentives for devices for small markets—while still preserving the ability to ensure the safety of new products once on the market. It provides assistance to innovators, streamlines regulatory processes, and elevates pediatric device issues at the Food and Drug Administration (FDA) and the National Institutes of Health.

Despite support for the Chairman's mark, we are disappointed that a key provision to make PRIA permanent has been omitted. As this legislation moves to the floor of the Senate, we urge you to restore the permanent authority of the FDA to ensure that children have properly studied medications as a matter of fact, not chance.

We are grateful for your longstanding leadership and commitment to improving the health of our nation's children and look forward to working with you toward swift Committee action and passage of these pediatric therapeutic bills by the full Senate.

Sincerely,

American Academy of Pediatrics; Elizabeth Glaser Pediatric AIDS Foundation; AIDS Alliance for Children, Youth & Families; American Academy of Child and Adolescent Psychiatry; American Brain Coalition; American Pediatric Society; American Psychiatric Association; American Thoracic Society; Arthritis Foundation; Association of Medical School Pediatric Department Chairs; Children's Cause for Cancer Advocacy; National Association of Children's Hospitals (N.A.C.H.); National Organization for Rare Disorders; National Research Center for Women and Families; Society for Pediatric Research.

MAY 1, 2007.

Hon. CHRISTOPHER J. DODD,
U.S. Senate,
Washington, DC.

DEAR SENATOR DODD: As organizations working to ensure better health care for the nation's children, we write to express our support for your legislation to reauthorize the Best Pharmaceuticals for Children Act (BPCA), which has been included in S. 1082, the "Food and Drug Administration Revitalization Act." Since its original enactment in 1997, this legislation has directly resulted in an extraordinary increase in the number of drugs tested and labeled for children. In the past ten years, BPCA has prompted over 780 pediatric studies and yielded 115 new drug labels for children, fundamentally changing the practice of pediatric medicine and the quality of health care for our nation's children.

Since the inception of BPCA, Congress has recognized the need to ensure that it strikes the appropriate balance between cost to consumers and benefits to children. This year we have the data to show that we can adjust the exclusivity provision without losing pediatric studies. In February, the Journal of the American Medical Association (JAMA) published a study of the profits drug manufacturers received from the additional 6 months of pediatric exclusivity. The study found that "the Pediatric Exclusivity Program overcompensates blockbuster products for performing clinical trials in children."

The approach taken by your BPCA reauthorization legislation appropriately addresses the small number of products for which the benefit of additional exclusivity has far exceeded the incentive it was intended to provide. By limiting exclusivity only for those products with sales over \$1 billion, your proposal can address concerns about excessive profits without jeopardizing the extraordinary benefits of BPCA for children's health. The adjustment will significantly reduce the overall cost of pediatric exclusivity to consumers. We therefore oppose Senator Allard's amendment to strike this reasonable exclusivity adjustment from S. 1082.

We are grateful for your leadership and commitment to improving the health of our nation's children and look forward to swift passage of BPCA by the full Senate.

Sincerely,

AIDS Alliance for Children, Youth & Families; American Academy of Child and Adolescent Psychiatry; American Academy of Pediatrics; American Brain Coalition; American Pediatric Society; American Psychiatric Association; American Thoracic Society; Arthritis Foundation; Association of Medical School Pediatric Department Chairs; Children's Cause for Cancer Advocacy; Elizabeth Glaser Pediatric AIDS Foundation; National Association of Children's Hospitals (N.A.C.H.); National Organization for Rare Disorders; Society for Pediatric Research.

Mr. DODD. To anyone offering to flyspeck this proposal and offer variations to it, I would say that months and months have gone into this legislation which we think has had the dual effect of ensuring that the ramifications of expanding the length of exclusivity, as some have proposed, have been carefully considered along with proposals to limit the length of exclusivity to 3 months for all drugs, as others have proposed. The bill before us balances many viewpoints on this program and is a proposal that 15 major organizations involved with the effort strongly support.

Throughout the 10-year history of the Best Pharmaceuticals for Children Act, Congress has recognized the need to ensure it strikes the appropriate balance between the cost to consumers and benefits to children. By instituting a 5-year sunset in both the original legislation in 1997 and the first reauthorization in 2002, Congress was acknowledging the ongoing need to evaluate the cost of the incentive under this act to consumers in relation to the benefit of having medications properly studied and labeled for children.

The 6-month incentive of exclusivity has been very successful in generating pediatric studies. Yet after 10 years,

experience and data have shown us that for a small number of drugs, pediatric exclusivity has far exceeded the carrot that was designed to encourage people to move forward.

In February of this year, the Journal of the American Medical Association published a study of the profits drug manufacturers received from the additional 6 months of pediatric exclusivity.

The study found that most of the drugs studied under the Best Pharmaceuticals for Children Act in recent years received relatively modest returns. In fact, data shows that many drugs came close to breaking even with respect to financial returns on investment for conducting pediatric trials. In one place they may have had a negative return.

However, the study also found, and I quote them here, that "the pediatric exclusivity program overcompensates blockbuster products from performing clinical trials in children."

S. 1082 contains a very reasonable, workable mechanism to address cost concerns. By adjusting exclusivity from 6 months to 3 months only for those products with U.S. sales over \$1 billion, I think S. 1082 can address consumer concerns about excessive profits without jeopardizing the extraordinary benefits of this legislation.

I don't think it is too much to ask. That is why we have the sunset provisions in this program, to be able to go back and analyze how this is working every 5 years. So for those products in excess of a \$1 billion, we shorten exclusivity. I am satisfied.

Pfizer, a leading drug company in this country, supports this proposal. The producer of the largest blockbuster drug in the world says this is a good compromise. Why are my colleagues having a hard time? If a major drug company who has benefitted under this exclusivity and manufactured blockbuster drugs says this bill is a sound compromise, what is the problem my colleagues have with this proposal?

If Pfizer, a company that has benefitted from this program says this balance is a healthy one, why can't my colleagues be happy with it?

This bill is a good bill. It has done a good job for people. But let's remind ourselves that we also have a responsibility to consumers. And when consumers find themselves in a situation where they can't afford lifesaving medicines, then it is time for us to strike a balance. This bill has a sunset provision in it. I am for the sunset provision. I am for it because we need to come back again in 5 years and assess where we are on this issue rather than make a determination that in perpetuity this is a program and a balance that makes sense forever.

According to the Congressional Budget Office, eliminating the exclusivity adjustment, as the amendment offered by my colleague from Colorado would do, would increase the cost of exclusivity to the Federal Government by

\$50 million over 10 years. So in addition to the consumers, taxpayers are going to be asked to pay an additional \$50 million under the Allard amendment.

Again, if we have drug companies saying they think this proposal is a good balance, why are we adding a \$50 million pricetag to the taxpayers with the Allard amendment, not to mention the cost of these drugs increasing as a result of extending exclusivity from 3 months to 6 months for products with sales in excess of \$1 billion?

As I said, this is something I have worked on for a long time in a bipartisan fashion: to strike a balance as we've tried to do for 10 years between benefits to children and cost to consumers. To now say all of us who have worked on this program are wrong, all of the organizations involved with children's health are wrong, and drug companies that have benefitted from this program are wrong—but we know best. We know best. We think those billion-dollar products deserve to be protected. We think the taxpayers should foot the \$50 million bill and the cost of these drugs are irrelevant in this debate. Well, they are not irrelevant.

We may do great damage to something we are trying to achieve after a decade of hard work on a bipartisan basis to put this together. I say respectfully to my friend from Colorado and the Senator from Wyoming, we have worked hard to strike these balances. It is not easy. These are complicated issues. It requires cooperation on both sides of the aisle to get the job done. That is what I have done for a decade with Members of that side of the aisle to see to it that we have a good, strong bill. The result is a program which has gone far beyond what we anticipated might happen.

The slight adjustment we have made after analyzing this bill after 10 years is little to ask. If one of the largest beneficiaries of the program is satisfied, and if the organizations who support this program believe it is all right, why are we adding a \$50 million pricetag and asking consumers to pay more?

I urge my colleagues to reject the Allard amendment when the vote occurs. I thank Senator KENNEDY and others who have worked so hard to make this possible. This is a very important piece of legislation, and one that can do an awful lot of good. The amendment offered by my colleague from Colorado puts that at risk. Our children in this country deserve better than what he is offering, which is to try to break up the delicate balance I have tried to put together for a decade.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Utah is recognized.

Mr. HATCH. Mr. President, I thank my dear colleague from Tennessee for allowing me to go first, and also my two colleagues on the Democratic side, Senators CARPER and STABENOW.

I ask unanimous consent that Senator ALEXANDER be permitted to go

next and then Senator CARPER and then Senator STABENOW.

The PRESIDING OFFICER. Is there objection?

Mr. KENNEDY. Reserving the right to object, I think it would be useful if we rotate it back and forth.

Mr. HATCH. I think we have an agreement among the four of us.

Mr. KENNEDY. If the Senator from Delaware is satisfied, that is fine with me.

Mr. ENZI. One of the things we are trying to do is keep the debate on the children's amendment so we can get a conclusion to the children's amendment before time deadlines come up. So if those who wanted to speak on other issues can reserve their time until later, that would be very helpful.

Mr. HATCH. I would add to that request the Senator from Oklahoma after Senator STABENOW.

Mr. KENNEDY. We still have the Pastore rules in effect, which means the debate on the first 2 hours is supposed to be on matters which are subject to it. I mean it is not generally enforced, but Senator ENZI and I are trying to move forward.

The PRESIDING OFFICER. Is there objection to the unanimous consent request from the Senator from Utah?

Without objection, it is so ordered. The Senator from Utah is recognized.

Mr. HATCH. Mr. President, I thank my colleagues, including the two managers of the bill on both the Democratic and the Republican side.

I rise in support of the Allard amendment. I want to take a few minutes to talk about pediatric testing and research provisions included in this bill. I have strongly supported both the Best Pharmaceuticals for Children Act and the Pediatric Research Improvement Act.

As my colleagues know, current law provides 6 months of exclusivity for drugs that do research and development in the area of pediatric use. I am very interested in keeping it that way. That has proven very efficacious in the Hatch-Waxman bill. It keeps companies involved in developing great drugs for children in this area. So it is a very important part of this.

I was deeply involved in those negotiations in 1997 with my former colleague, our former colleague, Senator Mike DeWine. I have supported these efforts from Ohio Senator Mike DeWine that brought additional pediatric testing of prescription drugs to our attention during consideration of the FDA Modernization Act of 1997. He fought long and hard to encourage drug companies to conduct clinical trials on pediatric uses of their drugs.

His efforts paid off and this program has been extremely successful. As a result, pediatric drugs are safer and more effective for children. The bill before us today reduces the 6-month exclusivity period for blockbuster drugs to 3 months.

I emphasize again this market exclusivity has provided the incentive needed to increase research and development for pediatric drugs. We used the

same type of an approach on the orphan drug bill many years ago. At that time there were only a few orphan drugs. Today there are over 300 being developed. It is the same principle here.

The Allard amendment restores current law and provides 6 months of exclusivity for all drugs. As I mentioned last night, my good friend and colleague from Connecticut, Senator CHRIS DODD, has also shown great leadership on this issue when FDAMA was being considered in 1997. He held a hearing on this issue earlier this year with his ranking Republican member, Senator LAMAR ALEXANDER, who has served long and well on this committee.

That hearing was very insightful, and I believe many of us are trying to do the right thing as we reauthorize both programs. I urge my colleagues not to lose sight of the purpose of these two programs as we make decisions on this part of the bill. We want good solid information about the safest way to prescribe drugs for children.

By giving companies market exclusivity to conduct clinical trials, we will know the safest dosage levels for children. So let's not lose sight of the original purpose of these programs: to help children have the safest dosages for prescriptions.

Now, it is no secret I support the Allard amendment. I would just like to add a few more facts. Nearly two-thirds of the drugs prescribed for children have not been studied and labeled for pediatric use. I know the importance of accurate clinical information about a drug's use in the pediatric population. This smaller body mass and higher metabolic rates of children mean they often respond differently to drug dosing than adults do.

A drug that is safe and effective in adults may not always be safe for children. The question is not whether we should study the safety of drugs for children but how we make that research happen.

In 1997, Congress considered this issue and created an incentives program for companies to study the use of their drugs in pediatric populations. The program offers an additional 6-month patent protection or exclusivity to drug manufacturers to help recoup the cost of investing in these critical pediatric studies. It is a win-win situation. Drug companies have the incentive to invest time and extra resources for a small share of the market, and, more importantly, children get the research they need.

The evidence is that the incentives for exclusivity should be maintained, not lowered. Despite the fact that the bill providing the incentive for pediatric studies was enacted a decade ago, nearly two-thirds of the drugs prescribed for children have not been studied and labeled for pediatric use.

We have had a great deal of study about the need for this incentive and how it should work.

The fact remains that there is a persistent public health need for accurate clinical information about how adult drugs will work in children.

Children are not adults, for reasons that the Senator from Oklahoma, Dr. COBURN, has well explained to this body.

Much of what our colleague from Connecticut, Senator DODD, has just said underscores the need for a continued, strong, exclusivity provision.

The statistics he cited about the success of this program are truly remarkable and a significant milestone in the history of public health.

The only place where there seems to be disagreement on Best Pharmaceuticals for Children Act is the exclusivity period for what some define as "blockbuster drugs." I know the Senator may call the 6 months period "gouging" but that "gouging" may very well be the incentive that has led to the FDA receiving more than 400 proposed pediatric-study requests and receiving 144 completed studies.

Those who support the Senator's amendment—and I know it is well-intentioned—suggest that without the 6 months' incentive, the pediatric testing will still continue and will be robust. Who knows if this is true?

I wonder if we want to call their bluff and take away this powerful incentive? I don't think we can take that chance.

The PRESIDING OFFICER. The Senator from Tennessee is recognized.

Mr. ALEXANDER. Mr. President, first I would like to congratulate Senator DODD and others who over the past 10 years have developed this piece of legislation. It has been remarkably effective. I think it is important as we talk about this that we remind ourselves what we are saying. What we are saying is, we live in this country with all of these wonderful pharmaceutical drugs for adults, but in many cases, before this legislation had been enacted, doctors were flying blind. They were guessing about the effect of these drugs on children.

That sometimes had very unfortunate results. I know that in my home State of Tennessee a drug for whooping cough was given to a number of children. There had been a clinical trial for the effect it would have on adults but not on children. And the children were so seriously harmed by the drug that the Centers for Disease Control later found that the drug was the reason they needed stomach surgery.

So it is remarkable that 10 years ago Senator DODD and others—Senator DeWine, Senator HATCH, and many others who have been mentioned—came up with the idea that if we strike this balance that Senator DODD has referred to several times and give the companies that make the drugs a little more time, 6 months with their patent, that they in return would then conduct trials on these drugs on how they affect children.

No one knew at that time exactly what would happen. They were guess-

ing. This is long before I came to the Senate. But they guessed well. As a result, as has been said, about one-third of the drugs that are given to children now have had testing and trials for use in children. Now doctors, when we bring our babies and grandbabies in, have a better idea of what they are doing. They are guessing less. It is better for the children.

In my family we have two new grandchildren under the age of 2. Senator DODD, being younger than I am, has two children who are young like that. Maybe he has heard what I have heard. My mother used to say to me when I would go to the babies and they were happy, she would say: "Son, don't try to make a happy baby happier."

In effect, what she was saying is, leave it alone if it is happy. Well, this is a happy piece of legislation for which Senator DODD and others should have a lot of credit. My suggestion would be let's not try to make a happy piece of legislation happier. It is happy because one-third of medicines are being studied, and doctors know more about what they are giving to their patients who are children.

What the Allard amendment would do is keep the law the way it is. It is the bill that is on the Senate floor that would change things.

I understand this is an estimate, but I listened to the testimony. The Senator from Connecticut suggested we are all racing here at the last minute and changing it. Wait a minute. We had a hearing on this some time ago. It was a terrific hearing. I was there. We heard various points of view, a lot of celebration about the effect of this act over the last 10 years. The only reason I was not a cosponsor of this legislation was because I wanted to hear the testimony about what the effect would be of changing this law that is a happy law that has worked so well for so long. As a result, it created the situation where a third of the children have drugs that doctors know more about.

After listening to all the testimony, if I were going to change the law, I would make the incentive 7 months or 8 months or 9 months. Why would I do that? The reason is, at the hearing it was said that while a third of the drugs that are administered to children have had been tested for use in children, probably we need two-thirds of the drugs that are ready for adults to have that sort of testing. In other words, we are about halfway where we want to go if we want to have drugs that are tested to see what their effect will be on children.

So my question was, if giving 6 months' incentive has gotten us halfway where we want to go, then maybe to get all the way where we want to go, we should go to a 7 months' or 8 months' incentive. But my feeling at the end of the hearing was, well, the existing law has worked well by providing an incentive of 6 months. Let's leave it like it is. The end result of the legislation that is on the floor is not to

leave it like it is but to change it, to reduce it from 6 months to 3 months, which is exactly backwards.

What the effect of this reduction will be is to reduce the opportunities for tests of drugs for children, which would fail to move us along toward the goal of having two-thirds of drugs studied for use in children.

I applaud Senator DODD. I give him great credit for this. When he retires from the Senate in another 30 years, this will be one great feather in his cap, as well as for Senator CLINTON and others who have worked on this. But I would go back to what my mother said: "Don't try to make a happy baby happy." Let's not try to make a happy piece of legislation happy. Let's leave it the way it is. It has worked for 10 years. Let's let it work for another 5 years the way it is. Adopting the Allard amendment would keep it the way it is.

I have one suggestion for Senators KENNEDY and ENZI, if I may. Maybe they would want to consider it as part of the managers' amendment. We heard testimony at our hearing that perhaps our goal should be someday to get two-thirds or three-fourths of the drugs that are for adults studied for use in children. Today it is one-third. I think it would be useful for us at a future time to know exactly what our goal ought to be. Maybe it ought to be 90 percent. Maybe it ought to be 50 percent. But I wanted to suggest to the Senator from Massachusetts and the Senator from Connecticut that we might want to include in this legislation asking the FDA or the appropriate agency to study what percent of drugs approved for adults should also be tested for children, what is that proper goal, so that the next time this issue comes up we have some informed judgment about it. A quick review of the medical literature shows there hasn't been any such study. I could be corrected if there has been. If there hasn't been, I suggest we make that a part of the legislation. I make that simply by suggestion, not amendment. I intend to vote for the Allard amendment, and I have stated the reasons why. If we have a happy piece of legislation, let's keep it happy. That will do it.

I yield the floor.

The PRESIDING OFFICER. The Senator from Delaware.

AMENDMENT NO. 990

Mr. CARPER. Mr. President, I wish to change the subject for a moment, if I may. The overall subject is the same; that is, the legislation that is before us. I salute Senators KENNEDY and ENZI and their staffs for providing an excellent piece of legislation. It was not an easy thing to do on a difficult subject. I thank them for their efforts and for getting us to this point.

Yesterday evening, our colleagues and friends, Senators DORGAN and SNOWE, filed an amendment to S. 1082 that would allow for reimportation of prescription drugs from Canada and from certain other countries. In pre-

vious years, a number of us, including me, supported reimportation legislation, so long as the Secretary of Health and Human Services certifies that the reimportation of prescription drugs can be done both safely and cost-effectively.

Earlier this morning Senator COCHRAN filed a second-degree amendment to the Dorgan-Snowe legislation that seeks to require that certification in the context of this legislation that is before us today. Senator COCHRAN's amendment would require the Secretary of Health and Human Services to certify that the provisions within the Dorgan-Snowe reimportation program would pose no additional risk to the public's health and safety.

In addition, the Cochran amendment would require the Secretary of Health and Human Services to certify that this reimportation program would result in a significant reduction in the cost of prescription drugs to the American consumer. So there are two goals. These few lines that Senator COCHRAN just introduced were passed by unanimous consent 4 years ago in 2003. In 2002, this language passed the Senate by a vote of 99 to nothing. It is clear, at least to me, from these past votes that this is not the first time the Senate has taken up this issue and, again, with some consensus.

Since the last time reimportation was before this body, Senators DORGAN and SNOWE have worked hard to address many of the safety concerns folks had raised in previous iterations. I commend both of them and their staffs for working diligently to try to address a number of these concerns. I believe they have made significant progress. For instance, concerns were voiced earlier that the FDA would not have enough funds to operate a reimportation program. To provide the FDA with additional resources, the revised Dorgan-Snowe proposal would increase user fees paid by those drug wholesalers and pharmacies participating in the program from 1 percent to 2.5 percent of the total price of the drugs that are reimported. This moves us closer to ensuring that FDA will have the resources they need to operate this program effectively.

Senators DORGAN and SNOWE's new legislation would also allow the FDA more time to phase in the number of drug exporters and importers that want to participate in the program. A slower phase-in would give the FDA more time to ensure that the importers and exporters are aboveboard and should help alleviate concerns that we would unknowingly allow unscrupulous vendors into this reimportation program.

Although Senators DORGAN and SNOWE address a number of the drug safety concerns, I believe a couple of possible shortfalls remain, especially when it comes to stopping the proliferation of counterfeit, adulterated drugs. Specifically, this legislation relies on what are called paper pedigrees

to show a drug's chain of custody, but there is no guarantee that these paper pedigrees could not be forged to hide possible counterfeiting, possibly leaving American consumers with a less safe drug supply. Moreover, this bill relies on what some believe are unproven and untested anticounterfeiting technologies to guarantee drug safety. While I give credit to my friends for trying hard to build safety into the proposal, it is not yet clear that anticounterfeit technologies, which the proposal relies so heavily upon, is yet at the point of being both widely available and, more importantly, cost effective.

In addition, it is unclear to me if this reimportation program would give the FDA the authority to conduct inspections of foreign manufacturing plants. It is unclear to me whether the countries permitted under this bill to export drugs into the United States have the same kind of safety and quality control standards that we enjoy at home.

In the end, drug reimportation will only work if we are able to ensure that the drugs we import are as safe as those manufactured and sold in the United States. If the Secretary of Health and Human Services, the person who directly oversees the FDA to ensure the public's health and safety, is not prepared to certify that the importation is safe, then that gives me pause, and I believe it should give us pause. We don't have a reimportation program operating right now, but the incidence of drug counterfeiting and adulterated drugs still exists. In the last few years, prescription drugs that contained bogus or dangerous ingredients as well as actual drugs that were deceptively labeled to hide their origin have made their way into the United States. For example, 4 years ago, counterfeits of the cholesterol drug Lipitor were found in the United States and made their way to a number of American consumers. Recently, FDA warned consumers about counterfeit drugs from multiple Internet sellers.

Many would argue that the FDA already has its hands full. If that is true, how do we in good faith add another layer of complexity such as reimportation to an already overburdened and underresourced system without also demanding that the Secretary of Health and Human Services certify that reimported drugs are safe for American consumption.

Similar to most of my colleagues, I am not opposed to reimportation, but I do firmly believe that despite the very real progress that has been made with respect to the earlier Dorgan-Snowe proposal, some uncertainties remain in the revised legislation they offered yesterday. Because of those remaining concerns, I support the Cochran amendment and ask my colleagues to do the same.

Similar to some of my colleagues, I have held in my hands medicines that appear to be the same as the prescription medicines manufactured in this

country. They were the same size, same shape, same color. They have the same markings. The wrapping and the materials they come in are the same. They appear to be, for all intents and purposes, the same legitimate prescription medicines. They were not. In some cases, they contained materials that were unsafe, and in other cases they contained materials that were not helpful to the person suffering from a particular malady. I would like to say that those concerns for that kind of behavior have gone away. They haven't. The profit motives for those who would like to sell bogus drugs, counterfeit drugs, the economic attraction of doing that is enormous. As a result, I think we need to proceed with caution.

I again commend Senators DORGAN and SNOWE. They are trying hard. Their staffs are trying hard to get us to the point where the Secretary of Health and Human Services can actually certify that we can reimport these drugs in a way that is safe and cost effective. We will be voting later today to determine whether we have gotten that far. The Cochran amendment made sense before, and I think it still makes sense.

I yield the floor.

The PRESIDING OFFICER (Mr. CASEY). The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, for the benefit of the Members and the greatest convenience, we will vote on the Allard amendment at 12:25. What I would like to do is propose a consent agreement that we vote at that time. I know the Senator from Oklahoma and the Senator from Michigan want to talk. We have 35 or 40 minutes. Probably Senator ALLARD and Senator DODD would want to make a comment before we get to the vote.

I ask unanimous consent that at 12:25 the Senate vote in relation to the Allard amendment 982 and that the time until then be for debate with respect to the amendment, with the 40 minutes divided as 20 minutes being divided equally between Senator ALLARD and Senator DODD and 20 minutes between the Senator from Michigan and the Senator from Oklahoma; furthermore, that no amendments be in order to the amendment prior to the vote.

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

The Senator from Michigan.

AMENDMENT NO. 1011

Ms. STABENOW. Mr. President, first, I ask unanimous consent that the pending amendment be temporarily set aside and call up amendment No. 1011 for the purposes of offering the amendment.

The PRESIDING OFFICER. Without objection, the pending amendment is set aside. The clerk will report the amendment.

The legislative clerk read as follows:

The Senator from Michigan [Ms. STABENOW], for herself, Mr. THUNE, Mr. LOTT, Mr. BROWN, and Mr. KOHL, proposes an amendment numbered 1011.

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

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

The amendment is as follows:

(Purpose: To insert provisions related to citizens petitions)

At the appropriate place, insert the following:

SEC. ____ CITIZENS PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is amended by adding at the end the following:

“(r) CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.—

“(1) IN GENERAL.—

“(A) NO DELAY OF CONSIDERATION OR APPROVAL.—

“(i) IN GENERAL.—With respect to a pending application submitted under subsection (b)(2) or (j), if a petition is submitted to the Secretary that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of the application, including a delay in the effective date of the application, clauses (ii) and (iii) shall apply.

“(ii) NO DELAY OF CONSIDERATION.—The receipt of a petition is not just cause to delay consideration of an application submitted under subsection (b)(2) or (j) and consideration of a petition described in clause (i) shall be separate and apart from the review of an application submitted under either such subsection.

“(iii) NO DELAY OF APPROVAL WITHOUT DETERMINATION.—The Secretary shall not delay approval of an application submitted under subsection (b)(2) or (j) while a petition described in clause (i) is reviewed and considered unless the Secretary determines, not later than 30 days after the submission of the petition, that a delay is necessary to protect the public health.

“(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A)(iii) that a delay is necessary to protect the public health the following shall apply:

“(i) Not later than 5 days after making such determination, the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement shall include a summary of the petition and comments and supplements, the specific substantive issues that the petition raises which need to be considered prior to approving a pending application submitted under subsection (b)(2) or (j), and any clarifications and additional data that is needed by the Secretary to promptly review the petition.

“(ii) Not later than 10 days after making such determination, the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

“(2) TIMING OF FINAL AGENCY ACTION ON PETITIONS.—

“(A) IN GENERAL.—Notwithstanding a determination made by the Secretary under paragraph (1)(A)(iii), the Secretary shall take final agency action with respect to a petition not later than 180 days of submission of that petition unless the Secretary determines, prior to the date that is 180 days after the date of submission of the petition, that a delay is necessary to protect the public health.

“(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A) that a delay is necessary to protect the public health the following shall apply:

“(i) Not later than 5 days after making the determination under subparagraph (A), the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement should include the state of the review of the petition, the specific outstanding issues that still need to be resolved, a proposed timeframe to resolve the issues, and any additional information that has been requested by the Secretary of the petitioner or needed by the Secretary in order to resolve the petition and not further delay an application filed under subsection (b)(2) or (j).

“(ii) Not later than 10 days after making the determination under subparagraph (A), the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

“(3) VERIFICATIONS.—

“(A) PETITIONS FOR REVIEW.—The Secretary shall not accept a petition for review unless it is signed and contains the following verification: ‘I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; and (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is filed on or about _____.’

I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to file this petition: _____. I verify under penalty of perjury that the foregoing is true and correct.’, with the date of the filing of such petition and the signature of the petitioner inserted in the first and second blank space, respectively.

“(B) SUPPLEMENTAL INFORMATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and that the subject document is signed and contains the following verification: ‘I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents. I further certify that the information upon which I have based the action requested herein first became known to me on or about _____.’

I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to submit this information or its contents: _____. I verify under penalty of perjury that the foregoing is true and correct.’, with the date of the submission of such document and the signature of the petitioner inserted in the first and second blank space, respectively.

“(4) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITION.—The Secretary shall annually submit to the Congress a report that specifies—

“(A) the number of applications under subsection (b)(2) and (j) that were approved during the preceding 1-year period;

“(B) the number of petitions that were submitted during such period;

“(C) the number of applications whose effective dates were delayed by petitions during such period and the number of days by which the applications were so delayed; and
 “(D) the number of petitions that were filed under this subsection that were deemed by the Secretary under paragraph (1)(A)(iii) to require delaying an application under subsection (b)(2) or (j) and the number of days by which the applications were so delayed.

“(5) EXCEPTION.—This subsection does not apply to a petition that is made by the sponsor of the application under subsection (b)(2) or (j) and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

“(6) REPORT BY INSPECTOR GENERAL.—The Office of Inspector General of the Department of Health and Human Services shall issue a report not later than 2 years after the date of enactment of this subsection evaluating evidence of the compliance of the Food and Drug Administration with the requirement that the consideration by the Secretary of petitions that do not raise public health concerns remain separate and apart from the review and approval of an application submitted under subsection (b)(2) or (j).

“(7) DEFINITION.—For purposes of this subsection, the term ‘petition’ includes any request to the Secretary, without regard to whether the request is characterized as a petition.”.

Ms. STABENOW. First, Mr. President, I thank Senator KENNEDY for his incredible leadership and work on this very important legislation, and Senator ENZI, as well, for his leadership and work and partnership with Senator KENNEDY on this legislation. I also thank Senator DODD for his years of advocacy for children. I join with him in opposing the Allard amendment, and believe Senator DODD has given us the first step as to where we need to go in terms of more medicines being available for children. I thank him for all of his leadership.

Mr. President, I today am offering an amendment—a bipartisan amendment, with Senator THUNE, as well as Senator LOTT and Senator BROWN; we also have Senator KOHL joining us—to close a loophole that the brandname pharmaceutical companies are using to prevent competition by delaying the entry of generic drugs.

Our amendment is based on the citizen petition provision that is included in a bill Senator LOTT and I introduced last session and again this session, but it has been greatly improved by contributions from Senator BROWN. I particularly thank him for his hard work and contributions to this amendment.

The citizen petition process is intended to allow citizens to raise legitimate issues regarding drug products, and it is very important we have that. However, the brandname pharmaceutical companies have increasingly used citizen petitions to delay access to safe, effective, and affordable generic drugs.

Simply put, citizen petitions have become PhRMA petitions to block consumers from having access to affordable medicines, unfortunately. The cost to employers, consumers, health insurance plans, and Government health plans, as a result of delayed

entry of generics, amounts to hundreds of millions of dollars—and in some cases billions of dollars.

For that reason, our amendment has the support of a very broad range of consumer groups, business groups, labor, pharmacy, and other organizations, including the AARP, the chain drugstores, General Motors, Ford, DaimlerChrysler, the AFL-CIO, the Alliance for Retired Americans, CalPERS, the National Committee to Preserve Social Security and Medicare, Families USA, the Pharmaceutical Care Management Association, the UAW, and the Coalition for a Competitive Pharmaceutical Market, which is a broad coalition of our employers and insurers across the country.

What would our amendment do? Our amendment would, first, preserve the right to file citizen petitions and raise legitimate safety issues. This is very important. We do nothing to take away the citizen petition. It would reduce the filings, though, of frivolous citizen petitions, and it would stop frivolous petitions from delaying generic entry—and thus costing businesses, consumers, and taxpayers—by allowing needed competition to bring down prices in the pharmaceutical market.

It would do so by, first, requiring the generic approval process to move forward while a petition is considered, unless the petition has raised legitimate public health concerns about the drug.

Second, it would require that final action on a petition be taken within 6 months of the petition being received.

Third, it would require petitions to be signed and include a verification that the petitioner has taken reasonable steps to ensure all relevant information is included in the petition and whether any payments have been made in exchange for filing the petition. This is very important.

And, fourth, it would ensure transparency surrounding FDA's decisions on whether to delay generic drugs on the basis of a citizen petition.

Our amendment improves upon the language in the Stabenow-Lott bill in that it sets timelines for FDA to evaluate petitions and absolutely ensures that if it is a legitimate public safety issue, then medicines will not be approved unless and until the safety issues are resolved.

Why do we need this amendment? Any person or organization can file a citizen petition with the FDA raising concern. We certainly want people to be able to do that. However, the process right now is being used in ways that are unintended.

The Medicare Modernization Act closed a lot of loopholes that the brandname companies were using to delay generics from going into the marketplace. So, unfortunately, they have looked to another tool. They are now using these frivolous citizen petitions.

Between passage of the Medicare Modernization Act and April 30, 2006, brandname companies filed 45 citizen

petitions requesting that the FDA delay approval of a competing generic drug. Of the 45 petitions, the FDA has ruled on 25 of them. Of the 25 petitions, 92 percent of them were denied.

The brandname companies often file these petitions right on the eve of the generic drug being approved, making it very clear that delay is the goal. These are “11th hour” petitions, as they have been called, and 12 of those “11th hour” petitions—12 of them—were denied in whole and 1 in part by the FDA.

What do the petitions ask for? Do they raise new and important issues? Unfortunately, the answer is no. Although the petitions are filed before or after a generic drug has received tentative approval from the FDA, they commonly simply request additional studies or additional data, based on mere speculation by the brand companies.

The FDA typically will not approve a generic drug until all the underlying issues of a citizen petition have been addressed. As a result, although the FDA regulators provide that citizen petitions should be addressed within 6 months—and that is what our amendment says—the average review time is 10 months. And 10 months means lots of lost dollars. It leaves consumers paying more, businesses paying more, and insurers paying more.

The fact is the vast majority of petitions filed by brand companies have nothing to do with science and everything to do with delaying generic drugs, stopping the competition. Consumers lose as a result of that.

In December 2005, Merrill Lynch released a report analyzing brand company use of the FDA citizen petition processes. The analysis involved a review of citizen petitions filed by brand companies since 2001. They said there was a “sharp uptick” in the number of citizen petitions filed by brand companies in 2004 and 2005 and,

In many instances, the filing of [these citizen petitions] by branded companies coincided with the expiration of a product's patent (or other marketing exclusivity) effectively delaying generic competition for months and sometimes years.

Why is this important? Well, I want to give you a few examples.

Flonase is a drug that is used to treat nasal symptoms and allergies. It is a very commonly used drug. In this case, the brand company filed multiple citizen petitions in an effort to delay the generic competition, a lower priced drug, from going on the market. All three citizen petitions were denied.

According to the FDA:

[The brand company] has not articulated sound public policy grounds for supporting a stay. In addition, [the brand name company] has not demonstrated that the delay resulting from the stay is not outweighed by public health and other public interests.

In other words, no sound public policy, but, unfortunately, the delay took months to resolve.

The following quote from Gary Buehler, Director of the Office of Generic Drugs at FDA, was reported in

the New York Times on February 23, 2006:

The agency was required to consider the petitions and to write responses. That took time and delayed the approval [process].

So what happened? Even though all of these petitions were denied by the FDA, it took so much time, and generic entry was delayed by 656 days, and the brand company was able to get \$1.65 billion more in sales.

We see with all of these drugs shown on this chart delays that have, in fact, allowed the brandname company to be able to continue sales. Unfortunately, these higher costs are paid by our seniors, consumers, and businesses that offer medication, as well as by insurers themselves.

We have not only large delays, but even in the case of 5 days, \$17 million more in sales. So there is great incentive to use delaying tactics in order to be able to continue this process.

Mr. President, I see my time is up. Let me say this amendment was carefully constructed to allow citizen petitions to continue. The overwhelming evidence from the Federal Trade Commission, the Office of Inspector General, as well as the FDA, and others—the overwhelming evidence is we are seeing this as a new loophole that is being used to delay effective competition and lower cost medicine from going into the marketplace. We can fix that and keep the citizen petition for legitimate issues. We certainly want that. We certainly are concerned about safety, as is the FDA. But it is time to close this loophole.

I thank my colleagues who are co-sponsoring this amendment and urge support for the amendment.

THE PRESIDING OFFICER. The Senator from Oklahoma.

AMENDMENT NO. 982

Mr. COBURN. Mr. President, I rise to speak for a minute in support of Senator Allard's amendment. I also want to recognize Senator DODD's work, and I believe he truly cares about us getting pharmaceuticals to children. But I think the bill as written today has some very great risks for our children.

I practice medicine. I can remember 25 years ago, for so many of the drugs, we did not know what we were doing as they related to children. We had sometimes great outcomes and sometimes poor outcomes as to the availability and knowledge of pharmaceuticals for children.

We have a system that started 10 years ago that has been highly successful. Mr. President, 144 drugs have now been studied in kids. We know what we are doing with 144 drugs. With 25 of those drugs, we now know not to use them for children.

How did we get there? We created an incentive that said: We will give you a 6-month patent extension if you will study pediatric indications and do a study on pediatric patients for this drug. It worked. As a matter of fact, it worked great.

Now, I am having trouble understanding, as a physician, the therapy

Senator DODD wants to put on this. He is back to practicing medicine the way we did pediatrics 25 years ago with his amendment. I certainly hope he is right if he wins because there are going to be a lot of children in trouble if he is not.

What his amendment actually says is, if you made \$1 billion off a drug, you only get a 3-month extension. I can see how we could look and say they are making too much money. But only 1 out of every 10 drugs we studied in pediatrics was a blockbuster drug. So what is happening with these high-profile drugs they are making a lot of money off of is they are the things that are funding the other 130 studies of drugs that are not blockbusters, that are not profitable.

So what Senator DODD has put in this bill—and I know it is well-meaning—is to limit that profitability, hoping drugs will become more reasonable, and gambling—a very risky gamble—that the research on pediatric drugs will continue with that 3-month extension.

He may be right. But as someone who cares for kids in my own practice, I am not willing to take that gamble. I am not willing to say: What if he is wrong? What if the studies go from 144 to 15?

Now that we are seeing all these new drugs coming out, we are not going to have a study for kids? We are going to take away opportunities for young children to have the benefits of a new drug because they are not studied? Or we are going to use the drugs anyhow, even though they are not indicated and we do not know what we are doing, in a hope—not in a knowledgeable, scientific way but in a hope we are doing some good?

We have a system that has worked very well. Senator DODD was supportive of that system. I do not know that he is right. He could be right. But the question will be: What if he is wrong? What if the next 100 drugs that come out for maladies that could have an application for children—especially some very small used drugs, specialty drugs for chemotherapy, and have a very low incidence of usage in kids—what if they are not available? What if they are not made available? How many children are not going to get that drug? Now the system is paying for 90 percent of the studies on drugs that aren't the blockbusters, and we are going to cut the incentive in half. It may work. I don't know where the knowledge is, the scientific inquiry, or the study that says that going from 6 months to 3 months is the right amount. What about 2 months? What about 1 month? What about 5 months? We don't know. So what are we going to do? We are now going to go back and practice on pediatric drug studies the way we used to practice on children. We are going to guess.

What the Allard amendment says is: We are not real happy there is this amount of tremendous profit, but we do understand that the profit off the

blockbuster drugs is actually paying for 90 percent of the studies on non-blockbuster drugs for kids, that we are going to take away that incentive. It is really comforting as a physician to know now what I didn't know before in terms of giving a kid a medicine and knowing how it is going to be metabolized, knowing its half-life, knowing it is different in a child and being able to dose it correctly, and confidently saying to a parent: I have given you something that is going to fix your child, that is going to cure this illness, and I know you are not going to have a side effect from it.

What we have done has worked. Why would we mess with it unless we know? I have listened to this debate. I don't see anybody telling me how we know we are not going to disincentivize further drug studies. If somebody can show me that, then I will be happy to vote against the Allard amendment. But there is not anybody who can show me scientifically that we are going to have another 144 drugs studied if we cut this in half. Maybe we will, maybe we won't. I can't see into the future, but I am cautious enough to know I love the progress we have made.

If we change this, if we change it—and it sounds as if, from the debate here, the Allard amendment isn't going to be approved—we better darn sure know what we are doing, and we better darn sure say that taking money away from drug companies in terms of extending patents is not going to have a negative impact in terms of positive benefits.

I am not the greatest defender of the drug companies. I authored the first bill that was signed by President Clinton which allowed reimportation of drugs into this country. Why did I do it? I think we need to have a worldwide market on pharmaceuticals. We don't. We have a controlled market everywhere except in this country. The American taxpayers end up subsidizing the research and subsidizing the profits. But I also recognize that some of these drugs' profits are the very things that allow me to now give comfort to a mother and a father when they have a very sick child.

I hope Senator DODD has the wisdom to know that he has done it just right and that there is not going to be one cancer chemotherapeutic agent that wasn't studied in children because it is not a blockbuster drug, and now that we are going to cut it to 3 months, that there will still be an incentive to make sure that the next child with a sarcoma or the next child with an aplastic anemia or the next child with a leukemia that is resistant to bone marrow transplant or anything else is going to be able to have the medicine.

We are going to go back to the way we practiced medicine 10 or 12 years ago. We are not going to know, and we are going to shoot from the hip and pray and hope. What we have today is we don't have to pray and hope anymore. We now have the studies.

I don't know the answer to it, and I am not saying Senator DODD is wrong, but I think a legitimate question to ask is, What if he is wrong? What if he is wrong? How many children aren't going to have drugs? How many children are going to have a drug complication? How many children are going to have a drug interaction? How many children's lives aren't going to be saved because we decided the drug companies are making too much money and we are going to tell them how much they should make?

Mr. President, I yield the floor.

The PRESIDING OFFICER. Who yields time?

Mr. DODD. Mr. President, if I may, I would like to divide my 10 minutes, and I would like to spend a few minutes on another part of the bill, the Pediatric Medical Device Safety and Improvement Act.

I thank Senator KENNEDY and Senator ENZI for including this bill which I authored in the underlying legislation.

The pediatric medical devices provision of the underlying bill is not subject to an amendment, but I want my colleagues to know what we have done with this provision, which is a complementary piece of legislation dealing with a similar set of issues as under the Best Pharmaceuticals for Children Act. That is, ensuring that medical devices used in children are safe and designed specifically for children. One of the fundamental hurdles with respect to children is that the market for products designed for them is relatively small. However, I believe the proposals in the underlying bill will make a huge difference in the lives of children.

This initiative provides a very comprehensive approach to ensuring that children are not left behind as cutting-edge research and revolutionary technologies for medical devices advance.

Like drugs, where for too long children were treated like small adults and were just given reduced dosages, many essential medical devices used by pediatricians are not designed or sized for children, and that has been the case for many years. Pediatric providers have had to resort to jury-rigging or fashioning makeshift device solutions for pediatric use. When that is not an option, providers may be forced to use more invasive treatments or less effective therapies. This legislation addresses the need to promote pediatric device development by providing incentives to manufacturers while at the same time equipping the Food and Drug Administration with appropriate authority to monitor and ensure the postmarket safety of medical devices used significantly in children.

One such example which highlights the need for this legislation is a device known as the Vertical Expandable Prosthetic Titanium Rib, a device invented, developed, and brought to market by Dr. Robert Campbell, Professor of Orthopaedics at the University of Texas Health Science Center. Dr.

Campbell appeared before the Health, Education, Labor and Pensions Committee in late March and testified about the arduous 14 years it took to bring the titanium rib to market. Dr. Robert Campbell made remarkable breakthroughs with this technology but the hurdles he faced were, at times, seemingly insurmountable.

I want to put up a photograph of a boy named Devin Alvarez, of Hialeah Gardens, Florida, which shows the remarkable difference this device has made for him. Devin was born with six ribs missing and a very small left lung and kidney. At birth, the doctors did not believe he was going to survive his first night. In May 2002, Devin underwent titanium rib implant surgery and the curve of his spine was reduced to 45 degrees. Devin stood straight for the first time in his life and, at present, Devin is a very typical 9-year-old boy who enjoys playing sports such as golf and baseball.

Again, remarkable ideas for pediatric medical devices happen regularly, but the incentives to transform ideas into new FDA-approved devices simply don't exist. So the motivation for the Best Pharmaceuticals for Children Act legislation 10 years ago dealing with pharmaceutical products for children is the same motivation behind this legislation—to encourage the medical device industry to develop and to engage in the kind of research to allow these technologies to emerge.

In describing the pediatric medical devices bill which is now included in this legislation, Dr. Campbell, who has been so instrumental in all of this, said:

This bill represents an historic step forward for children's medical and surgical devices similar to those steps taken on drugs. It will help future medical inventors of pediatric devices to avoid my mistakes and my frustrations so that they can get their devices "off the napkin," if you will, and into the pediatric patients who need them, in a safe and timely fashion.

I thank my colleagues from Massachusetts and Wyoming for working hard to make sure this will be a part of the underlying bill. I am grateful to them. It is my understanding that concerns have been raised by some in the medical device industry regarding a particular provision of the bill related to equipping the Food and Drug Administration with authority to ensure the safety of medical devices in children once they are already on the market.

The provisions in the bill mirror the recommendations made by the Institute of Medicine in its 2005 report on pediatric medical device safety. The Institute of Medicine found serious flaws in the current postmarket safety surveillance of these devices and the provisions in my bill correct those serious flaws. I am disheartened by those who would attempt to deprive children and physicians with information that pertains to device safety.

I think we have made some tremendous advances for children and their families in this legislation.

Mr. President, I ask unanimous consent that relevant material relating to the medical device provision of this legislation be printed in the RECORD.

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

ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION,

Washington, DC, March 5, 2007.

Hon. CHRISTOPHER DODD,
Russell Senate Office Building,
Washington, DC.

DEAR SENATOR DODD: On behalf of the Elizabeth Glaser Pediatric AIDS Foundation, I would like to thank you for your leadership in introducing the Pediatric Medical Device Safety and Improvement Act of 2007 and offer our strong support for this legislation, which will improve the health and well-being of children across the country.

This legislation will ensure that children enjoy the same protections as adults do when using necessary medical devices. Over the last few decades, countless innovative medical device products have been developed as a result of cutting-edge research and new technologies. As you know, children are being left out of the equation. Many challenges limit children's access to safe and effective medical devices, including differences in size, weight, metabolism rates, etc. With very few devices available for pediatric use, pediatric providers must resort to fashioning make-shift devices for their patients. Left with no alternative options, providers may be forced to use older or less optimal interventions, which can be less effective and could pose greater risk.

The Pediatric Medical Device Safety and Improvement Act of 2007 recognizes the urgency for greater development of medical devices created with children's special needs in mind. It provides a comprehensive approach to improving children's access to medical devices and includes provisions to assist innovators with technical and financial resources, streamline the regulatory processes, elevate pediatric device issues at the FDA and NIH, and improve incentives for devices for small pediatric populations—while still preserving the ability to ensure the safety of new products.

Thank you for your leadership and commitment to this issue. We look forward to working closely with you to ensure that children across the U.S. benefit from this important piece of legislation.

Sincerely,
PAMELA W. BARNES,
President and Chief Executive Officer.

THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY AND INTERVENTIONS,
Washington, DC, March 15, 2007.

Hon. CHRISTOPHER J. DODD,
Chair, Subcommittee on Education and Early Childhood Development, Senate Committee on Health, Education, Labor and Pensions,
Washington, DC.

DEAR CHAIRMAN DODD: I am writing to express our support for passage of your Pediatric Medical Device Safety Act of 2007. We greatly appreciate your efforts to expand pediatric patients' access to safe medical devices. Your proposal will be an important step forward.

The Society for Cardiovascular Angiography and Interventions is a professional association representing over 3,700 invasive and interventional cardiologists. SCAI promotes excellence in cardiac catheterization, angiography, and interventional cardiology through physician education and representation, and quality initiatives to enhance patient care.

Fortunately, cardiovascular disease is far less common in the pediatric population

than it is in the adult population. This good fortune does however frequently lead to unique challenges for the pediatric interventional cardiologist who treats these patients. Some of the challenges are clinical and we are more frequently solving those problems, saving children's lives and avoiding the trauma of surgery. Other challenges, and perhaps the most frustrating ones are related to obtaining the safe medical devices necessary to treat these patients. Devices that are available to our colleagues in Europe are not available in America. We support the FDA's efforts to ensure that only safe and effective medical devices are used on patients in our country, but when the entry barriers into the American markets are so high that manufacturers refuse to enter—some patients suffer and die needlessly. Required is an appropriate balance between the sometimes mutually exclusive goals of safety and availability.

We are especially pleased that your legislation will require the FDA to issue guidance to institutional review committees (IRCs) on how to appropriately consider the use of the humanitarian device exemption (HDE) at their institution. When HDE devices are not part of an ongoing trial, IRCs (which focus on reviewing the care of patients in trials) are sometimes confused.

We believe that giving the FDA explicit statutory authority to extrapolate from adult to pediatric patients in appropriate situations could help FDA officials expedite their review of some pediatric medical devices.

We applaud the provision that allows companies to make a profit on HDE devices designed for children. This change will encourage the development of more devices by providing an opportunity for profit and also by reducing concerns about audits, specifically those using different assumptions which could determine a profit was made when a manufacturer calculated their financial situation differently. We note that the 4,000 cap is arbitrary and far below the 200,000 patient limit that is placed on orphan drugs. We believe that more devices could be made available to pediatric patients and those with congenital heart disease if that cap is raised. We encourage you to consider such an increase either as a part of this legislation or broader FDA reform legislation.

We also understand that there are some concerns on the part of industry about the section 522 provisions of this proposal. As clinicians, we are not in a position to evaluate the precise impact of those provisions but we certainly hope those concerns can be resolved.

We look forward to working with you and your staff to support passage of this legislation and thank you once again for your efforts. Our Senior Director for Advocacy and Guidelines, Wayne Powell will be coordinating this effort for the Society and he may be reached at (202) 375-6341 or wpowell@scai.org.

Sincerely,

GREGORY J. DEHMER, M.D., FSCAI,
President.

FEBRUARY 28, 2007.

Hon. CHRISTOPHER J. DODD,
U.S. Senate,
Washington, DC.

DEAR SENATOR DODD: On behalf of the 60,000 primary care pediatricians, pediatric medical subspecialists, and surgical specialists of the American Academy of Pediatrics who are committed to the attainment of optimal physical, mental and social health and well-being for all infants, children, adolescents, and young adults, we write today to express our gratitude and support for the "Pediatric Medical Devices" legislation.

This legislation is an important step towards improving the process for the development of needed pediatric medical devices.

Children and adults often suffer from many of the same diseases and conditions, however their medical device needs vary considerably. Children are not just small adults and medical device technologies manufactured for adults often do not fit the needs of children. This problem forces pediatricians to "jury-rig" adult medical devices that are often too large, in order to make them fit smaller bodies. This practice, however, is not always effective and leaves children without optimal treatment. Additionally, children's device needs vary considerably due, not only to size, but also to different rates of growth, anatomy, physiological differences and physical activity levels.

This legislation offers incentives to device manufacturers to create needed medical devices specifically designed to meet the needs of pediatric patients and it gives the FDA the authority to require post-market studies to ensure continued efficacy and safety of these devices. The need for pediatric medical devices to treat or diagnose diseases and conditions affecting children is clear; it is essential that medical devices be manufactured with children's needs in mind.

Thank you for your continued commitment to improving the health and well-being of children. We look forward to working with you as this important legislation moves through Congress.

Sincerely,

American Academy of Pediatrics.
American Pediatric Society.
Association of Medical School Pediatric
Department Chairs.
Society for Pediatric Research.

STRYKER CORPORATION,
Washington, DC, March 6, 2007.

Senator CHRISTOPHER J. DODD,
Russell Senate Office Building,
Washington, DC.

DEAR SENATOR DODD: On behalf of Stryker Corporation ("Stryker"), I am pleased to announce our support for your legislation to improve the availability and safety of pediatric medical devices—the Pediatric Medical Device Safety and Improvement Act of 2007. Like you and your colleagues, we want our children to have access to the fullest and best range of possible medical treatments, even if that means doing or inventing something new just for them.

We view this as our responsibility both as the leading manufacturer of orthopaedic oncology prostheses in the United States and as a global medical technology company with a significant presence in other medical specialties, including craniofacial deformities such as cleft lip and palate. We take pride in partnering with and sponsoring a range of medical organizations, including one which last year was able to provide free cleft lip surgeries to 8,531 children in 23 countries. The surgery took only about 45 minutes and cost \$750 per child, but the corrective surgery changed, in a positive way, forevermore the lives of each and every child and the lives of their families, too.

We sincerely appreciate your leadership role on children's issues. We take very seriously not only our commitment to children with cancer and craniofacial deformities but also our responsibility to ensure that our devices are safe and effective for use in pediatric patients.

As you may know, there has been significant progress over the past two decades in the management of patients with musculoskeletal cancers that has improved both the survival rates and quality of life of afflicted individuals. Twenty years ago, the standard treatment for any primary malignant bone

and soft tissue sarcomas of the extremity was amputation of the affected arm or leg. Since that time, Stryker is proud to have partnered with leading pediatric oncology surgeons to develop limb-sparing, surgical solutions, including the implantation of a growing prosthesis that can be elongated to account for children's growth.

As with cancer, the treatment of craniofacial deformities is an area in which Stryker has also significantly improved and broadened its range of available medical products and solutions. With continued innovation of new and improved craniomaxillofacial technologies, Stryker hopes to continue to transform the lives of children with craniofacial deformities, such as craniosynostosis and cleft lip and palate.

It is our hope that your legislation will further spur the evolution of novel health care solutions for children. The bill's efforts to streamline approvals for devices with pediatric indications, improve incentives for the development of devices for small pediatric populations, and encourage the establishment of non-profit consortia for pediatric device development should be commended.

Stryker stands ready to assist you in your drive to stimulate the further development of child-centered medical technologies while closely monitoring the safety of such products after they have entered the market. Thank you again for your leadership on this important issue, and we look forward to working with you to advance your bill as medical device reauthorization legislation moves forward in the 110th Congress.

Sincerely,

ED ROZYNSKI,
Vice President,
Global Government Affairs.

ADVANCED MEDICAL
TECHNOLOGY ASSOCIATION,
Washington, DC, March 6, 2007.

Hon. CHRISTOPHER J. DODD,
Chair, Subcommittee on Education and Early
Childhood Development, Senate Committee
on Health, Education, Labor, & Pensions,
Washington, DC.

DEAR CHAIRMAN DODD: On behalf of the Advanced Medical Technology Association (AdvaMed), I am writing in support of the Pediatric Medical Device Safety Act of 2007. We particularly appreciate your willingness to work together with all stakeholders in the development of this legislation. Your bill is an important step in ensuring expanded access to medical devices for children.

As you may know, AdvaMed represents over 1,300 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Its member companies are devoted to helping patients lead longer, healthier, and more productive lives through the development of new life-saving and life-enhancing technologies.

AdvaMed fully supports the development of medical devices for pediatric patients. Your bill goes a long way to encourage the development of pediatric devices. As your legislation is considered, AdvaMed would like to continue to work with you to strengthen your legislation to enhance development of and access to pediatric devices. For example, we have a number of proposals to highlight existing FDA regulatory tools that could improve the number of devices cleared and approved for pediatric use. We also have recommendations to improve the proposed pediatric Humanitarian Device Exemption (HDE) and propose a compassionate use provision for extremely small pediatric populations to enhance your legislation.

Sec. 522 of the Federal Food, Drug, and Cosmetic Act (FFDCA) provides the FDA with broad authority to require postmarket

surveillance for any product for which FDA has concerns. We believe that the FDA's authority under Sec. 522 is sufficient to cover pediatric patients. In fact, we are concerned that the language in your bill may unintentionally reduce access to medical devices for pediatric patients.

Finally, although we recognize and appreciate your efforts to restrict the types of studies in your postmarket database to only "scientific" studies, we believe the language in your bill duplicates both the database that FDA is currently working to establish and the clinical trial registry legislation and legislation currently being contemplated by the HELP Committee.

In closing, thank you once again for your work on ensuring access to medical devices for children. We look forward to working with you on these and other improvements to your legislation as the bill moves through the Committee and the Senate.

Sincerely,

STEPHEN J. UBL.

RESPIRONICS, INC.,
Murrysville, PA, August 16, 2006.

Hon. MIKE DEWINE,
Russell Senate Office Building,
Washington, DC.

DEAR SENATOR DEWINE: Respiroics, Inc. is a global medical device company based in Pittsburgh, Pennsylvania. We are the worldwide leader at anticipating needs and providing valued solutions to the sleep and respiratory markets. We employ approximately 4,700 employees and have annual sales in excess of one billion dollars.

In our business, we often are called upon to work with pediatric patients. Based on this work, it is clear that changes are needed to facilitate an improvement in the availability of diagnostic and therapeutic medical devices for children.

Currently, a draft of a bill entitled "To improve the process for the development of needed pediatric medical devices" is being circulated among some Senators for discussion. After reviewing this bill, Respiroics believes that the changes contemplated by this bill could help improve the availability of medical devices for children. Therefore, Respiroics supports enactment of the bill.

We hope that you will join Respiroics in supporting this important legislation.

Sincerely,

DAVID P. WHITE, M.D.,
Chief Medical Officer.

BREAS MEDICAL AB,
Mölnlycke, Sweden, August 17, 2006.

Hon. CHRISTOPHER J. DODD,
Hon. MIKE DEWINE,
Russell Senate Office Building,
Washington, DC.

DEAR SENATORS DODD AND DEWINE: On behalf of Breas Medical, I would like to thank you for your efforts to expand the availability of medical devices for children. We appreciate your long-standing leadership on behalf of children and welcome your interest in ensuring that they are not left behind when it comes to critical medical advances. Our devices were developed in Europe and are available for home use in the pediatric population there. We have partnered with companies in the United States, including Sleep Services of America, and now have FDA approval for device use in adults. We are seeking approval for the use of our devices in children where there is a great need.

While children and adults suffer from many of the same diseases and conditions, their device needs can vary considerably. Cutting-edge research and revolutionary technologies have led to the development of many innovative medical products, however, very few are designed specifically for chil-

dren. We support your efforts to address the barriers to pediatric device development through legislation, particularly in the following areas:

1. Improving the ability of the Food and Drug Administration (FDA) to track how many and what types of devices are approved for children each year;

2. Streamlining pediatric device approvals by allowing the extrapolation of adult data to support pediatric indications, as appropriate;

3. Encouraging device manufacturers to create products for conditions that affect small numbers of children by removing existing restrictions on profit;

4. Improving federal support for pediatric device development by creating a coordinated research agenda and establishing a contact point at the National Institutes of Health to help innovators access existing funding;

5. Improving pediatric device availability by establishing demonstration grants to promote pediatric device development, including connecting inventors and manufacturers, product identification, prototype development, and testing; and

6. Improving post-market safety of pediatric devices by allowing FDA to call for postmarket pediatric studies, establishing a publicly accessible database of postmarket studies, and giving FDA the ability to require studies longer than 3 years if needed to answer longer-term pediatric questions.

Thank you for your leadership and commitment to this issue. We look forward to working closely with you toward passage of legislation to improve children's access to medical devices.

Sincerely,

ULF JÖNSSON,
President.

SELEON, INC.,
Baltimore, MD, September 23, 2006.

Hon. MIKE DEWINE,
Russell Senate Office Building,
Washington, DC.

DEAR SENATOR DEWINE: On behalf of Seleon Inc., I want to encourage you to continue your efforts to improve access to medical therapies for children by introducing the bill, "to improve the process for the development of needed pediatric medical devices" this fall.

Seleon Inc., a medical device manufacturing company, strongly supports this bill. Thank you for your ongoing support of children's health and this important issue.

Sincerely,

MICHAEL LAUK, Ph.D.,
President.

ELIZABETH GLASER PEDIATRIC
AIDS, FOUNDATION,
Washington, DC, April 17, 2007.

Hon. EDWARD KENNEDY,
U.S. Senate,
Washington, DC.

Hon. CHRISTOPHER J. DODD,
U.S. Senate,
Washington, DC.

Hon. MICHAEL B. ENZI,
U.S. Senate,
Washington, DC.

Hon. HILLARY RODHAM CLINTON,
U.S. Senate,
Washington, DC.

DEAR SENATORS KENNEDY, ENZI, DODD AND CLINTON: As organizations working to ensure better health care for the nation's children, we write to thank you for your long-standing commitment to children's health and to express our support for legislation to reauthorize the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) and to improve children's

access to safe medical devices. We are very pleased that BPCA and PREA reauthorization language and S. 830, the Pediatric Medical Device Safety and Improvement Act, have been included in the Chairman's mark of S. 1082, the "Food and Drug Administration Revitalization Act," for consideration by the Senate Health, Education, Labor and Pensions Committee tomorrow.

Over the past decade, Congress has enacted bipartisan legislation that has dramatically increased the number of drugs tested and labeled for children. The results from BPCA are extraordinary—over 336 requests have been generated for over 780 pediatric studies, resulting in over 115 new drug labels for children. Senator Dodd's BPCA reauthorization language strengthens this very successful existing program in several important ways, including ensuring prompt label changes, requiring that all study protocols and results be made public, improving adverse events reporting for children, and identifying and addressing important gaps in treatments for children's diseases. In addition, the BPCA language includes a reasoned approach to address the small percentage of drugs for which the exclusivity provision has far exceeded the incentive it was intended to provide pharmaceutical companies.

S. 993, the Pediatric Research Improvement Act (PRIA), introduced by Senator Clinton and included in the Chairman's mark, reauthorizes the Pediatric Research Equity Act of 2003 (PREA), which requires drug manufacturers to test their products for use in children. This law ensures that children are not a therapeutic afterthought and has generated impressive and invaluable safety and dosing information for children. Since the 2003 passage of PREA, 55 drugs have new or improved pediatric labeling. These drugs range from treatment of ear infections to the prevention of rejection of organ transplants. S. 993 places children on equal therapeutic footing with adults by creating the presumption that medicines coming onto the market for illnesses and conditions that occur in children will be labeled for pediatric use and be available in formulations (e.g., liquids, chewable tablets) that children can take.

The Pediatric Medical Device Safety and Improvement Act of 2007 provides a comprehensive approach to ensuring that children are not left behind as cutting-edge research and revolutionary technologies for medical devices advance. Like drugs, where for too long children were treated like small adults, many essential medical devices used extensively by pediatricians are not designed or sized for children. According to pediatricians, the development of new medical devices suitable for children's smaller and growing bodies can lag 5-10 years behind those for adults. S. 830 improves incentives for devices for small markets—while still preserving the ability to ensure the safety of new products once on the market. It provides assistance to innovators, streamlines regulatory processes and elevates pediatric device issues at the Food and Drug Administration (FDA) and the National Institutes of Health.

Despite our support for the Chairman's mark, we are disappointed that a key provision to make PRIA permanent has been omitted. As this legislation moves to the floor of the Senate, we urge you to restore the permanent authority of the FDA to ensure that children have properly studied medications as a matter of fact, not chance.

We are grateful for your long-standing leadership and commitment to improving the health of our nation's children and look forward to working with you toward swift

Committee action and passage of these pediatric therapeutic bills by the full Senate.

Sincerely,

American Academy of Pediatrics.

Elizabeth Glaser Pediatric AIDS Foundation.

AIDS Alliance for Children, Youth & Families.

American Academy of Child and Adolescent Psychiatry.

American Brain Coalition.

American Pediatric Society.

American Psychiatric Association.

American Thoracic Society.

Arthritis Foundation.

Association of Medical School Pediatric Department Chairs.

Children's Cause for Cancer Advocacy.

National Association of Children's Hospitals (N.A.C.H.).

National Organization for Rare Disorders.

National Research Center for Women and Families.

Society for Pediatric Research.

Mr. DODD. Mr. President, let me go back, if I can, to my proposal on the Best Pharmaceuticals for Children Act and the objections raised by my colleague from Colorado to it. Just for the record and so we understand what we are talking about, according to a study recently published in the *Journal of the American Medical Association* that looked at the costs and benefits of these pediatric trials. It showed that the overwhelming majority of drugs studied under this incentive program are not blockbusters.

In fact, the study found that less than 20 percent were. That leaves 80 percent of drugs completely unaffected by the underlying bill which the Allard amendment seeks to amend. To be clear, the proposal in the underlying bill that would adjust exclusivity from 6 months to 3 months affects less than about 20 percent of drugs studied under this program. Using data from this recent study, 80 percent of drugs studied under BPCA—those which do not fall into the blockbuster category—the 6 months' exclusivity would remain unchanged. It doesn't change that at all; only in cases where there has been over \$1 billion in prior year drug sales will the underlying bill change the exclusivity to 3 months.

This is to strike a balance. Obviously, I feel very strongly, having authored this legislation, about ensuring that appropriate clinical trials occur to protect children's health. Our notion was, when we wrote the legislation 10 years ago, that the 6 months of exclusivity would be the carrot that would incentivize the industry to go forward. There were some concerns expressed at the time that 6 months wasn't going to be anywhere near enough and that we would need more exclusivity. Some in the industry suggested a year or even 3 years of exclusivity. We settled on 6 months as the appropriate balance at the time.

What happened, of course, is we had this wonderful explosion of work that occurred. It resulted in nearly 800 clinical trials involving more than 45,000 children, with new pediatric labeling information on more than 119 drugs

where previously there was none. I recall the debate on this program ten years ago very well, the industry said: Six months is never going to be enough; none of us will step up to the plate on this. And they really argued very strenuously for something longer than the 6 months. In fact, the 6 months has worked well, and almost all requests issued to drug companies to conduct pediatric trials under this program have been accepted.

What I have had growing concern about is the 20 percent of drugs receiving exclusivity where the profit realized as far exceeded the carrot intended to provide to drug companies. So to strike that balance between the cost to taxpayers and the benefits to children, we are saying that where sales of a drug being studied under this program exceed \$1 billion in prior years, the company can get 3 months' exclusivity.

I don't know what the right answer will be on this issue. Neither me nor my colleague from Oklahoma can say with absolute certainty. But I recall the debate 10 years ago when many said 6 months will never be enough. Six months has done very well by the industry, as it turned out.

So by striking this balance and having the sunset provision which I strongly support in this legislation—and I have from the beginning—it will allow us to review periodically how we are doing with all of this.

There is an increase in Federal spending of \$50 million over 10 years as a result of the Allard amendment. I can't invoke a point of order because the impact on federal spending is outside our current budget window, but the Allard amendment comes with a \$50 million pricetag to taxpayers.

I believe this program is working well. We think by adjusting the length of exclusivity from 6 months to 3 months for a limited number of drugs, we are striking the right balance. The 5-year sunset will give us a chance to assess the program again and make a judgment: How are we doing here? Are we getting more or less of what we thought we would in the process? At that time, we will make a judgment again as to how we ought to go forward.

It is not easy to strike these balances. I know my colleagues who have engaged in these debates, try to come up with answers that will satisfy the various elements and concerns various Members have. That is what Mike DeWine and I did 10 years ago and why I had such a good partner in this where we struck that balance. Mike was under a lot of pressure to have a lot more than 6 months of exclusivity. I was under pressure in saying: Why do we give them any exclusivity? So we compromised on 6 months to see what happened. We got great results.

I would love to predict with absolute certainty that what we craft here will produce those same results. I can't say that absolutely. But based on the analyses of others who have looked at this,

their conclusion is this is a pretty healthy balance between consumer interests, taxpayer interests, and the needs of children. We will see what happens over the next 4 or 5 years as to whether this is continuing to produce the desired results. I believe it will. I think we will get that.

Here again, based on recent data, under my proposal, 80 percent of drugs studied under this program will see no change in the exclusivity award of 6 months. Again, for the 20 percent of drugs in the blockbuster category, they can receive 3 months of exclusivity. I still believe many will go forward, given that incentive.

So respectfully I say to my friend from Colorado—we serve on two committees together and we work well together on a lot of issues here. I respect him immensely. I do not question at all his motivations in offering this amendment. This disagreement is over the impact of his language versus the language I have crafted in this legislation as part of the committee print.

So I urge my colleagues to reject the Allard amendment and to stick with what we put together in the underlying bill. It is a good balance between taxpayer interests, consumer interests, and the interests of children and their families.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Colorado is recognized.

Mr. ALLARD. I understand I have 10 minutes allocated to me. I would like to take 4 minutes and allocate those to the Senator from North Carolina.

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

Mr. BURR. Mr. President, let me say, as Senator DODD finishes, that nobody has worked more tirelessly than he on behalf of children's health and specifically as it relates to prescription drugs. He did list a long list of people, including taxpayers and so forth.

This is about children, plain and simple. It is one group. It is our children, this country's kids. In 1997, I authored what became the Food and Drug Cosmetic Modernization Act. Prior to that, there weren't any clinical studies done for pediatric purposes. It was on the heels of that that Senator DODD and others created the exclusivity—exclusivity that Senator ALLARD is not changing. What we are changing is in the base bill and going from 6 to 3 months.

The reality is that, prior to the enactment, we didn't have companies that were studying the right dosages, what side effects there were, and whether it was effective in children. Sure, we had it for adults but not for kids. We have made tremendous progress. Under this pediatric exclusivity, though, we would cap it at 3 months. Companies that exceeded a dollar value—we pulled this out of the sky. Why \$1 billion and not \$2 billion? If it was \$2 billion, why not \$4 billion? Why not \$100,000? The reality is that none of us knows. There is no expert

who can tell us what is the right amount of incentive needed for a company to go through the types of trials to get these indications for kids. Why? Because every drug is different, and, more importantly, every child is different. So if we are going to err, I suggest that we err on the side of what has worked. Eighty-seven percent of all pediatric drugs have pediatric indications. It has been the carrot of 6 months.

Members will come to the floor and vote for or against the Allard amendment. I believe it is crucial that if we err, we err on the side of what already has worked and what continues to work. If Senator DODD prevails, I hope he is right. I hope he is right because we won't know, until this bill sunsets, whether in fact the incentive wasn't great enough for companies to go through this process to find out the indications for children.

The people who will suffer because of our willingness to arbitrarily change will be the kids. That is the same group I started with—the ones we should be solely focused on. It was the kids when this was created 10 years ago; it should be the kids today. If we are going to err, let's err on the side of the kids and not use this as a way to potentially alter the profitability of an industry or a given company. Let's make sure that the true beneficiary of the work of this body is in fact the children of this country.

I thank the Senator from Colorado for yielding me the time.

I yield the floor.

Mr. ALLARD. Mr. President, I join my colleagues in recognizing the fine work that Senator DODD has done in the area of children and children's health. He recognized one decade ago how important it was to have incentives in place for drug companies to properly label drugs so they are available and a physician has some guidance when they are putting therapy out.

I particularly thank Dr. COBURN for bringing a message to the floor that reflects his practical experience, in a period of time when there weren't a lot of drugs specifically labeled for children, to help him establish the proper dosage and to be aware of the side effects that may happen to various age groups. Also, I thank the Senator from North Carolina for his comments.

I think I bring a certain degree of practical experience to this debate as a veterinarian. We are frequently put in a position where we have to recommend drugs for therapy without having had research done. You have to extrapolate what you think might happen. The drug companies will do research on those products on which they can make a profit. I am talking about veterinary prescription drugs right now. There is a plethora of medications available in the human market. Many times, in treating eye conditions or some exotic problem in a species where there isn't much of a market, we have to take the scientific literature that

we know, and perhaps we know what the reaction may be in humans or maybe in some other species, where the drug company has done the research to reflect what the adequate dosage is, and we extrapolate that and predict as best we can what the reaction and how effective that drug may be at a certain dosage.

I think our children's health is too valuable to put a physician in a position where they have to make those sorts of subjective evaluations. I happen to believe the incentives we put in place a decade ago are working. That belief is substantiated by people who have looked at the program—the Best Pharmaceuticals for Children Act—and what happened as a result of that. I am not the only one who believes that. We had a study by the GAO, whose responsibility it is to look at programs to see whether they are working. They give this program a strong A. It is working. I don't think we ought to be messing with a program that has worked. Three months may be adequate, but there are a lot of other drugs that we have to still get on the market.

Several years back, during the Reagan administration—and it might have been President Reagan who said it—there was a general belief in Washington that if it is making a profit, let's tax it; if it is working, let's regulate it to death. Here is a program that is working because we have backed off on the rules and regulations. I don't think we ought to be making a decision, in light of the work that has yet to be done in moving pediatric medications to the market, to mess with this. Maybe 10 years from now it might be even more appropriate; I don't know. This is, to a certain degree, subjectivity. I think we have a huge need in making sure we have adequate medications available to treat children.

I agree with many of my colleagues that we should not be messing with a program that works, and we need to support this. I also wish to point out that this doesn't have an impact. There is not a budget point of order on this particular amendment. It doesn't add to the deficit of this country. So it is a program we can move forward on, without increasing the cost to the Federal Government.

I hope my colleagues will join me in supporting this most important amendment because it is very important, it is important to the practitioner who is trying to provide the best care that scientists will allow him to provide to patients—in this case, children. If we don't keep these choices available for the practitioner, then what happens is he doesn't have the options he should have to give the best care to our children?

So for our children's health in the future, I think we need to pass this amendment and go back to current law, which has been working so very well for us today.

Mr. KENNEDY. Mr. President, I ask unanimous consent that we be able to

proceed for 2 minutes. I yield myself 1 minute and 1 minute to the Senator from Wyoming.

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

Mr. KENNEDY. Mr. President, for the benefit of the membership, we are having a good, substantive debate this morning. We are going to vote on this amendment in a few minutes.

Because of the meetings of the leadership at the White House, we will not be able to have votes until 4 o'clock this afternoon. That doesn't mean that Senator ENZI and I are not prepared to move ahead in lining up some other amendments. We have that intention.

After this vote, the next vote will be at 4 o'clock. If there are those who have additional amendments, we ask them to come over. We are moving along. We have several items that are almost complete, which we will include. If there are any final amendments, we hope Senators will be in touch.

I thank my friend and colleague from Wyoming for his good cooperation and for making progress on a very important bill for the health and safety of American families.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Mr. President, I, too, encourage people to get their amendments to us, so we can talk about the amendments. The amendment process is a difficult thing around here because it doesn't allow for some of the tweaks noticed by people who have expertise in that area. If we get to talk about them first, sometimes there can be modifications to them before they are put in. We want to move this along and have some things to vote on at 4 o'clock today. I hope everybody will cooperate on it.

I thank Senator KENNEDY and his staff and my staff who have been working together with anybody who has an amendment. They were working at 3 and 4 o'clock this morning on different things, trying to get them ironed out so that it would be possible to move the bill forward.

Mr. President, what's wrong with limiting exclusivity for blockbuster drugs? It is the exact opposite of what we should do. The whole point of the law is to leverage the large adult market for the benefit of the smaller kids' market. The effect of the cap will be to discourage companies from studying the effects of the most-widely used drugs on kids. Seventy-five percent of the drugs are not being studied under the current incentive. We need more studied, not less.

Are not companies only studying blockbuster drugs that make the most money, not the drugs needed most in kids? No. According to a Tufts University study, only about 10 percent of drugs with pediatric exclusivity are blockbusters. GAO says most products obtaining exclusivity have annual sales of less than \$200 million.

Do companies get to choose the drugs they study? What is to stop companies

from “cherry picking” to make money, not help kids? No drug is eligible for pediatric exclusivity unless FDA requests, in writing, a pediatric study of the drug. FDA’s decision is based on whether more information about safety and efficacy for children is necessary.

Doesn’t the Duke/JAMA study demonstrate that 6 months of additional exclusivity is a windfall? It’s been said that a cynic is someone who knows the cost of everything, and the value of nothing. That applies here. The Duke/JAMA study concluded that the financial benefit of exclusivity for blockbuster drugs often exceeded the cost of the pediatric study. This completely misses the point. This law is not about micromanaging drug company profits. It’s about helping kids. In fact, the very last sentence of the study reads: “Clearly, however, the greatest return of the exclusivity program is the benefit derived in obtaining new information relevant and applicable to the care of children, and this benefit should not be compromised.”

Companies can spend only a few million dollars on a study and get many millions in return. Shouldn’t the reward be equal to the amount spent on studies? The incentive is designed to raise the priority of pediatric studies among all the competing research priorities for drug development within companies. Just covering the cost of the studies will not do it—the drug company knows it can put those same dollars into the development of a drug for adults that will earn much higher profits. Incentives work by making pediatric study more attractive than other studies for drug companies.

Aren’t windfall profits unfair? No. The benefits to kids, and to society in general, from pediatric studies far outweighs the cost.

What are workability issues with the exclusivity cap? FDA says the cap has “serious workability issues.” It is unclear how FDA will obtain the right type of sale data or how the data’s accuracy can be verified. FDA would spend lots of time litigating the validity of exclusivity decisions, and less time making drugs safe for kids.

Why shouldn’t we restrict excessive drug company profit? The problem is not excessive profits. The problem is that most drugs aren’t tested for kids. It is wrong to play the politics of drug pricing at the expense of kids.

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

The PRESIDING OFFICER. Is there a sufficient second? There is a sufficient second.

The question is on agreeing to the amendment.

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 South Dakota (Mr. JOHNSON), and the Senator from Washington (Mrs. MURRAY) are necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from New Mexico (Mr. DOMENICI), and the Senator from Arizona (Mr. MCCAIN).

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

The result was announced—yeas 41, nays 53, as follows:

[Rollcall Vote No. 148 Leg.]

YEAS—41

Alexander	DeMint	Martinez
Allard	Dole	McConnell
Bennett	Ensign	Murkowski
Bond	Enzi	Roberts
Bunning	Graham	Sessions
Burr	Grassley	Shelby
Chambliss	Gregg	Smith
Coburn	Hagel	Specter
Cochran	Hatch	Stevens
Coleman	Hutchison	Sununu
Corker	Inhofe	Thomas
Cornyn	Isakson	Voinovich
Craig	Kyl	Warner
Crapo	Lugar	

NAYS—53

Akaka	Feinstein	Nelson (NE)
Baucus	Harkin	Obama
Bayh	Inouye	Pryor
Bingaman	Kennedy	Reed
Boxer	Kerry	Reid
Brown	Klobuchar	Rockefeller
Byrd	Kohl	Salazar
Cantwell	Landrieu	Sanders
Cardin	Lautenberg	Schumer
Carper	Leahy	Snowe
Casey	Levin	Stabenow
Clinton	Lieberman	Tester
Collins	Lincoln	Thune
Conrad	Lott	Vitter
Dodd	McCaskill	Webb
Dorgan	Menendez	Whitehouse
Durbin	Mikulski	Wyden
Feingold	Nelson (FL)	

NOT VOTING—6

Biden	Domenici	McCain
Brownback	Johnson	Murray

The amendment (No. 982) was rejected.

Mr. DODD. Mr. President, I move to reconsider the vote.

Mr. KENNEDY. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

AMENDMENT NO. 990

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. DORGAN. Mr. President, I offered an amendment yesterday that a number of my colleagues have spoken on, both in favor and against. When I laid down the amendment yesterday, I did not speak on it, so I wish to take some time to describe what the amendment is, why it is important, and why those who have spoken against it are wrong.

Let me describe, first of all, what the amendment is about, and let me do it, if I might, by asking unanimous consent that I be allowed to show on the floor of the Senate two bottles of medicine.

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

Mr. DORGAN. Mr. President, these two bottles of medicine contain Lipitor. Most people know about Lipitor. It is a cholesterol-lowering drug. This particular prescription drug

is produced in Ireland, and it is sent from that production point, in a plant, by the way, that is approved by our Food and Drug Administration. We inspect that plant, as we do others. So they produce an FDA-approved drug—this drug has been approved—in a plant in Ireland that has been inspected by the FDA. These two bottles of medicine containing Lipitor, 20 milligrams, identical bottles with a difference in color, are sent to two different places in this case but sent to many places around the world. This one is sent to the United States to be sold to consumers in the United States that want to lower their cholesterol. This one is sent to consumers in Canada for those Canadians who wish to take Lipitor to lower their cholesterol.

There is a difference. Oh, not in the medicine, not in the bottle, and not in the instruction. What is the difference? The American consumer is told: You have to pay twice as much. Let me say that again. The difference is the price. The Canadian consumer is told: You pay half the price. The American consumer is told: You pay double the price.

Now, I use the Lipitor as an example only to describe a very significant problem. We have price controls on prescription drugs in this country. Those price controls are not established by the Government. They are not established by the Congress. These price controls are imposed by the pharmaceutical industry.

I have a problem with the pharmaceutical industry saying to the American consumer: We have a deal for you; we want you to pay the highest prices in the world for prescription drugs. We are going to sell them all over the world: Italy, Japan, Germany, France, China. We are going to sell our prescription drugs, and in almost every circumstance, in other countries, we are going to give them a lower price. But to you consumers in the United States, we say: You pay the highest prices.

Let me give you a couple of examples, and I will use Canada, but I could be using any number of countries around the world. Lipitor. We pay 96 percent more. Plavix, 46 percent more. Prevacid, 97 percent more than if you were to buy it in Canada. Zolof, 52 percent more. It goes on and on.

I said yesterday that I actually sat on a bale of straw on a farm talking to a bunch of folks, and there was a fellow in his 80s sitting on a straw bale talking about life and things, and he said: You know, Mr. Senator, my wife has been fighting breast cancer for 3 years. Every 3 months, we have driven to Canada to buy Tamoxifen because we save 80 percent by buying Tamoxifen to help my wife fight her breast cancer—we save 80 percent by buying it in Canada. So every 3 months, for 3 years, we have been driving back and forth to Canada because it is the only way we can afford that drug. He said: How do you justify that? How do you explain the

difference in price? I said: I can't. It doesn't make any sense to me.

I don't come here to be critical of the pharmaceutical industry, I come here to be critical of their pricing policy. Their pricing policies are unfair to the American consumer. Yes, the pharmaceutical industry produces miracle drugs; a fair amount of them are produced with research we pay for through the American taxpayer at the National Institutes of Health. Others are produced with the research and development done by the drug industry themselves. But I would say that miracle drugs offer no miracles to those who can't afford to buy them, and that is the point.

What is fair pricing for pharmaceutical drugs, and why is it so unfair at this point to the American people? I introduced a piece of legislation with many of my colleagues, and let me read a list of the bipartisan cosponsors, Republicans and Democrats, who sponsored the legislation that we introduced in this Congress, the very legislation I have now offered as an amendment to this bill. Let me go through a list of some of the names. Myself, Senator SNOWE, Senator KENNEDY, Senators STABENOW, BINGAMAN, FEINSTEIN, NELSON, KOHL, SCHUMER, INOUE, BROWN, SANDERS, Senators GRASSLEY, MCCAIN, SPECTER, COLLINS, DURBIN, PRYOR, LEVIN, LEAHY, TESTER, CONRAD, MCCASKILL, JOHNSON, CASEY, BOXER, SALAZAR, CLINTON, LINCOLN, FEINGOLD. Thirty-three sponsors for this legislation that I have offered as an amendment here today.

Let me now begin to describe a few of the opponents' arguments and then respond to them. My colleague, Senator COCHRAN, came out and offered an amendment that says in order for this to be effective, the Secretary would have to certify that it poses no additional risk to the public health and safety. Well, that is an amendment that is designed to kill the bill because the Health and Human Services Secretary will not certify to anything.

Does anyone think the Health and Human Services Secretary or the FDA or anybody is going to certify that the chicken feed served to 3 million chickens with contaminated material from China, which now goes into our food source that humans are eating in this country today, that poses a risk? Or how about we say that we want them to certify that the vegetables imported into this country from Mexico pose no additional risk? Does anyone think anybody is going to certify to that? Do you, really?

I could go on at great length. Does anybody know of any circumstance in which any part of our food supply is certified by anybody saying that the import of this poses no additional risk? No. So this is an amendment designed to make this inoperative.

What my amendment does is actually make our drug supply safer with respect to the importation. Because the fact is people are now going back and

forth across the border, those who can get there by car. Most Americans can't, but most are bringing prescription drugs back across the border for a 3-month supply. This makes that even safer.

I am going to go through a number of the safety areas here, but first let me say this. I understand that the pharmaceutical industry wants to continue its pricing policies. I understand that. It is perfectly understandable. I have some differences with them.

In the morning, perhaps while you are brushing your teeth or shaving, getting ready for work, you might turn on the television and what do you hear them saying on television? They say, well, you need to go talk to your doctor. You are brushing your teeth and thinking, why on Earth should I go talk to my doctor? Because the television advertisement says that you need to see if the little purple pill is right for you. You need to ask your doctor whether you ought to take the purple pill. I don't know what the purple pill is, but you get this urge that you think, maybe I should go ask somebody. If everybody is taking the purple pill, maybe I should find out if the purple pill is right for me. Maybe it is right for my colleague from Wyoming or West Virginia. Maybe we all ought to be taking the purple pill. I don't know.

If they ever describe what the purple pill does, they also have to then describe what the potential risks might be of the pill. But in most cases, the TV just says, go talk to your doctor to see if it is right for you. So we have a lot of advertising going on, and we dramatically increase the use of prescription drugs. Go talk to any doctor and ask them if patients are coming to them and telling them what kind of prescription medication they want to take because they heard it on television. Go ask a doctor, and I tell you what the doctor will say. Absolutely.

Of course, these are medicines that you can only get because a doctor has said you need them and, therefore, I prescribe them. Television advertising is creating a demand. I am not here with an amendment on television advertising, but I am observing that every morning they ask whether the purple pill, or whatever other medicine they are talking about, is right for you and that you ought to be visiting with your doctor about it.

In addition to the issue of demand, there is the issue of pricing. I don't know. Somebody doesn't have to give me five reasons or three reasons or even two reasons. I want somebody to give me one reason, just one, that says we think it is perfectly defensible that the American people ought to be charged the highest prices for prescription drugs. Or in the specific case I mentioned, we think it is perfectly defensible that the American consumer taking Lipitor ought to be charged twice as much as the Canadian consumer. Give me one reason. I am not

asking for five, just one reason. I can't believe there is one person on the floor of this Senate that has the ability to construct one thoughtful reason in support of that policy.

Let me put in the RECORD a letter the AARP has written yesterday. Let me read a little bit of it:

On behalf of the AARP's more than 38 million members, we urge you to support the Dorgan-Snowe importation amendment. This amendment provides for the safe, legal importation of lower price prescription drugs from abroad.

In the quest for lower-priced prescription drugs, many Americans are already importing prescription drugs from abroad. [The Dorgan-Snowe] amendment would create a framework for the safe, legal importation of prescription drugs that will better protect the health and pocketbooks of those desperate for lower-priced prescription drugs. We are also very pleased to see that the [Dorgan-Snowe] amendment includes a number of safety requirements including inspections and measures to prevent the counterfeiting of imported drugs.

I ask unanimous consent that the entire letter be printed in the RECORD.

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

AARP,
April 30, 2007.

Hon. BYRON DORGAN,
U.S. Senate,
Washington, DC.

DEAR SENATOR DORGAN: AARP is pleased to endorse your importation amendment to S. 1028, the Prescription Drug User Fee Amendments of 2007. Your amendment will provide for the safe, legal importation of lower-priced prescription drugs from abroad. We applaud your continued leadership on this important measure to help reduce prescription drug costs.

Brand name prescription drug prices continue to rise at unsustainable rates. AARP's latest Rx Watchdog report released in March 2007 found that manufacturers' prices for nearly 200 of the brand-name medications most commonly used by older Americans rose 6.2 percent in 2006—nearly twice the 3.2 percent rate of general inflation. These prescription drug price increases particularly burden the tens of millions of Americans who lack access to affordable prescription drug coverage.

In the quest for lower-priced prescription drugs, many Americans are already importing prescription drugs from abroad. Your amendment would create a framework for the safe, legal importation of prescription drugs that will better protect the health and pocketbooks of those desperate for lower priced prescription drugs. We are also very pleased to see that your amendment includes a number of safety requirements including inspections and measures to prevent the counterfeiting of imported drugs.

We believe the phase-in set forth in your amendment will enable better management of those important new activities. It is important that any importation system begin with Canada. However, ultimately in order to be sustainable, any importation system would have to go beyond Canada. Finally, no importation system could function if entities (particularly pharmaceutical manufacturers) were allowed to shut off or manipulate supply of their product. Your amendment grants the Federal Trade Commission the authority to prevent such abuse.

We understand that there may be attempts to limit consumers' ability to import prescription drugs by attaching a certification

requirement to your amendment. AARP believes that your amendment strikes the right balance between providing a workable system of importation while at the same time ensuring the safety of imported pharmaceuticals. Thus, we believe that any amendment that would require Administrative certification in any form would be nothing more than an attempt to prohibit the implementation of an importation system. We oppose such a change to your amendment.

As you know, our members widely support legislation that would allow for the safe, legal importation of prescription drugs. They have expressed strong interest in knowing how their elected officials vote on key issues that affect older Americans. As part of our ongoing effort to let our members know of action taken on key issues, we will be informing them how their Senators vote on your amendment when it comes to the Senate floor.

We look forward to working with you and your colleagues on both sides of the aisle to enact this needed legislation. If you have any further questions, please feel free to contact me, or have your staff contact Anna Schwamlein Howard of our Federal Affairs staff at 202-434-3770.

Sincerely,

WILLIAM D. NOVELLI,
Chief Executive Officer.

Mr. DORGAN. It is interesting to me that those who have spoken against this come to the floor of the Senate with the specter of counterfeiting. Counterfeiting exists at this point. My amendment will make it less likely. This puts in place the very safety features and the very capability to try to shut that down. But if they are talking about counterfeiting that is existing now, it is existing without these kind of safety precautions on importation.

Let me describe a man, a very courageous man named Dr. Peter Rost. He came to testify at a hearing we held on the subject of reimportation. Peter Rost was responsible for a region in northern Europe where they did this routinely. They had an approach in Europe called parallel trading. If you are in Germany and want to buy a prescription drug in France, that is not a problem. If you are in Italy and want to buy a prescription drug in Spain, that is not a problem. They have done this for a couple of decades. Dr. Peter Rost was in charge of a region in northern Europe. He said:

I never once—not once—heard the drug industry, regulatory agencies, the government or anyone else saying that this practice was unsafe. And 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.

This from Dr. Rost. He actually paid a price for speaking out and speaking the truth. He actually was working for Pfizer Pharmaceuticals at the time. He has had a little problem with his employer, but that is another story perhaps for another day. But Dr. Rost said it right, in my judgment.

Let me, if I might, show this quote from Tommy Thompson, former Health and Human Services Secretary. He says:

The law is this: In order to import drugs from any country, and especially Canada, I

have to certify that all those drugs are safe. That's an impossible thing. If Congress wants to import drugs, they should take that provision out, because the Secretary of Health and Human Services cannot certify that all drugs coming into America are safe.

Let me tell you something about Tommy Thompson. I like Tommy Thompson. He was a Governor from Wisconsin. That's a guy with spirit. I kind of like him. In fact, I think he is thinking about running for President. I probably will not vote for him because I am going to vote for a Democrat in this coming election, but I like Tommy Thompson. Do you know what he said to me at the elevator, right outside this Senate door after he left Health and Human Services? He was getting off the elevator as I was coming on the elevator, and I had been down to see him about this issue of reimportation of prescription drugs. I said: Secretary Thompson, why don't you work with us to get this done?

He said: I can't.

He explained there are lots of things going on, including the White House makes the call on this policy, et cetera. At any rate, after he left as Secretary of HHS, he was coming off an elevator out here and I was getting on the elevator. We said hello. I like him. I think he was a good Secretary.

He turned around and said to me: BYRON, he said, keep going on that imported drug issue. You are right about that. You are right about that.

That is after he left office. He comes from Wisconsin. He knows. That is a State that borders Canada. He knows his constituents are able to just go miles up into Canada and seek prescription drugs for a fraction of the price.

Let me respond for a moment to this issue of safety because my colleague from Mississippi and others have spoken about it. David Kessler, he served for 8 years as FDA Commissioner. He is a terrific public servant. In my judgment, there has been none better than Dr. Kessler over at the FDA. Here is what he said:

[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 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 those standards and are not counterfeit.

Let me make one with respect to this. A couple of my colleagues stood on the floor and said: Well, you would create a giant bureaucracy in order to do this. That is interesting. The Congressional Budget Office actually scored this bill we have introduced. Do you know what the score was? This will save \$50 billion in a 10-year period.

Mr. BYRD. With a "b"?

Mr. DORGAN. With a "b," \$50 billion; just over \$5 billion of that savings is to the Federal Government; just about \$45

billion of that savings is to the American consumer. Is that an illusion? No, that is the score we have.

We come to the floor of the Senate and the question is asked: Whom do you stand for? Whom do you stand with? Some will say: You know what, we believe—they will not say that. I do not believe they will stand and say: We believe the current surprising strategy is right, by which Americans are charged the highest price. I don't think they will say that. I think what they will see is we think there are serious safety issues with this.

Let me again refer back to the expert who would perhaps know more about this than any other American. I have heard things read on the floor of the Senate by the assistant this or the assistant that. The last assistant we had come over to a hearing I held had not even read the bill. That is some assistant. At any rate, we don't have to worry about assistants. Let's worry about Dr. David Kessler, who I think is the preeminent authority. He said we can do this; we can do this, and it will make the drug supply in this country safer.

I wish to talk about the issue of safety. It is not as if prescription drugs are not coming into this country from other countries. They, of course, are. Our pharmaceutical industry, and others, manufacture all over the world and then they ship these drugs into our country to be sold here. But there is a law that prohibits anyone other than the manufacturer to ship them in. Lipitor is made in Dublin, Ireland; Nexium is made in France; Tricor is made in France; Actos is made in Japan; Vytorin is made in Singapore and Italy and the United Kingdom. Those are pills made elsewhere, the medicines are made there and they are shipped here. Are they safe? Sure. I believe they are safe. I believe we have an enormously safe drug supply, despite the fright that is discussed on the floor of the Senate about counterfeiting.

Is counterfeiting an issue? Sure, it is. It has nothing to do with this subject. Counterfeiting exists now and we have to take action and steps to fight it and we should fight it aggressively. But the fact is, this legislation that we introduce has a range of safety features that will guarantee the safety of FDA-approved prescription drugs that are imported into this country.

First of all, we provide that only FDA-approved medicines with a "chain of custody" will be sent into this country. Dr. Mark McClellan, who used to head the FDA, and I was very critical of him because he continued to speak as if he represented the pharmaceutical industry instead of regulating it as head of the FDA, he and I had substantial differences, but even he said the chain of custody in Canada is safe, almost identical to the chain of custody for prescription drugs in the United States.

If that is the case, and he said it, then tell me with respect to this risk,

I go to a little one-room drug store in Emerson, Canada, with a woman named "Sylvia" and a number of other senior citizens. We take a little bus up to a one-room drugstore in Emerson, Canada, and they bring their prescriptions.

That drug store has a licensed pharmacist, as the drug store a few miles south of the border has, a licensed pharmacist and a chain of custody from the drug manufacturer to the wholesaler to the retailer to the drug store. We go to that drug store and Sylvia and her friends buy prescription drugs at a fraction of the price they would have bought it in Fargo, ND, that morning. Tell me, is there a risk in that transaction? The answer is no. Don't represent there is because there is not.

The chain of custody is nearly identical. I am speaking now of Canada. Tell me there is a risk and you are wrong, there is not.

All the protestation on the floor of the Senate on this issue is protestation in support of the pharmaceutical industry. I like the industry. I have been helpful to them. I support research and development tax credits to find new prescription drugs. I have done a number of things to say I want us to be able to have a successful pharmaceutical industry in this country. But I am not willing to go so far as to say it is OK to me, I will be quiet if you decide the pricing strategy is we are going to price our prescription drugs at the highest prices for the American consumer. I will not sit in this chair and say it is fine with me. It is not, and that ought not be fine for any Member of the Senate. It should not.

Mr. BYRD. No. No.

Mr. DORGAN. Let me make some comments on safety. One-quarter of the prescription drugs taken in this country are produced outside this country in foreign manufacturing plants. In the last 5 years, the FDA has inspected more than 850 foreign drug factories in 41 different countries. The drug industry wants to take advantage of the global economy to manufacture their drugs in lower cost countries, but they do not want a licensed U.S. pharmacist and drug wholesalers to be able to take advantage of the global economy to get the best price for the American consumer.

Let me say that again. The pharmaceutical industry wants to take advantage of the global economy for the purpose of their manufacture and profitability, but they do not want a licensed U.S. pharmacist or licensed wholesaler to be able to access those same drugs from a licensed wholesaler or pharmacist in another country in order to pass along lower prices to the American consumer. I do not think that is right.

We have addressed all the issues that have been raised by two former Secretaries of Health and Human Services, saying in order for me to certify, we need to have this and that. We have ad-

dressed those safety issues in this legislation. Yet if you listen to the opponents who stand on the floor of the Senate with the talking points, there are safety and security issues and all these issues—I mean I have gotten the talking points, too, from the pharmaceutical industry. Heck, if I were in their position, I would want to keep this situation as long as possible. You have a good deal, don't give it up.

But one of my colleagues yesterday, speaking on the floor, said: The people who are offering this amendment—and again this amendment goes from Senator KENNEDY to Senator MCCAIN to Senator GRASSLEY to Senator STABENOW back and forth, Republicans and Democrats. One Senator, one of my colleagues, stood up and said there are political motives.

I said I hope you don't mean that, and I hope you will withdraw that. This is a thoughtful serious debate. There are plenty of people who feel strongly in opposition to my amendment. Fine. But then you should stand and debate the proposition that you support. We support the current situation. We support the circumstance in which a pricing policy that prices the prescription drugs higher for the U.S. consumer is already with us. That ought to be the proposition you stand and support.

You ought not stand and say there are significant safety issues here because that is not the case. It is not.

There is much to say, and a number of my colleagues will continue to debate this issue. My own view is this is a hard issue to get passed on the floor of the Senate. I say that having had some experience with it.

I must say I admire the pharmaceutical industry. They have been tough opponents. They feel strongly about their profitability. They say a couple of things. No. 1, this is unsafe. It is not. No. 2, it would somehow exacerbate counterfeiting. It will not. Counterfeiting now exists. We need to address that, but this would in many ways make the supply of drugs safer. They say a number of other things they believe—that this would cause the American people to change their buying habits in ways that would be unhelpful to them. They believe you do not have a chain of custody that you can control or see that is transparent. That is not true.

You know, I mentioned earlier about this issue of the industry itself. I want the pharmaceutical industry to succeed. They succeeded. This has been a very successful industry. They have made a great deal of money. But on this issue of research and development, I want them to engage in research and development. We are doing it here in the public sector of the NIH. We turn that material over to the pharmaceutical industry. They do research and development. Good for them. They spend a massive amount of money on promotion and development. I think that is of some concern for a number of people, but I am not here saying I do

not want the pharmaceutical industry to succeed. There are those who also say, in addition to safety and other issues, they will say, all right, if you do not allow a pricing policy that prices prescription drugs at the highest level for the American consumer, it will mean less research and development by the pharmaceutical industry.

The fact is, more research and development has gone on in other countries in which they charged lower prices for the same prescription drugs. So how does that hold water? It does not. My hope is, at long last, perhaps, this Senate will stand up for the interests of the American consumer. At long last, we can put to bed these specious arguments about safety because they are not applicable. Read the bill. These arguments about safety are not accurate. Let's put to bed this connection between counterfeiting. It is not accurate. Let's also stop talking about how this would shut off research and development. That is not accurate.

Let's talk about what this bill would do, what this piece of legislation, this amendment we have now offered is. It would save about \$50 billion over 10 years, \$5 billion a year. It would probably require the drug industry to reprice for sure because, the fact is, if they are pricing at the highest levels to the American people, and they say that is the only way they can recover their costs, perhaps others ought to be paying more to recover costs. I don't know. I am saying that the industry, I believe the top seven U.S. pharmaceutical companies, a couple of years ago made \$34 billion together. The industry has done very well. But there are a whole lot of folks in this country who haven't.

It was about 9:30 one night in a tiny town north of Highway 2 in North Dakota. I had a town meeting. At the end of the town meeting, an older woman came up to me, and she was probably in her early eighties. She said: Mr. Senator, may I speak to you? I said: Sure. She grabbed my elbow with her hand. She began to speak. Her eyes welled up with tears and her chin began to quiver. She said: I am in my eighties. I don't have much money. She said: I have got heart disease and diabetes. My doctor prescribes medicines for me that are too expensive. I cannot afford them. Is there any way you can help me, Mr. Senator? Is there a way you can help me?

This woman, with tears in her eyes, was asking: Is there someone who can help me manage this disease of mine because I cannot afford these medicines?

We have taken steps to try to be helpful. I might say that some in the drug industry have taken steps by offering programs to low-income people. It is not enough. But I commend those who have and recognize it. But we should not have to do that in this country. We should not have the highest prices for prescription drugs. We should not have an 80-year-old woman driving

to Canada to pay four-fifths less in cost for Tamoxifen to treat her breast cancer. That should not happen.

So let's do this. Let's create a regime of safety—which we have done. Wonder about it? Go talk to Dr. David Kessler. You find a better expert, you tell me his name. We have created a regime of safety here that will work. Then let us decide to proceed, as Europe has done, as others have done, to allow the global marketplace to work for real people, to work for ordinary folks, not only the big interests. The big interests always do well. At the end of the day, when all of the dust settles, and all of the shouting is over, guess who almost always wins. Yes: Them that's got is them that gets and I ain't got nothing lately. I think that was Ray Charles.

Isn't that always the case? When the dust settles, the big interests always win. Let's hope when the dust settles here tomorrow morning, and we have a vote on something that is important, is something that will help a lot of American people, millions, tens of millions, hundreds of millions, let's hope when the dust settles here, ordinary Americans will say, you know what. We won today in the Senate. Hallelujah, we won a vote in the Senate. Let's hope that is the case tomorrow morning.

I yield the floor.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. SANDERS. Mr. President, there is not much I can add to the brilliant remarks made by Senator DORGAN. I think he, in a very comprehensive manner, made clear why the Senate and this country should move to prescription drug reimportation. I think he very ably answered the objections that we know are sure to come and made the case as well as could be made.

I want to touch on some personal reflections on this issue. Some years ago, as the Congressman then from the State of Vermont—and I live an hour and a half away from the Canadian border. My State borders Canada. Some years ago, I put together what, in fact, turns out to be the very first bus trip to take constituents over the Canadian border to buy low-cost prescription drugs.

All of us have days which are transformative where something happens we will never forget, and that is the day I will never forget. On that day we took a busload of Vermonters, mostly women, many of the women struggling with breast cancer. We went from St. Albans, VT, to Montreal, Canada. I will never forget the look on the faces of those women who were struggling for their lives when they bought breast cancer medicine at 10 percent of the cost they were paying in the State of Vermont. The drug was Tamoxifen, a widely prescribed drug for those people who are struggling with breast cancer.

These women walked in fighting for their lives, many of whom did not have a lot of money. They walked in there and they could not believe, literally could not believe, the cost of that med-

icine which they needed to keep them alive. At that moment some years ago—it may well have changed since then—the cost was one-tenth what it was in the United States of America.

The question is a very simple question: How do you have a drug manufactured by a company, manufactured in the same factory, put in the same bottles, sold in Canada, in some cases for one-tenth the price that same medicine is sold in the United States of America? How possibly can that happen?

Now, as it occurs, I am not a great fan of unfettered free trade. I have very serious concerns about what our trade policy is doing in terms of throwing American workers out on the street, moving plants to China and other low-wage countries. But I am always amazed that on the floor of Congress, when it comes to representing the interests of multinational corporations, people are always speaking about how great unfettered free trade is; it is not a problem; American workers going down the street; workers in China paid 30 cents an hour. That is okay. That is part of globalization.

Well, why isn't it part of globalization that prescription drug distributors and pharmacists can pick up FDA safety-approved medicine at a fraction of the price they are currently forced to pay, and lower the cost of prescription drugs in this country very substantially? Why is that not a process of globalization that every Member of the Senate should be supporting?

We should not kid ourselves as to what this debate is about. I think most Americans understand that large multinational corporations have enormous power over the Congress. You have big oil running up recordbreaking profits, receiving tax breaks and corporate welfare. You have credit card companies with tremendous power over what goes on in Congress, able to charge Americans 25, 28 percent usurious interest rates. You have insurance companies blocking national health care efforts so all of our American people can have health care as a right of citizenship. But at the top of the list of powerful, greedy special interests, at the top of that list, that very impressive list, stands the pharmaceutical industry. They are at the top.

So when you talk about powerful interests, look at the pharmaceutical industry and the impact and the power they have in terms of what goes on here in Congress. Since 1998, the pharmaceutical industry has spent over \$900 million on lobbying activities; \$900 million since 1998. That is more than any other industry in the United States of America.

It is hard to believe, but there are now over 1,200 prescription drug lobbyists right here in America, many of them right here on Capitol Hill. That amounts to more than two lobbyists for every Member of the House and the Senate. They have us well covered. These people are paid top dollar as lobbyists. These are former leaders of the

Republican Party, former leaders of the Democratic Party.

Let me tell you, they are hard at work today. They will be hard at work tomorrow. What they have done successfully, year after year after year, is when an effort comes up in the House and an effort comes up in the Senate, they descend like locusts into the offices of Members of Congress and say: Don't vote for change. Keep the status quo alive. Make sure the American people continue to pay the highest prices for medicine in the entire world.

Since 2000—I don't know if you are supposed to talk about these things on the floor of the Senate. I will. Since the year 2000, the pharmaceutical companies have contributed almost \$250 million in campaign contributions. Let me repeat that. Since the year 2000, the pharmaceutical companies have contributed almost \$250 million in campaign contributions.

What this debate is about is not just whether we are going to lower the cost of medicine in this country and save billions and billions of dollars for the consumers of our country, for people with acute and chronic illnesses, for our seniors; it is also about whether the Congress of the United States is, in fact, prepared to stand up to the most powerful, the greediest special interest in the United States of America.

In my view, the time is long overdue for us to begin to make some fundamental changes in our prescription drug policies in this country. The time is long overdue for us to lower the price of medicine for our people, which not only will help people, of course, pay for their prescription drugs, it will lower the entire cost of health care in the United States.

We spend far more money per capita on health care than does any other country on Earth. If we lower the cost of prescription drugs, we will have an impact on that.

Tomorrow I will be speaking at greater length on this issue, but I think the arguments are so clear that prescription drug reimportation makes sense. The idea, as Senator DORGAN has mentioned, that somehow we can import tomatoes and lettuce from farms in Mexico and in Latin America, that is okay, but we cannot reimport prescription drugs from Canada with FDA regulations, that is impossible, makes sense to nobody at all. Food coming in from China, no problem; FDA-regulated prescription drugs coming from Canada, oh, my word, it can't be done. Give me a break. Of course, it can be done.

What this issue is about is not drug safety. What this issue is about is the profits of the pharmaceutical industry and the enormous power they have over Congress. Now is the time for us to say to the drug companies: You have dominated what goes on year after year after year. You, in the drug industry, wrote the prescription drug Medicare bill. You have resisted year after year every effort to reform how we price medicine in the United States.

Maybe the year 2007 might be the moment in which Members of Congress have the courage to stand up and say enough is enough. Let's support the men and women and children, the seniors of our country. Let's lower the cost of prescription drugs. Let's pass prescription drug reimportation.

I yield the floor.

The PRESIDING OFFICER. The Senator from West Virginia.

Mr. BYRD. Mr. President, thank God for BERNIE SANDERS, the Senator from Vermont. Thank God. Sail on, brother. I thank the Chair.

Mr. SANDERS. I thank the Senator.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Mr. President, I will have a lot more comments on this bill at a later time. In light of the comments by the Senator from North Dakota about the importance of reading the bill, I wasn't sure that I had read the most recent copy of it. I think I have the most recent copy of it now. It is a fascinating 140 pages that is being attached to our 300-page drug safety bill. The reason I am checking it is because in the past we have noticed some strong implications for safety problems with drug importation, and I want to make sure we are not opening the door for even more safety problems. I had hoped that the bill on safety wouldn't have to get into the safety of imported drugs, but I can see that is not the direction we are going. I am more than happy to address it.

I am fascinated by the discussion today because the people who normally are talking about free trade are now talking about some restrictions. That would be my side of the aisle. Those who normally rail at any kind of opening of the market to anyplace outside of the United States are the ones who are supporting this bill. It is kind of a reversal of situations.

I have heard the Senator from North Dakota talk about the way the Canadian Government is subsidizing the grain in that country and how that gives them an unfair advantage in the United States market and how we have to be sure that doesn't happen. Yes, the Canadian Government subsidizes. Yes, the Canadian Government gives an unfair advantage to their citizens. On drugs, the Canadians do some interesting things, too. They are a very small, limited market compared to the United States.

Sometimes in business when you are trying to price things, you say: I could pick up a little bit more in the market if I changed my price a little bit. But I am only willing to go after the fringe in order to do that. That is kind of what has happened in Canada. Canada has made it a little more difficult for the drug companies because they say: We are going to negotiate the price. I love that word "negotiate." Normally that means there is a little give and take on both sides and some advantages that are picked up on both sides in order for the outcome that is derived.

In terms of pharmaceuticals, usually "negotiation" is the code word for "price fixing." That is what they have done in Canada. They have fixed the price. If you want to be able to sell your drug up there, they will tell you what bid you better come in at and they are willing to have various pharmaceuticals bid against each other for the right to enter that fringe market, a small portion of what is in the United States but a potential customer. If you can cover your costs and pick up a few more sales, perhaps you can increase profits. It is a little accounting trick, but it happens. But they negotiate the price.

There are five drugs for heart that do similar things. They make the five drugs for heart bid against each other. That means one or two of them will win the bid. If your doctor prescribed one of the other three in Canada, you are out of luck. The decision by the doctor is taken away because you will get a good price on the pharmaceutical that may not be quite right for you, but it will be cheaper than what you could have gotten. That is not the way we work it in the United States. We try to have competition between all of the different products and hope that brings the price down.

There is some positive indication that it does bring the price down. We have the Medicare plan D. When they did the calculations on how much that was going to cost, it was considerably higher than what it actually came in at when there was competition among the providers, who in some cases represent more people than Medicare or Medicaid or the veterans and negotiate prices, but they negotiate realizing that we are forcing them to provide all of the pharmaceuticals, not just one or two out of five. If they are providing a plan, they have to provide for the prescription drugs.

When I was doing hearings across Wyoming, I had a little surprise almost at every meeting that I had to explain Medicare Part D. That was somebody saying: I can't get the prescriptions I really want. I was doing all of this promotion before Part D even went into effect. So I knew something was wrong with that kind of a response. It occurred to me that maybe those were veterans. We negotiate the price on drugs for veterans. That means when the Government is doing it, they have to say: You know, I don't think your price is low enough so we are just not going to make that available to our people.

Did you know that a whole bunch of veterans are taking prescriptions under plan D because they can't get what they want under veterans? It is an interesting situation. When you negotiate these things, you change some of the dynamics and you do not make everything available. I don't think we in the United States are going to settle for just having some, although if we can tap the cheap one in Canada where they fix the price, that will lend an ad-

vantage to people in the United States. I am ready to admit that. I am ready to admit if we didn't have restrictions on ethanol and subsidies in this country, we would bring in a whole bunch of ethanol from Brazil. But we are going to protect the ethanol. Again, it is a different group of people who are talking about that than are talking about drug importation.

Let me get back to drug importation because that is important. The Senator from North Dakota several times—in fact, all the time—used to say "where are all the dead Canadians?" when he was talking about safety. That is what my colleague from North Dakota used to come down to the Senate floor and say when he was talking about importation. He always asked that question. It may have escaped the notice of those of us in this body that he didn't ask that question anywhere in yesterday's debate or today's debate. Why not? Because two summers ago, five people in Hamilton, Ontario, died from taking counterfeit Norvasc. Norvasc is a blood pressure drug taken by millions upon millions of people who rely on it for their health and well-being. Since so many people take it, it is a target for counterfeiters looking to make a quick buck. I know he did say that counterfeiting is going to happen anyway. Probably. It happens in virtually every industry, and there are some countries that actually specialize in it. But imagine opening an opportunity for counterfeiters, an opportunity for them.

In the portions of the bill I have gotten through already, I know there are some pretty tight restrictions on who can be an exporter and who can be an importer and how packages will be labeled and all of those sorts of things. It is a marvelous effort to try to tighten it up so that what you buy is what you think you are getting. But how many of us, when the program was to first start, would know what to look for or even who to order from in order to be sure the drugs we are getting are safe? How do you do that? It is a tremendous opportunity for counterfeiters. We already have a problem with counterfeiters. There is no way you can write off the counterfeit argument.

I ask unanimous consent that I be able to show some three-dimensional objects on the Senate floor, the same as the Senator from North Dakota.

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

Mr. ENZI. I will leave this on the desk so people can take a look at it. This is the Norvasc product with which the Canadians had a problem. It killed people. I want Members to take a look at the packaging. I have the external packaging. I have the internal packaging. I have the pills themselves. I challenge anybody to see the difference. We are going to put some special labels on anything that gets shipped into the country. I am sure nobody would ever be able to counterfeit any labels that were coming into the

country. It just couldn't happen. There are now dead Canadians, and it saddens me to say that I believe there will be even more. These unfortunate individuals got their fake pills from a brick-and-mortar pharmacy. If that is what is happening when you buy drugs in person in Canada, who knows what you might get when ordering from a Web site that says it is in Canada but could really be based anywhere in the world.

In fact, some of the drugs that have been intercepted by the FDA have come through Canada but actually were from Saudi Arabia. Communication worldwide is transparent these days. Whom you think you are ordering from is not always whom you are ordering from. Right now that practice is referred to as hiding the maple leaf.

I would like to invite my colleagues to visit with me when I am finished my remarks. I have these pills I would like them to take a look at. There are other examples, too.

So anybody who holds up two bottles and says, this one is this and this one is this, they can't be sure if the one that is being imported is really from the country they are talking about. It has to be a concern. That has to be tightened up. There have to be some ways people can really tell.

There is also a difference between whether you are importing for an individual or you are importing for a pharmacy. If you are importing for a pharmacy and they get a counterfeit load, it is not just one person who dies. It is the whole community, everybody who is taking that medication. So there needs to be some concern with these things.

As I said earlier, we all want to have affordable drugs. We would like to bring down the cost of medicine every way that we possibly can. But a counterfeit or tainted drug is unsafe at any price.

I want to add another thing on the counterfeit drugs. You can take the pills and you can grind them up and do a chemical analysis of one pill against the other, and they will come out identical. Now, part of the problem is the way you put these together to make them dissolve properly so what you need in your bloodstream gets into your bloodstream.

A number of the imported drugs that have been confiscated are shown they will not even dissolve. If you take a pill, and it goes completely through your whole system, you could die. It is a serious problem. It looks good, it even checks out good, but there are processes for putting these things together.

From my brief reading of the bill, I am also worried about some of the biologic information that may be in there that could be imported as well.

The Food and Drug Administration Revitalization Act is about restoring the trust of the American people in the FDA. That is where it belongs. We should have a lot of concern.

There is an amendment that is going to come up everybody is working on

right now to make sure it would work, and it talks about some increased safety with food. Now, food, some of it, such as tomato packaging, is pretty well there. It is not put in another container. It is hard to fake. But there can be problems. We had problems with spinach in this country. We have a big problem with pet food right now, and it is because of China.

China—how much do you trust them with your drugs? We have been trusting them with our pet food, and they are killing our pets. It took a little thing called melamine that increases the protein count in the food. It does not increase the protein, it just increases the protein count. It makes it look like a much richer food than it is. Unfortunately, it kills. Unfortunately, they have not just been using it in pet food; they have it in their regular food chain, and children—young children—got it, and the children died. When they checked on it, they found out they died of starvation, even though they had what should have been a good protein diet. There was a little melamine in it, and it was starvation rather than poisoning.

But if they do that to food products, how much would we worry about drug products that come in from there? I know there are some limitations on where they can come from, but if they get into the European Union, there does not appear to be any constraint on it then, and it could be transferred on over to the United States. So throwing our borders open to drug importation would, instead, falsely place trust in criminals trafficking in illegal pharmaceuticals.

I think the American people deserve better. I hope we do not make this move at this point in time, and that we constrain the bill to those things we know will add safety to our pharmaceuticals and medical devices and things for children in this country.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from New Hampshire.

Mr. GREGG. Mr. President, I join with the ranking member of the HELP Committee—the Health, Education, Labor, and Pensions Committee—in raising the concerns and agreeing with the concerns he has raised about the reimportation proposal which has come forward from the Senator from North Dakota, which has been debated on this floor a number of times.

The issue, of course, is the safety and efficacy of products which Americans buy. The FDA has been given the responsibility and has executed that responsibility extraordinarily well to make sure when an American citizen buys a pharmaceutical product or a medication, it is what it says it is and it does what the doctor prescribes.

If you start buying medications internationally, you are in the position where you have no capacity for the FDA to monitor that purchase. So the drug may be represented to be an FDA-

approved drug, but it could easily not be. In fact, case after case has been discovered of adulterated and changed medication coming into this country under the representation the medication which is being purchased is medication which has been approved by the FDA. So you are basically opening up a massive loophole in the area of safety for the American citizenry.

Now, the demand for this comes from the cost of the drugs. People want to be able to go across the border to Canada, which is obviously a very sophisticated nation, and buy a pharmaceutical product there, which costs significantly less than the same pharmaceutical product may cost in the United States. That is a natural instinct of the market economy and of people. But critical to this exercise, of course, is the ability to get a safe drug.

If you go across the border, and you buy a pharmaceutical product which is alleged to be one thing, and it turns out to be another thing, the damage it causes you is going to be economically much more significant than the savings which you may have accomplished by purchasing that drug across the border.

Also, it should be noted that with the Part D pharmaceutical program which we now have relative to Medicare, the pressure—because pharmaceutical products are now insured and people receive them under the insurance plan as created under the Part D program, which has been an extraordinary success to supplying pharmaceuticals, though its cost remains extraordinarily expensive for the next generation of Americans—but pharmaceutical products are now available under an insurance program to most American seniors, and, as a result, if you are a senior, one of the people most likely to use a large number of drugs, and most often are on a fixed income and have problems purchasing drugs as a result of the fixed income situation—those issues were addressed by Part D to a large degree relative to the senior purchasing drugs; and it did create the ancillary problem of creating a huge cost which has to be borne by the next generation—but relative to the supplying of drugs, the pressure which was forcing people to take the chance of purchasing a drug internationally has been relieved to some degree, significantly in the area of senior citizens.

I proposed language which would create a safe pharmaceutical approach, where you would create an Internet pharmacy approach, where you would create a regime under the FDA where people could go on the Internet and buy pharmaceutical products knowing they have been approved by the FDA.

Today, unfortunately, that is not the case. If you go on the Internet, and you purchase something through a pharmaceutical firm off the Internet, you do not know whether that product—even though it may be represented to be FDA-approved—is FDA-approved because there is no way to certify the

site you are purchasing from is an FDA-approved supplier.

So this reimportation bill is essentially going to create an atmosphere where those Internet pharmacies are going to become basically the “wild west” of supplying drugs in this country, and you are going to see people going on to these Internet pharmacy sites and purchasing drugs they think are being represented as an American-approved drug that has been reimported—and is at a lower price—but may actually be a totally adulterated drug which will do significant harm to you.

We have seen instances of that already—dramatic instances. Case after case has been reported of people being significantly harmed and in some instances dying as a result of buying pharmaceuticals off the Internet that turned out not to be what they were represented to be from international sites.

So at a minimum, this reimportation proposal, which has received significant support in the past because it has a motherhood name on it—even though it might be actually creating significant problems for children and for other people in this country as a result of the risk it puts people at—at a minimum, this proposal should be subject to creating some sort of a regime where FDA has the ability to monitor and to approve and to make available to the public the knowledge that Internet pharmaceutical sites have been approved by the FDA. That is what my amendment does. It tries to address that.

So we should not move forward precipitously in the way that is proposed by the Senator from North Dakota. We should not be supporting this simply because it has a nice name on it and because he can hold up two bottles which are the same drug but costs differently in a managed economy in Canada and a market economy here in the United States. We should, rather, set up a structure where FDA can be sure that when you buy that pharmaceutical product through an Internet site that is international or from a Canadian pharmacy, that you are getting what they claim you are getting, so when you take that drug, you benefit from it and are not harmed by it.

This all, however, gets to a bigger issue. Probably, there is not time right now to go into it in depth. But the bigger issue is, where do pharmaceutical products come from? Where do all these amazing products, the biologic products that are saving lives in this country and are creating such a much better lifestyle come from? Remember, they do not come from trees, and they are not grown in North Dakota in the sugar beet fields. They are developed through processes which involve years—years of investigation and research.

The average pharmaceutical product in this country takes 12 years and \$800 million to bring to the market. Think

about that: 12 years and \$800 million before you can produce a product Americans can take. That is a pharmaceutical product. If you are getting in the biologics area, which is a much more complicated area, it takes even longer. It is even more complex, and in many instances it is even more expensive.

It is these products that are changing the life expectancy of people and making the quality of life of people so much better. We have basically gone from a medical regime in this Nation where invasive action was always the first call, was always the first event, where you basically went under the surgical knife, to a regime where you are given pharmaceuticals or biologics to try to address a very serious illness. It is a huge step, an exponential step in the direction of better health care and a better lifestyle for Americans and for the world.

Where are these products developed? Well, they are developed here in the United States. Why are they developed here in the United States? Why are almost all the major pharmaceutical breakthroughs and all the biologic breakthroughs coming in the United States? Because we have a market system which allows people to take the risks to develop those products.

We do not fix prices, as they do in Canada or in England, at a rate that is so low that nobody would be willing to invest in developing that product because the return on that investment is too low. We allow people who make the investment, who take the risk, who put the 12 years in, who invest \$800 million, to get a reasonable return on their investment and on their effort. As a result, we have the explosion in advances in technology, in medical technology, in biologics, and in pharmaceuticals.

It is a result of the fact that people who want to take that risk, and who have the ability to pursue that type of opportunity to make life better for people by creating these pharmaceutical products and these biologic products, have the capacity to get resources to do it. It is called capital markets.

Now, capital does not flow for goodwill. People do not invest in things because it makes them feel good, in most instances. People invest where they are going to get the best return on the dollars they invest, or a reasonable return on the dollars they invest. So we have to maintain an atmosphere in this country where people are willing to put money—cash, capital resources—into the investment and research and development of pharmaceutical and biologic and device products.

But if you listen to the other side of the aisle, almost every proposal they come forward with seems to be of the view that these products are grown in some wheatfield in North Dakota, that they do not take any effort, that they do not require any capital, they do not require any expertise, research, or time. All they require is to be price

fixed, to be limited in their ability to be distributed relative to the price that is charged.

Time and again, the other side of the aisle has come forward with proposals which basically undermine the incentive for capital to flow into these research areas. Believe me, if capital is disincentivized from going into these areas because they do not get a reasonable return, they will go somewhere else—they will go into developing software, into gaming, into whatever it is that happens to give them a reasonable return, into investing in some other country's activities in some area.

Capital does not flow out of goodwill into pharmaceutical production, into biologic production, into device production. It flows into those accounts because they expect a reasonable return.

Now, sure, the countries of Canada, England, and the European common market, to some degree, are living off of the fact that we give people a reasonable return on our pharmaceuticals and biologics in this country. That is absolutely true, and it is reasonably disgraceful. In fact, in Canada, they threaten to take people's patents away if they don't—they basically capture American patents if they don't sell these drugs at a price which nobody would have invested in them in the first place to produce them were the price fixed at that level. But that is their policy.

Now, we could subscribe to that policy, which is what the other side of the aisle wants us to do. They proposed it in Medicare negotiations, they proposed it now and passed it here in the child drug review. They proposed it in this reimportation, and they proposed it in the negotiated language relative to Medicare, and in biologic generics. In all of these areas they are basically saying: Well, drugs must appear in the marketplace. We don't have to be concerned with the fact of getting capital into the investment exercise. We don't have to be concerned with the fact that it takes years and years to research these products and hundreds of millions of dollars to bring them to the market, they just appear. We can basically, for lack of a better term, kill the goose that is laying the drug or the biologic or the pharmaceutical or the device that is saving people and not worry about it.

Well, that is not true. If you were to follow all of the proposals from the other side of the aisle, or even a significant amount of them, we would see investment in this area start to dry up. We would see a contraction of the production of pharmaceuticals that save lives, of biologics that save lives, of devices that save lives. We would see fewer and fewer of those coming to the American people and to the world because people wouldn't invest in that activity any longer, or the investments would be significantly curtailed because money would flow in other directions.

This concept of the marketplace totally escapes the other side of the aisle. This concept that drugs have to actually have some flow of capital behind them to be produced because it takes so long to get them to the market, and it takes so much money to actually research them—and that is especially true in biologics and equally true in devices. It totally escapes the other side of the aisle. Their idea is, we have a good line, we have a motherhood statement, let's let people go buy the drugs somewhere else at a price that is fixed at which nobody would have ever produced the drug in the first place if that was the price. Let's negotiate so we have a regime of price setting at the Federal level, which basically eliminates the capacity for that drug to be competitive.

Let's create a biologic generic which basically wipes out the capacity of the true biologic to actually come to the market and be successful. Let's create an atmosphere where testing on children of the drugs will basically not have a fiscal return which will make it worthwhile to test them on children. Let's do all of those things in the name of the motherhood language of getting a better price for drugs for Americans, ignoring the fact that what you are actually going to end up doing is dramatically limiting the number of drugs coming to the market for Americans, and therefore significantly impacting the quality of life of Americans and our ability to advance the dramatic and revolutionary activity that we are seeing in bringing biologics to the marketplace, which are basically curing and have the potential to cure diseases which have been extraordinarily threatening to the American population for so long.

It makes no sense, if you look at the substance of the issue, what they are proposing. It is totally inconsistent. They are saying they are doing this to help people. What they are actually ending up doing is harming not only the people of today who won't be able to get the drugs because they won't be produced but people in the future because the drugs won't be brought to the market. There is a blindness to the fact that market forces are at work. I guess it is just a function of the fact that you want to get out a good press release, so you are going to send it out. Of course, anybody who takes the position I just outlined is immediately demagogued, and the pejorative tool of the drug industry is thrown out there.

Well, I am hardly that, since I was one of the few people in this Chamber who actually aggressively opposed and tried to stop the Medicare Part D Program, which was the biggest windfall the drug industry ever got and which was voted for by many of my colleagues on the other side of the aisle and which ended up putting an \$8 trillion bill which is unpaid for onto our children's future.

More importantly, the reason I take the position I take is because I believe

very strongly that America should not give up its lead in one of the industries where it is at the cutting edge and where it is producing jobs and where it is producing the intellectual capital that is going to keep us a vibrant, strong economy. In addition, we should not give up an industry or undermine an industry and geniuses and creative individuals who are producing products which are saving lives and are giving people a better livelihood. So I am not going to sign on to these various jingoistic proposals which are brought to the floor for the purposes of putting out good press releases about how I did this or that for motherhood at the expense of undermining the quality of care for future generations by basically limiting dramatically the ability of people to get capital who want to be creative, who want to invest, and who want to do research in the area of producing biologic products, pharmaceutical products, and medical devices.

That is why I take the position I take, to say nothing of the fact that if you start haphazardly importing products from the Internet and from countries such as Canada, as strong as Canada is, without any FDA oversight or approval of those products, you are going to harm a lot of people at the end of the day. A lot of people are going to be hurt, and some people are going to die as a result of buying products which have not gone through FDA approval and which are not subject to FDA oversight because they are bought from a pharmacy or a provider in Canada, and that product may have come out of India or it may have come out of Afghanistan. It may have come out of Pakistan. It may be adulterated, and it may kill. The same can be said by a factor of 10 relative to purchasing on Internet pharmacies.

So there are some big issues at play. There are big issues at play relative to the future of the health of Americans on the issue of importation, on the issue of negotiation and Medicare, on the issue of biologic generics, and on the issue of making sure that children are adequately tested relative to the application of drugs which are brought to the market. There are big issues relative to safety and big issues relative to whether this country remains on the cutting edge of producing products that help people and give them a better lifestyle with a biological, pharmaceutical, or medical device. We shouldn't just pass these proposals willy-nilly for the sake of putting out a nice press release.

Mr. President, I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from South Carolina is recognized.

Mr. DEMINT. Mr. President, I ask unanimous consent that the pending amendment be set aside.

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

AMENDMENT NO. 1018

Mr. DEMINT. Mr. President, I have an amendment at the desk and ask for its immediate consideration.

The ACTING PRESIDENT pro tempore. The clerk will report the amendment.

The legislative clerk read as follows:

The Senator from South Carolina [Mr. DEMINT] proposes an amendment numbered 1018.

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

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

The amendment is as follows:

(Purpose: To amend the notification provision with respect to drugs deemed to have risk evaluation and mitigation strategies)

In section 214(b)(3)(B) of the bill, insert “, except with respect to the drug Mifeprex (mifepristone), such assessment shall be submitted 6 months after the applicant is so notified” before the period at the end.

Mr. DEMINT. Mr. President, my amendment calls for the Food and Drug Administration to conduct an assessment of the risk evaluation and mitigation strategy, which we refer to as REMS, for Mifeprex, commonly known as RU-486, within 7 months of the effective date of this legislation.

According to the legislation before us, any drug that is currently on the market with restrictions on its distribution or use, which includes RU-486, would be required to have a risk evaluation and mitigation strategy. This means that RU-486 would be subject to periodic assessment of how well the risk management plan, including its restrictions, is working. Unfortunately, the bill does not establish a deadline for the risk evaluation for RU-486.

The current RU-486 abortion regimen was approved by the Food and Drug Administration in September of 2000. Since that time, the regimen has been linked to the deaths of seven women, including three Americans. The public has learned since November of 2004, through the release of documents by the FDA through a Freedom of Information Act request, that over 1,000 additional women have experienced adverse effects from the RU-486 regimen, including 9 life-threatening incidences, 232 hospitalizations, 116 blood transfusions, and 88 cases of infection. It should be noted this dangerous drug is attacking young, healthy women.

I also want to point out the approval process for RU-486 was highly irregular in the first place. The drug regimen was approved under FDA subpart H, which is a regulation that applies to certain new drugs used for treating serious or life-threatening illnesses. While certain conditions may arise during pregnancy that are dangerous, pregnancy itself is hardly a serious or life-threatening illness.

The RU-486 regimen actually requires the use of two drugs: RU-486, which kills the child, and misoprostol,

which causes the uterus to expel the dead baby. G.D. Searle, the manufacturer of misoprostol, never sought to have its drug approved by the FDA for abortions. Nevertheless, the FDA, in what appears to be an unprecedented decision, mandated that misoprostol be used for unapproved "off-label" use in an abortion regimen along with RU-486.

Finally, the FDA approved the RU-486 regimen based on data submitted from clinical trials in which there was no control group comparison. This directly violates Federal law and appears to be unprecedented as well.

In my opinion, the FDA has not done enough to curb the use of this deadly drug, and for far too long the FDA has put politics ahead of science and ahead of women's health. When the Clinton administration expedited the approval process for RU-486 in the final days of its tenure, many medical professionals expressed serious concerns about the FDA's rush to bring RU-486 to market. Since then, the statistics have proven these concerns to be well-founded.

The legislation we are considering today has everything to do with drug safety. Yet we have a drug on the market that has killed several women and injured many others. My amendment simply sets a 7-month deadline for the FDA to assess the risk evaluation and mitigation strategy for RU-486. Given all the adverse events associated with this drug, this is the least we can do.

This is not an abortion issue, it is a women's health issue. Even those who support abortion agree there are serious problems with this drug. Let me read several quotes from abortion supporters which were part of a New York Times story that ran last year: "None of these women should be dying; it's shocking," said Dr. Peter Bours, an abortion provider in Portland, OR, who is rethinking whether to offer pill-based or medical abortions.

Dr. Warren Hern, an abortion provider in Denver, said the latest reports demonstrated that abortions by RU-486, or Mifeprex, were far riskier than the surgical ones. "I think surgery should be the procedure of choice," Dr. Hern said. "Pills," he said, "are a lousy way to perform an abortion."

I quote again from another source: "The complications associated with RU-486 far exceed the complications of surgical abortion," said Dr. Damon Stutes. He is an abortion provider in Reno, NV. He refuses to offer pill-based abortions.

Dr. Stutes, whose clinic has been bombed, said he was uneasy about agreeing with abortion proponents on anything. But the truth is the truth, he said.

Another quote:

One needs to tell patients that the medical procedure, even though it seems more natural, may be more likely to result in death.

That is Dr. Phillip G. Stubblefield, a professor of obstetrics and gynecology at Boston University.

It is clear that even the supporters of abortion believe this drug is dangerous.

It also appears that even the leader of the abortion industry—Planned Parenthood—supports actions by the FDA to further examine the safety of the drug. Dr. Vanessa Cullins, vice president for Medical Affairs at Planned Parenthood, told the San Francisco Chronicle:

We are glad there will be continuing investigations by the FDA. We will work with the CDC, the FDA, and academicians to figure this out.

The FDA needs to quickly complete its risk evaluation on RU-486. That is what my amendment guarantees. I urge my colleagues to support it. I understand that Senator KENNEDY will accept a voice vote on this. I look forward to supporting it, along with all of my colleagues.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from North Dakota is recognized.

AMENDMENT NO. 990

Mr. DORGAN. Mr. President, I have listened to some of the debate on the floor of the Senate in opposition to the amendment I have offered with many colleagues dealing with the reimportation of prescription drugs. Especially entertaining was to hear the Senator from New Hampshire, Mr. GREGG, describe North Dakota wheatfields. The Senate is a place of fascinating and interesting debate. I expect we will have more of that in the coming hours, leading up to a vote tomorrow on a cloture motion on this amendment.

The continued and insistent reference to this amendment posing safety risks, or risks of unsafe prescription drugs, is at odds with everything we know to be the case. I described Dr. David Kessler, and I suggested if anybody knows a more important, better informed expert than Dr. David Kessler, who was head of the FDA for nearly 8 years, tell me his or her name. I described the statement that Dr. David Kessler made that says this will make the prescription drug supply safer. In fact, the regime of safety we have put into this amendment is appropriate, important, and will mean that we will be able to allow reimportation without a safety risk.

Despite the evidence, we continue to hear this issue. I was thinking, as I was listening to this a while ago, about the Lincoln-Douglas debates, when Lincoln became enormously exasperated at one point and he said to Douglas: Tell me, how many legs does a horse have?

Douglas said: Well, four, of course.

Lincoln said: Now, if you were to call the tail of a horse a leg, then how many legs would a horse have?

Douglas said: Well, five.

Lincoln said: You see, that is where you are wrong. Just because you call the tail a leg doesn't make it a leg at all.

The same principle holds true now on the floor of the Senate. You can say what you want, but that doesn't make it true. Safety issues? That doesn't exist in the amendment we are talking

about. This will make the drug supply safer. While I am speaking of Lincoln and Douglas, let me say something else that Lincoln said, which has always been interesting to me. He was describing his opponent's arguments. He said: Your argument is as thin as the homeopathic soup made from boiling the shadow of a pigeon that has been starved to death.

Wasn't Abraham Lincoln wonderful? That description can still exist for some of the arguments we are hearing these days on some of these issues.

I hope my colleague was not serious a few moments ago when he said this is an amendment that is not worthy and is put out by a bunch of people who want to put out press releases and aren't concerned about the safety of the drug supply. My colleague surely doesn't mean to say that Senators GRASSLEY, MCCAIN, SNOWE, and COLLINS on his side and Senators KENNEDY, STABENOW, BROWN, and so many on our side—the 33 Senators who have come to a serious issue with a thoughtful proposal—did so because they want a press release. My colleague knows better than that. He perhaps ought to tell the Senate he knows better than that.

I respect those who disagree with this amendment. I hope they will respect as well our determination to correct something we see as a serious problem. When my colleague says we don't want to give up our lead, describing our lead in pharmaceuticals and the development of prescription drugs, I don't want to give that up. Let me tell you another lead we don't want to give up; that is, the lead in providing the highest prices in the world to the American consumer who needs prescription drugs. That is a lead we ought to relinquish right now. I wonder if my colleague would agree with that.

Mr. President, this is an interesting debate, a useful debate. It will conclude tomorrow with the vote. My colleague from Michigan, Senator STABENOW, has gone across the bridge that connects our two countries, taken busloads of senior citizens and has been involved in this issue for many years, believing that we ought to insist on fair pricing for prescription drugs for the American people. I am pleased that she was one of the people who helped put together the bill introduced by 33 Senators, and I am pleased that she is a strong advocate for the amendment that we have added to this piece of underlying legislation.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Michigan is recognized.

Ms. STABENOW. Mr. President, I rise to support the amendment we have put together, led by the Senator from North Dakota. I thank him for his passionate leadership and advocacy and the way he is able to speak in very commonsense terms about what this is all about. What we are talking about is common sense. We are talking about whether we have the most competition

that will allow the best price for people related to their medicine. I also am looking around for Senator BROWN, who is also here to speak. I thank him publicly for his help on another amendment that relates to competition and closing patent loopholes relating to generic drugs. I thank him again. Senator BROWN has been a wonderful advocate on these issues.

I find it so interesting whenever we hear that we cannot lower the price of prescription drugs without losing research. Let me comment on that first. Here is what is happening today as it relates to the development of new medicine. We all want that. We all want that, those of us who supported overwhelmingly, the 63 Members of the Senate who voted for stem cell research to provide new lifesaving research and tools for our researchers. We came together and said, yes, we want new lifesaving research.

That is not what this debate is about. The debate is about whether there is going to be a closed market to folks who get to set the price without competition or whether there will be competition so people can afford to buy medicine. The reality is that our structure is such right now, as it relates to the way we bring drugs to market, that you start with basic research, of which last year \$29 billion was paid for by the American taxpayer—\$29 billion. Now, the industry then added another \$39 billion, according to the PHARMA Web site. They are allowed to write off their research as a business expense, or take an additional amount—the R&D tax credit on top of that to write off their research. So the taxpayers are paying, it is fair to say, the majority of what it costs in basic research right now for new lifesaving medicine.

Personally, I am willing to do that because I think it is incredibly important. It is in our public interest. Having all of us together as taxpayers invest in the National Institutes of Health and other lifesaving research makes sense to me. After we do that, we allow the companies to take that information and research and begin to develop medicine. That is fine, too. We then allow up to a 20-year patent, so that the company that does this development can recoup their costs without the same kind of competition from a generic company, another kind of company. So we give them a privileged status. We cover their costs, after we as taxpayers have helped them or may have fully funded the research done in the beginning. So we go through all this, and all that I ask on behalf of the people of Michigan and all I think we are asking for is, when they get done with the patent, people be able to afford to buy the medicine and that we have the kind of competition that allows that to happen.

One piece is to make sure patents are not extended beyond 20 years unfairly by manipulation. I will have an amendment that deals with closing some loopholes. The other is to make sure

we open our borders to allow our pharmacies, our hospitals, our medical schools, all those who are providing prescription drugs to consumers, to be able to purchase those and get the best price.

In Michigan, it may be from Michigan or it may be from Ohio or Wisconsin, but it may be 5 minutes across the bridge in Canada. In fact, Mr. President, that is what we find 5 minutes across the bridge. I have had a lot of opportunities to put seniors on buses to go to a pharmacy in Canada to see the fact that you are looking at 30-, 40-, 50-percent cheaper prices. I think of my sister-in-law when I say this. She was diagnosed with breast cancer, and thank God is doing well and has recovered. But when I look at the drug Tamoxifen that many breast cancer patients are required to take, or are asked to take, in Michigan, the last time I looked, it was about \$360 a month for that medicine. Five minutes across the bridge, it is \$60. That is a huge difference. That is a huge difference in somebody's ability to get the treatment they need for breast cancer. That can be replayed over and over again as it relates to medicine.

Now, what is also interesting is that prescription drugs are being brought across the border every day legally by the companies themselves. Lipitor, which was developed in Michigan—and I am proud of that—is manufactured in Ireland. They bring it back. There is no argument about safety when they are bringing it back. We have, right now, around the world, from Slovakia to China to India, medications that are being brought into this country by the companies themselves, under safe conditions.

Our legislation puts into place safety requirements that will allow the same thing to happen if it is a wholesaler, a pharmacy doing business with another pharmacy. There is no rocket science here. The very same safety provisions can be put into place. We also know that, in doing that, it is important to put that language directly into this bill. It is important. We have put in there a chain-of-custody requirement to ensure that drugs are handled not only by authorized persons but shipments must use anticounterfeiting technology to assure the products' integrity.

We do a number of things that relate to registering with the FDA and agreeing to strict requirements to ensure safety. But those requirements are not all in the bill. Why is that? Because we know that in the past we have seen—we see again now—a second-degree amendment to say that citizens cannot get the best price, and pharmacies cannot do business with pharmacies across the border, unless the Secretary certifies safety. And we know that for whatever political reasons, that has not happened over the years. That is actually current law.

To get beyond the politics of this, we have worked on a bipartisan basis, with

wonderful bipartisan support, to actually put the safety provisions that are required into the bill so the certification by the Secretary is not necessary.

We have had legislation passed by the Senate with wonderful bipartisan support in the last few years on related issues that involve reimportation. Last July, 68 Senators voted for an amendment to prohibit U.S. Customs and Border Protection from stopping individuals from importing FDA-approved drugs—individual reimportation.

I thank Senator VITTER for his leadership. I have been pleased to work with him on this issue of individuals being able to import medicines for themselves. Senator VITTER and I also worked together to make sure trade agreements cannot be used as a backdoor way to stop reimportation of cheaper prescription drugs into this country.

We are already on record as supporting this effort to lower prescription drug prices and create competition. It is my hope that, once again, in this bill we will reaffirm that we support the FDA creating safety regimens—we know they exist—to be able to bring medicine safely into the United States from other countries, and we will no longer allow a group—it is the only group I know that is able to stop trade at the border. Everyone talks about free and open trade, and yet in Michigan you can bring auto supplies back and forth every day, you can bring all kinds of agricultural products, you can bring anything back and forth across the border except medicine, except prescription drugs, unless you are a drug company. Drug companies can, but if you are somebody trying to make sure you get the lowest possible prices to consumers through a pharmacy, a hospital, medical school, or other businesses, you are not allowed to do it. It doesn't make any sense.

I believe we need to take off this protectionism which has been in place for years which has put consumers and businesspeople, frankly, into a situation where they are paying higher prices for medicine than they should.

This is not about research. I conclude by saying that according to SEC filings, 2½ times more is spent on marketing and advertising brand-name prescription drugs in the United States than is spent on research. This is not about research. We as taxpayers are leading the way on funding research, and we all support doing that. This is about competition versus protectionism and whether consumers will get the very best price for lifesaving medicine.

I urge the adoption of our amendment.

The ACTING PRESIDENT pro tempore. The Senator from Ohio.

AMENDMENT NO. 1018

Mr. BROWN. Mr. President, I understand there is no further debate with respect to the pending amendment No.

1018, so I ask that the amendment be agreed to and the motion to reconsider be laid upon the table.

The ACTING PRESIDENT pro tempore. Is there objection?

Mr. COBURN. Reserving the right to object.

Mr. BROWN. Mr. President, amendment No. 1018 is the DeMint amendment.

Mr. COBURN. I have no objection.

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

The amendment (No. 1018) was agreed to.

The ACTING PRESIDENT pro tempore. The Senator from Iowa.

Mr. LEAHY. Mr. President, will the Senator from Iowa yield to me for 1 minute?

Mr. GRASSLEY. Yes.

The ACTING PRESIDENT pro tempore. The Senator from Vermont.

(The remarks of Mr. LEAHY are printed in today's RECORD under "Morning Business.")

Mr. LEAHY. Mr. President, I thank my dear friend from Iowa.

The ACTING PRESIDENT pro tempore. The Senator from Iowa is recognized.

AMENDMENT NO. 990

Mr. GRASSLEY. Mr. President, I am a cosponsor of Senator DORGAN's amendment called the Pharmaceutical Market Access and Drug Safety Act. We want to add the provisions on the importation of drugs to this measure. Obviously, I support that effort. That legislation is the result of a collaborative effort by this Senator, Senator DORGAN, Senator SNOWE, and Senator KENNEDY to finally make drug importation legal in this country. This is one effort which I hope the new Democratic Congress can finally get passed because last time, my own party did not want to see this passed, even though I worked hard to get that done.

Now is the time for us to make this happen. This is a golden opportunity this year to get it done. I think we are well on the way to getting it done.

I have been a longtime proponent of drug importation. In the years 2000, 2002, and 2003, I supported amendments permitting importation of prescription drugs from one country—Canada.

In 2004, Senator KENNEDY and I worked together on a bill that would authorize drug importation, but it did not survive the partisan politics of that year.

I then introduced my own drug importation bill in 2004 with the number S. 2307. After introducing my bill, I began working in conjunction with the efforts of Senator DORGAN, Senator SNOWE, and Senator KENNEDY. So in this provision before us, we combined our efforts so that we could all get behind the same bill and have a better chance of getting it passed. Of course, that is where we are, working together this very minute.

Making it legal for Americans to import their prescription drugs is a top

priority at the grassroots level, as it shows up in my 99 town meetings I have every year in each of our 99 counties, and I have been doing that for 26 years. So I think I have a feel for what the grassroots of my State wants Congress to hear.

This is one issue about which I constantly hear, although I am probably hearing it a little bit less now that we have the Part D provisions of the Medicare bill because for people who couldn't afford drugs, who maybe relied on imports or at least drugs from other countries, they are able to get them a little better through the subsidization under the Part D Program. But I still hear about this issue, and that is why I am still working to get it passed. So this needs to be a top priority in Washington as it is at the grassroots of America.

I have long advocated allowing American consumers access to safe drugs from other countries, but I have not looked at this solely or even most importantly as a health issue. I have looked at it more often as a free-trade issue. Imports of any kind coming into our country create competition and keep domestic industry of all segments of our economy more responsive to the consumer, giving the consumer what they want at a price they are willing to pay and a quality they care about.

In the United States, we seem to import anything that the consumer wants to buy in America, but we don't do it for pharmaceuticals. So why not, with this legislation, do for pharmaceuticals what we do for everything else American consumers want to buy? That is what breaking down the barriers to trade is all about. That is where our country has been for 50 years, breaking down barriers to trade around the world. Yet we keep this barrier up. Consumers in the United States then pay far more for prescription drugs than those in other countries.

If Americans could legally and safely access prescription drugs outside the United States, then drug companies would be forced to reevaluate pricing strategies. More competition would have an impact. They would no longer be able to gouge the American consumer by making them pay more than a fair share of the higher costs of research and development, which is a resource we need for research and development, but why should just the American consumers pay for that?

It is true that pharmaceutical companies do not like the idea of opening up America to the global marketplace. They want to keep the United States closed to other markets in order to charge higher prices here. However, with this amendment, prescription drug companies will be forced to be competitive and establish fair prices in America.

The drug companies will try to find, of course, loopholes to protect their bottom line, but I think our amendment is comprehensive enough to keep that action illegal. It would not allow,

for instance, manufacturers to discriminate against registered exporters or importers. It would prohibit drug companies from engaging in any activities to restrict, to prohibit, or to delay the importation of a qualifying drug. The amendment would give the Federal Trade Commission the authority to prevent this kind of possible abuse of the system.

I also understand that there will be an attempt to kill this amendment, as it has been, I believe, in the years 2000, 2002, and 2003, by an amendment that would require a certification about health and safety. That amendment is designed to kill the underlying Dorgan amendment. It is a clever amendment and for sure can legitimately be determined to be a poison pill.

Our efforts develop an effective and safe system that gives Americans access to lower prices. This amendment requires that all imported drugs be approved by the Food and Drug Administration. The amendment sets a stringent set of safety requirements that must be met before Americans can import drugs from that country.

The amendment requires all exporting pharmacies and importing wholesalers to be registered with the Food and Drug Administration, as well as being inspected. It gives the authority for the FDA to inspect entire distribution chains of imported drugs, and it sets very stringent penalties for violation of the safety requirements in this bill, including criminal penalties and up to 10 years in prison.

Don't be fooled by the poison pill amendment to which I just referred. Voting for that amendment is a vote to kill drug importation.

With the Dorgan amendment, we are going to get this job done because 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.

I think Americans have been waiting for this for a long period of time. When a country such as ours allows every other product to come into this country that the consumer wants for the best price and the best quality, there is no reason we should make an exception for pharmaceuticals. We must make sure they have access to these affordable prescription drugs. So I urge my colleagues to support the Dorgan amendment.

Mr. COBURN. Mr. President, I want to chime in for a minute on this amendment, and I want to set a little background. Why do we want to import prescription drugs? What is the reason behind it? The reason is that there is not a true international market in pharmaceuticals. Senator STABENOW quoted a figure of \$29 billion worth of Government research. That is not quite accurate. There is \$29 billion that goes to NIH, but that is not all related to drug development. Probably half of that is. So we do have a great investment in drugs. There is no question

that the American consumer subsidizes the pharmaceuticals of almost every other nation in this world. So the purpose behind this amendment is a good one.

I would draw attention to the fact that Senator BROWN and I passed a drug reimportation bill in the late 1990s that became law, and President Clinton signed it. Donna Shalala, however, under the same guidelines, refused to carry out that mandate—that bill is still on the books, by the way—claiming there was nothing they could do that would make them safe and that they could assure they were safe.

I am going to vote for this amendment, and I think it is right that we should develop a worldwide market on pharmaceuticals, but I am not sure we are going to accomplish this. Having authored the first bill on drug reimportation when I was a Member in the House, what I have seen is that the problem is much bigger than what we are attacking. I find it kind of peculiar and strange that we haven't gone a little further. What really needs to happen is we need to tell all our friends around the world that tell the pharmaceutical companies what price they will pay for drugs, we need to tell them what price we will pay for their products. As soon as we did that, guess what. There would be a worldwide market on pharmaceuticals. We may get there through reimportation, but I don't think so. I think it is going to get squeezed down. I think greed conquers technological difficulty almost every time.

So I think this is a good step, but if we really want to solve this problem, let us put an amendment on the floor which says that any country that essentially fixes the price on pharmaceuticals, their products coming into our country will have their prices fixed. Can you imagine if we were to tell BMW what they are going to get for a BMW 531, or Volkswagen what they are going to get for one of their vehicles, or Toyota what they are going to sell a car for? That is essentially what they are doing to the pharmaceutical industry in this country.

I believe this is a good amendment, and I am supportive of reimportation, but I don't believe it solves the problem. I don't want the American people to think that if we pass this, all of a sudden the price of drugs is going to come down. It will not. It is great that we are doing it, but we are not going far enough. We need to ask the administration to carry out the strength of their ability through Executive orders to create true competition throughout the country and throughout the world on pharmaceutical prices.

Regardless of all the precautions and the well-thought-out plans of Senator DORGAN—and I know Senator BROWN has worked on this for years, as has Senator STABENOW and Senator VITTER and several others—I believe they will get around it. I believe they will sign contracts for fixed quantities of drugs,

and then the countries that have the potential to take a drug that was produced here or produced by a manufacturer that is based out of this country, they will limit the amount of drugs that are available to them based on the contract they sign for the number of drugs. So we will have made everybody feel better, but we will not really have created a worldwide market for pharmaceuticals. That is what I think we have to do.

I would like to put out to the author of this amendment, as well as the sponsors, that we ought to think bigger on how to handle this because what we really have is one industry where there is not true free trading. We are not ever going to get the benefits, we are not ever going to relieve the burden of the American consumer, who is paying to subsidize drugs in Germany, in England, in France, and in Japan, we are not ever going to take that burden off until we really create a true worldwide market in pharmaceuticals. I am just hesitant to believe this is going to accomplish it.

Like I said, I am going to vote for it. I believe it is a step in the right direction, but I think we need to be more bold. If we really believe in the benefits of international free trade, then we should do whatever is in our power to insist it become an international market for pharmaceuticals. That way, the pharmaceutical companies won't have to use the only market there is in our country to subsidize the variable costs and the research that they contribute to a lot of the drugs that come today.

So I am supportive, I think it will pass, but I would reach out to the other Members who are interested and say: Let's do something bigger. Let's do something that will really fix it and do it fairly quickly. We will have a thriving pharmaceutical industry that way. It truly will be based on competition. Intellectual properties that are truly researched and supported by the country—we as Americans, if we have done that, we will get the better benefit from it if we have a true international market. I think the drug companies would like to see that as well.

I understand they are trying to get return on invested assets. I believe it is important that everyone has a fair price for a pharmaceutical and that people make money when they sell a pharmaceutical. But we have to have an international market, and we have to solve it that way.

I thank Senator BROWN for allowing me the time, and I yield the floor.

AMENDMENT NO. 985

Mr. BROWN. Mr. President, I thank Senator COBURN for his always innovative approach and his support of this and for all he does in working on health care issues generally and especially on prescription drugs.

Mr. President, I ask unanimous consent that the pending amendment be set aside, and on behalf of Senator BROWNBACK and myself, I call up amendment No. 985.

The ACTING PRESIDENT pro tempore. Is there objection?

Hearing no objection, it is so ordered. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Ohio [Mr. BROWN], for himself and Mr. BROWNBACK, proposes an amendment numbered 985.

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

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

The amendment is as follows:

(Purpose: To establish a priority drug review process to encourage treatments of tropical diseases)

At the appropriate place, insert the following:

SEC. ____ . PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

“SEC. 524. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

“(a) DEFINITIONS.—In this section:

“(1) AIDS.—The term ‘AIDS’ means the acquired immune deficiency syndrome.

“(2) AIDS DRUG.—The term ‘AIDS drug’ means a drug indicated for treating HIV.

“(3) HIV.—The term ‘HIV’ means the human immunodeficiency virus, the pathogen that causes AIDS.

“(4) NEGLECTED OR TROPICAL DISEASE.—The term ‘neglected or tropical disease’ means—

“(A) HIV, malaria, tuberculosis, and related diseases; or

“(B) any other infectious disease that disproportionately affects poor and marginalized populations, including those diseases targeted by the Special Programme for Research and Training in Tropical Diseases cosponsored by the United Nations Development Program, UNICEF, the World Bank, and the World Health Organization.

“(5) PRIORITY REVIEW.—The term ‘priority review’, with respect to a new drug application described in paragraph (6), means review and action by the Secretary on such application not later than 180 days after receipt by the Secretary of such application, pursuant to the Manual of Policies and Procedures of the Food and Drug Administration.

“(6) PRIORITY REVIEW VOUCHER.—The term ‘priority review voucher’ means a voucher issued by the Secretary to the sponsor of a tropical disease product that entitles such sponsor, or a person described under subsection (b)(2), to priority review of a new drug application submitted under section 505(b)(1) after the date of approval of the tropical disease product.

“(7) TROPICAL DISEASE PRODUCT.—The term ‘tropical disease product’ means a product that—

“(A) is a new drug, antibiotic drug, biological product, vaccine, device, diagnostic, or other tool for treatment of a neglected or tropical disease; and

“(B) is approved by the Secretary for use in the treatment of a neglected or tropical disease.

“(b) PRIORITY REVIEW VOUCHER.—

“(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a tropical disease product upon approval by the Secretary of such tropical disease product.

“(2) TRANSFERABILITY.—The sponsor of a tropical disease product that receives a priority review voucher under this section may

transfer (including by sale) the entitlement to such voucher to a sponsor of a new drug for which an application under section 505(b)(1) will be submitted after the date of the approval of the tropical disease product.

“(3) LIMITATION.—A sponsor of a tropical disease product may not receive a priority review voucher under this section if the tropical disease product was approved by the Secretary prior to the date of enactment of this section.

“(c) PRIORITY REVIEW USER FEE.—

“(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a drug that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

“(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the anticipated costs to the Secretary of implementing this section.

“(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, the amount of the priority review user fee.

“(4) PAYMENT.—

“(A) IN GENERAL.—The fee required by this subsection shall be due upon the filing of the new drug application under section 505(b)(1) for which the voucher is used.

“(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection is not included in such application.”.

Mr. BROWN. Mr. President, I rise today to offer the Brownback-Brown amendment, No. 985, which provides incentives for pharmaceutical companies to develop and manufacture treatments for neglected tropical diseases. According to the World Health Organization, more than 1 billion people—that is one of every six people worldwide—are affected by at least one neglected tropical disease. In addition, neglected tropical diseases claim roughly 500,000 lives every year. However, less than 1 percent of the roughly 1,400 drugs registered between 1975 and 1999 treated such diseases.

This disparity is obviously due to the lack of financial incentives for pharmaceutical companies to bring neglected tropical disease treatments to market because these diseases disproportionately affect low-income countries, mainly in Africa. Creating incentives for companies to invest in treatments for these diseases is not only in our country's national interest, but it is consistent with the longstanding tradition of this country of caring for those less fortunate around the world.

This amendment would award a priority review voucher to any company that brings a neglected tropical disease treatment to market. Priority review is an existing FDA process by which drugs are reviewed in 6 months as opposed to the average time of 18 months. This priority review voucher would be transferable and could be applied to any drug in a company's pipeline.

This voucher, which would be worth hundreds of millions of dollars for a

company with a new blockbuster drug, would also benefit consumers. That is because it would give consumers earlier access to a new prescription drug. Most importantly, creating incentives for pharmaceutical companies to develop and manufacture neglected tropical disease treatments will obviously save lives.

I commend Senator BROWNBACK for his hard work on behalf of impoverished populations who desperately need our attention. He is offering Members of this body the opportunity to simultaneously save lives in developing nations, get U.S. consumers access to new medicines more quickly, and engage the drug industry in a win-win proposition. It is a rare opportunity, and I urge Members on both sides of the aisle to support the Brownback-Brown amendment.

AMENDMENT NO. 1011

Mr. President, I would like to make a few comments on two other amendments, the first being the Stabenow amendment, which I have also cosponsored, along with Senators LOTT and THUNE. That amendment will save U.S. taxpayers hundreds of millions of dollars while restoring the integrity of the citizen petition process. That is important because the citizen petition process is fundamental to our Nation's democratic system.

Under U.S. law, individuals and organizations have the right and should have the right to petition the Federal Government, which is another way of saying they have a right to communicate their views and have their views heard. The Federal Government is, after all, an employee of the American people. Americans absolutely should have the right to weigh in on Government policies and actions.

Unfortunately, some brand-name pharmaceutical companies have regularly exploited the citizen petition process, filing frivolous petitions solely for the purpose of delaying the approval of generic drugs. They have been quite successful at it. Since 2003, brand drug companies have filed dozens and dozens of citizen petitions trying to stop or delay FDA approval of competing generic products. Ninety-five percent—roughly 19 in 20—of these petitions have been denied outright. What about the other 5 percent? FDA either hasn't acted on them or has approved them in whole or in part because they had no other choice—the brand companies had simply reiterated a factual issue that had already been addressed by FDA. In other words, even the approved petitions, the approved 5 percent, were frivolous.

While drugmakers waste FDA's time and taxpayers' money, American patients are forced to continue paying top dollar—the name-brand price—for the medicines they need. Frivolous citizen petitions have created delays that often range from 11 to 15 months, preventing price competition for drugs that generate millions of dollars in revenue each day. American consumers—

American taxpayers, who help finance Medicare, Medicaid, and VA health care—can't afford it. These costs are borne not just by consumers and taxpayers but also employers.

I have worked closely with Senator STABENOW to make sure this amendment doesn't interfere with the right of individuals or companies to petition FDA and that the amendment ensures these individuals that the concerns raised in their petitions will still be taken seriously by FDA. What this amendment does do is fight back against the unjustifiable and costly delays caused by frivolous petitions submitted for the express purpose of blocking price competition in the marketplace.

No one, not the drug industry or any other industry, should be allowed to make a mockery of one of our democratic rights—the right to petition our Government—particularly at the expense of patients and taxpayers. Ms. STABENOW's amendment, cosponsored by Senator THUNE and Senator LOTT, will put a stop to a tactic which is as costly as it is unethical. I urge every Member of this body to support it.

AMENDMENT NO. 990

Mr. President, I also would briefly speak out on the Dorgan reimportation amendment, joining Senators GRASSLEY and STABENOW and so many others in both parties in supporting the reimportation amendment.

Some time ago, about 10 years ago, from my northeast Ohio congressional district when I served in the House of Representatives, along with the Presiding Officer, I used to sponsor bus trips to Canada where we would take mostly senior citizens to a Canadian drugstore right across the river from Detroit—Windsor—which was about a 3- or 4-hour bus drive from Lorain County, where I lived. We would take a busload of 40 seniors and others—mostly seniors, as I said. We would buy prescription drugs in Canada—same dosage, same package, same drug manufacturer, for half or even sometimes a third the cost because the Canadian Government directly negotiated on behalf of 30 million Canadians, negotiated directly with the drug company for specifically less expensive drugs. It was clear to me then that reimportation was legislation we needed so seniors did not have to go to Canada; instead, that wholesalers, the Drug Marts and the CVS's of the world and the mom-and-pop drugstores can negotiate, could get those prices wholesale from Canadian drugmakers or companies and bring those prices significantly down for American consumers.

As Senator COBURN said, when we were House Members we passed legislation 8 or 9 years ago. That legislation was never implemented the way it should have been. The Dorgan amendment will save money for America's seniors, for America's drug consumers, for prescription drug users. It is an important amendment, and I ask for support for the Stabenow amendment, the

Dorgan amendment, and the Brownback-Brown amendment.

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

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

The Senator from Pennsylvania is recognized.

Mr. CASEY. Mr. President, I stand today in support of an amendment to S. 1082 offered by Senator DORGAN and several of our colleagues. This amendment is identical to a bill sponsored by the Senator from North Dakota, a bill I am proud to cosponsor.

We have a serious problem today with drug prices all across our land. The American people have asked us to do something constructive about this crisis. Why is it Americans pay the world's highest prices for prescription drugs? This is simply not fair, and I have to believe we can do better in America. While the issues contributing to prescription drug prices are many and complex, this amendment, the Pharmaceutical Market Access and Drug Safety Act, offers a genuine and workable piece of the solution.

It is no secret to anyone that Americans already import many prescription drugs, and I have heard from constituents in my home State of Pennsylvania about buying drugs outside of this country. A recent study shows that would cost from 35 to 55 percent less than constituents of mine are paying. They can pay a much lower price if they are able to get prescriptions from another country. Seniors who are living on limited incomes are especially vulnerable and need to cut costs wherever they can.

We all know the high cost of health care across all of our States is prohibitive for so many vulnerable citizens—children, working families, and older citizens. The reality is when the monthly budget has been spent on necessities such as food or childcare, doctors' visits, housing, transportation—when all those costs are incurred, many families do not have money left over for medicine. These individuals may have no choice but to forgo needed medicine and hope for the best.

Another recent study found 43 percent of uninsured Americans ages 19 to 64, and even 18 percent of insured adults, did not fill a prescription because of cost. This is in the richest country in the world. We can do a lot better than that, and we must do better than that.

I support this legislation because it gives us the opportunity to help families in America, and to do so safely. There are a number of safety features that are intended to guarantee that only safe and effective—let me say that again, only safe and effective—FDA-ap-

proved drugs are imported across our borders. These safety features are comprehensive. For purposes of time, I want to highlight a few.

First, this act allows only the importation of FDA-approved medicines with a chain of custody, to ensure that drugs are handled only by authorized persons. In most cases, the medicines that are imported under this act are identical to the medications sold in the United States—literally the same medications made by the same manufacturers.

Exporters would be required to maintain detailed records and a sample of each lot sent to the U.S., so that the FDA can conduct testing on any lot at any time. The FDA would have broad authorities, including the power to cease importation of a drug or to suspend a registered exporter without notice. The FDA also has the authority to inspect all facilities in the chain of custody of a drug.

The bottom line is this bill gives the FDA broad authority and the resources to ensure that imported drugs are in fact safe. It is unacceptable that working parents have to make a choice between medicine they cannot afford for their child and making the rent payment on time. It is unacceptable that older citizens have to choose between paying for needed medication and paying for food.

This Chamber can do something about this challenge, can do something about this Hobson's choice so many families face every day in America. The Dorgan amendment provides an effective regulatory framework to ensure that imported drugs are safe for our families. I urge all my colleagues to support this amendment which will provide an invaluable piece of the solution to making FDA-approved prescription drugs affordable for everyone.

The PRESIDING OFFICER. The Senator from Oklahoma is recognized.

Mr. INHOFE. Mr. President, I ask unanimous consent that I be permitted to speak as in morning business for up to 10 minutes.

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

(The remarks of Mr. INHOFE are printed in today's RECORD under "Morning Business.")

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

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

The PRESIDING OFFICER (Mr. WHITEHOUSE.) The senior Senator from Maine is recognized.

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

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

Ms. SNOWE. Mr. President, I rise in support of the amendment that has been introduced by Senator DORGAN

with whom I have joined as a cosponsor regarding drug importation.

First of all, I commend Senator DORGAN for his longstanding leadership and advocacy on this issue which has been for the better part of a decade. Regrettably, we are still at a point where we have been unable to pass legislation that would create a drug safety regime for drug importation.

That is the purpose of our amendment, Members of the Senate, as we today consider legislation to address an essential new function in how the FDA will finance the cost of reviewing new drugs; that is, the critical process of bringing new medications to market to Americans.

At the same time, this bill has directly raised a number of issues in how we assure that drugs are as safe as they should be, how we can bring new low-cost generic biologics to market. Key to this debate on this legislation that is pending before the Senate is the adage, which we have heard time and time again, that is: A drug which is not affordable is neither safe nor effective.

The simple fact is, even with the new Part D prescription drug benefit as part of the Medicare Program that has been in place for more than 2 years now, we still have at least 60 million Americans overall that today pay the full price of medications, have no help whatsoever because many have no health insurance or their insurance does not provide coverage for prescription drugs.

At the same time, the price that Americans are paying is the highest price in the world. For those of us who are fortunate to have prescription drug coverage, the estimated cost of medications is part of the major exorbitant increase in the cost of health care.

Many of my colleagues have recognized that our system lacks competition that would assure our constituents more affordable access to lifesaving medications. That is why I am very pleased to join with the Senator from North Dakota, and we have the support of a bipartisan group of colleagues in the Senate, along with Senators GRASSLEY and KENNEDY and Senators MCCAIN and STABENOW who are unified with us in supporting this bipartisan approach.

Today, our voices echo those of 8 out of 10 Americans who are calling for safe importation. After nearly 3 years of awaiting Senate consideration of our legislation in 11 related hearings on this subject in the Senate, we simply must move forward. The reason is abundantly clear. We know the cost of health care is rapidly rising in America.

Prescription drug prices have contributed to that exorbitant increase. Compared to 1990, nearly twice as much of our health care dollar goes to medications. As the GAO has readily told us, the cost of prescription drugs commonly used by seniors has consistently increased at two to three times the rate of inflation, as indicated by this

chart, when you are comparing brand drugs, generics, and the CPI.

That is why we can no longer afford to postpone any action. We have acted before. We acted on legislation back in 2000. Then we also took action with respect to the Medicare Modernization Act in 2003 which created a Part D prescription drug program. We have found the requirements for the Secretary of Health and Human Services to certify the safety and savings of drug importation have blocked any action; it has become a roadblock to safe importation.

While FDA was unable to point to a single individual harmed by Canadian drugs—and in Europe, where they have had a track record of more than 30 years of parallel trading—it has proven that this trade can be conducted safely.

Time and time again, they have demonstrated that their process of parallel trading has worked without any harm to their consumers. Without a doubt, Americans would not be turning to imports if there was not substantial savings. Indeed, the CBO has told us that countries from which we would import under this bill would pay 35 to 55 percent less for a brand prescription drug. Let me repeat that—35 to 55 percent less than we pay today.

In other words, American consumers are paying 35 to 55 percent more than foreign consumers when it comes to medications. That is remarkable. We have seen so many objections to this legislation for the better part of a decade. That is why we have taken it upon ourselves to develop a regime that has been incorporated in this amendment and in our legislation that would address every facet, every issue that is associated with safety in order to allow drug importation to occur.

As I said earlier, the European Union has already engaged in parallel trading for three decades without incident. As seen here on this chart, where we have incorporated 31 different key safety provisions in our legislation, and compare that to the Medicare Modernization Act that passed in 2003 that created the Part D prescription drug benefit to the Medicare Program, only 6 provisions that related to safety were incorporated in that landmark initiative.

We include 31 different initiatives to address every single safety-related issue that has emerged in this debate. Whether it has been on the floor of the Senate, whether it has been in the course of hearings or elsewhere, we have addressed every safety-related issue to create a regime that should create the assurance that this can be done safely and without harm to Americans so they can benefit from lower priced medications.

Americans deserve to have the lower priced medications. The FDA can conduct this program. They can conduct this regime. They should work proactively to assure these drugs are safe. We give them the means and the wherewithal and the resources in order to accomplish this. We comprehen-

sively address the various concerns that have been raised months and years about drug importation so we can get something done.

People say: Well, let's just certify safety. Well, as I have said earlier, it is a roadblock. It is an impediment to get anything done. It essentially becomes the poison pill. We have tried certification. We have given the Secretary of Health and Human Services under two administrations—this administration and the previous administration—the ability to do that, to certify it. They are unwilling to do so because they have said they do not have the resources, they do not have the means.

Well, we are giving them the means and the resources. But to pass another amendment that simply calls for the Secretary of Health and Human Services to certify drug importation is a roadblock. It is a road to nowhere with respect to this initiative. That is why Senator DORGAN and I took a different route.

We address all the safety questions. We do not certify to ensure safety, we take action with these provisions. What we do is employ the measures to actually make drug importation safe.

Opponents claim importation will cause harm. But they fail to note that the greatest threat to the safety of Americans is the inability to take a drug as it is prescribed. That exacts a toll on thousands, if not millions, of Americans each and every year, not to mention lives lost.

Some say Americans would receive drugs from illegitimate sources, but under our legislation, Americans will receive imported drugs from 32 countries with high standards. In most cases Americans will purchase an imported prescription drug from their local pharmacies just as they do today. The pharmacies will receive these drugs from the U.S. wholesalers which import them. These wholesalers will have been registered. They will be inspected. They will be monitored by the FDA. This higher level of safety is also a first step in establishing a higher standard for handling of prescription drugs right here in the United States where we have had the preponderance of problems.

Our legislation allows individuals to directly order medications using an FDA-registered and approved Canadian pharmacy. Again, just as with wholesalers handling prescription drugs, the FDA will examine, register, and inspect these facilities on a frequent basis. The FDA will assure the highest standards for such functions as making sure the medical history is recorded of the individual, verifying prescriptions, and tracking the shipments.

Some say consumers will get medications they should not be getting. Regardless of whether one purchases imported drugs from the local pharmacist or uses a Canadian pharmacy, we assure that a legitimate prescription and a qualified pharmacist will be vital ingredients to ensuring safety. In fact,

we have many standards incorporated in this legislation in which it would occur.

We adopted language that had been introduced by the Senator from California, Mrs. FEINSTEIN, with respect to Web sites and domestic Internet pharmacies so that we assure that properly licensed pharmacies and pharmacists are behind Web sites that are offering these medications.

Some say importation will allow unapproved drugs to enter the United States. Again, on that point, our legislation is abundantly clear. Every drug received will always be FDA-approved. If any difference exists in a foreign drug, even the most minute, our legislation assures FDA will evaluate the product and determine its acceptability. If the drug is not bioequivalent to a U.S. drug, the Secretary may reject approval of that medication.

Some say we will import counterfeits. The truth is, today the FDA does not know even the level of domestic counterfeiting where, as I said earlier, the preponderance of the problem exists. It is simply not employing the very anticounterfeiting technologies which our legislation demands in order to ensure that we protect against the threat of counterfeits. The fact is, we employ technologies today like the ones we use now for twenty-dollar bills. We can use the same for prescription drugs.

Moreover, this bill supports development of future anticounterfeiting and track-and-trace technologies, very effective methods which we hope will be used to protect all drugs. For those who say consumers would not know who has handled the imported prescription drug, again, our bill requires a chain of custody, a pedigree to be maintained and inspected to help ensure the integrity of imported medications. A pedigree for prescription drugs was mandated, believe it or not, by law in 1988 and still has not been implemented by the FDA. Under our legislation, at last we will require pedigrees to be implemented for all medications.

Some opponents will even attempt to alarm Americans about the countries from which we import drugs, citing Latvia, Estonia, Slovakia, and members of the European Union. But consider that another member is Ireland where Lipitor is made. Again, I call your attention to this chart which indicates the European Union and other countries from which we import drugs designated in blue. They either meet our standards or have even higher ones, ones as you can see in this chart, all of the blue countries from which we would import. They have our standards or they exceed our standards.

In contrast, this chart denotes the countries in red from which, again, our manufacturers import medications. That is interesting. The FDA inspects pharmaceutical manufacturing plants in these countries denoted in red. These are countries from which manufacturers will import products. It includes China, India, Bulgaria, Jordan,

and other countries. In fact, they have lower standards. So what I have indicated, based on what this map shows, is that we have the blue countries from which we would allow importation of drugs that would be FDA-approved, facilities inspected, documented. We would have pedigrees and technologies to track the shipments. These are countries that meet or exceed our standards. Today we already have FDA pharmaceutical manufacturing plants in these countries in red that, in fact, have lower standards. So we already, amazingly enough, allow medications to come in from countries that have lower standards. Why do we? Because they are inspected by FDA. So the same process can't work for countries that meet or exceed our standards already, that already have a track record in parallel trading in and amongst their own countries, and we can't do it today for those countries when FDA already does it for other countries that have lower standards? Because that is where many of our medications are manufactured. That is where our manufacturers import and FDA inspects those facilities before those medications enter the United States. So this is already done. It is done with countries that have lower standards, and we find that acceptable. Yet we say we are not finding it acceptable from countries that already have a track record of parallel trading amongst their own country without injury to any of their consumers over the last 30 years that meet or exceed our standards. It simply doesn't make sense.

We are setting a model for improving safety because we are saying we are going to create 36 different measures for establishing safety for the American consumer to assure all those concerned that we have the measures in place and the resources with which to do it. So to those who say importation is unsafe, we show them how it shall be safe under our legislation. It sets a model and a standard.

Some say consumers will not see significant savings. But drugs imported under this program will be labeled as imports so consumers will have the opportunity to do some comparative shopping. They will be able to take those prices and do a side-by-side comparison between the imports and those medications they buy in the United States. Consumers have become well aware of foreign pricing and the competition that exists between imported and wholesalers. We know they will achieve consumer savings; there is no question. That is why so many Americans, including many of my constituents from the State of Maine who have been able to access medications from Canada, have had to take bus trip after bus trip. They have been compelled to do that in order to achieve savings because of our unwillingness to address this issue in the Senate and the overall Congress. This legislation should have been accomplished a long time ago.

In terms of savings, it should be interesting to note the independent anal-

ysis of the Congressional Budget Office which has confirmed that the savings, indeed, should be substantial—not surprising. It would be very substantial, indeed. They estimate a 10-year direct savings alone of \$50 billion to the American consumer—\$50 billion. That is probably on the conservative side. The Federal Government stands to save \$6.1 billion in the Medicare and Medicaid Programs alone. This is only the savings that CBO projected from purchases of imports. With increased competition in our markets, we could indeed save more, having competition, having the pharmaceutical industry have some competition in their pricing. Understand, individuals can't import medications. Pharmacists can't import medications. Only manufacturers can. So we are saying: Let's set a standard. Let's allow imports that benefit the individual consumer with safety-related provisions put in place.

In fact, in a recent Commerce Committee subcommittee hearing, we had the opportunity to hear from a number of experts. We heard from a pharmaceutical economist who estimated that importation could result in a 12- to 20-percent reduction in domestic drug costs. That is an annual savings, not over 10 years, of up to \$40 billion per year, as competition is created for consumer savings. So as a direct result of the competition that would develop as a result of importation, consumers alone could save up to \$40 billion a year.

So at a time when health care spending is reaching 16 percent of GDP and is climbing, this competition is an imperative. It is central. It is central to the consumer who is facing double-digit increases in prescription drugs. Prescription drugs are not getting cheaper in America. They are getting more expensive. As I said, the American consumer is spending 35 to 55 percent more than the foreign consumer. Health care spending is 16 percent of the GDP. Much of the increase in health care spending is attributed to the rising cost in prescription drugs.

So that is why this becomes all the more important to the American consumer and, indeed, to the Federal Government that will save \$50 billion over 10 years and 6 billion alone in Medicare and Medicaid spending. That is important to our own interests and to our budgetary concerns about the growth in these respective programs.

Some have argued that we haven't provided the resources necessary to run an importation program. But we have established a means of financing, a small fee based on the value of imported drugs which will now be set at a cap of 2.5 percent. We have always agreed that the FDA should have adequate resources. In fact, we heard from previous Secretaries of Health and Human Services, we don't have the resources to certify safety. So now we are providing a certification for that by including this cap of 2.5 percent for a fee on the total import of medica-

tions. This is what CBO has indicated to us would be necessary in order to accomplish and implement these safety-related measures. We think it is important the FDA have the resources that are essential for regulation, for monitoring inspections of both domestic wholesalers, who would import the prescription drugs, as well as the Canadian pharmacies from which American consumers could order.

Some say our bill is intended to adopt Canadian prices. Again, quite the contrary. We open importation to 32 countries which meet our safety standards. We are not simply adopting the price of another country. Rather, we are purchasing in a world market. That is a critical point. We are allowing American consumers to benefit from worldwide prices because of the competition that would be allowed. Obviously, something is happening in other countries where we want to import these medications because they are paying 35 to 55 percent less than American consumers. Why should that be the case? These are countries, by the way, that meet or exceed our standards when it comes to drug safety. Yet American consumers are paying 35 to 55 percent more for the same medications.

Some say we compel manufacturers to sell the product. But our bill is very clear on that specific point. We never compel any manufacturer to sell any particular product. But when a manufacturer chooses to sell product, the bipartisan bill prohibits discriminatory acts against pharmacists and wholesalers who sell these medications. Those actions have reduced supplies of essential drugs for some Americans, at peril to their health.

We are saying they cannot take action that discriminates against a pharmacy because they have sold those drugs to an American consumer. They are not penalized because their supplies are cut off by the manufacturer as a means of punishment and discrimination.

Now, some say importation will threaten research and development. But the fact is, manufacturers will invest just as other industries do, in order to develop innovative products and remain competitive. The taxpayer is a partner in that investment. The American taxpayer is a partner. The taxpayer makes investments in research and development. In fact, we fund nearly \$30 billion a year to do basic and applied research at the National Institutes of Health alone—\$30 billion.

So as you can see on this chart, as to R&D spending from all the companies, we—the United States consumer and taxpayer—fund and underwrite much of their research and development.

As I said earlier, other industrialized countries pay 35 to 55 percent less for their drugs. But because of the higher prices Americans pay for their medications, the American consumer ends up

paying \$99 billion more for their prescription drugs each year than otherwise would be the case. Let me repeat that. Because we pay 35 to 55 percent more than foreign consumers, American consumers end up paying \$99 billion more for their medications.

With all that additional profit, the industry spends about \$9 billion more on research and development than they do in Europe. That is 10 cents return on the dollar for all that added profit margin. So while the American consumers spend \$99 billion more for their prescription drugs than foreign consumers, in Europe, for example, American pharmaceuticals spend only \$9 billion more—from that \$99 billion—on research and development than they do in Europe. We spend only \$9 billion more here than they do in Europe on research and development. That means American pharmaceuticals are netting \$90 billion more, that they are only investing \$9 billion more in research and development.

So it is not undercutting their ability for research and development, not to also mention, by the way, the American taxpayer invests more than \$30 billion at the National Institutes of Health alone for basic research as well.

In fact, if you look at the R&D spending of the largest pharmaceutical firms—as indicated again by this chart—it is not markedly different from many other firms. If you look at other firms, such as Intel, Microsoft, Lucent, and others with high research and development costs and relatively low production costs, their research and development spending averages about 14.3 percent of gross revenues—not much different—yet their products are highly competitive, very competitive. You have seen the software, cell phones, computers, laptops, whatever. You have seen the very competitive pricing today, yet they make an investment of 14.3 percent for research and development as a percentage of their gross revenues.

Yet, paying the world's highest prices for drugs does not ensure additional research, but it certainly does decrease access to drugs. So while they do not invest in considerably more research and development—since we pay \$99 billion more in prices for prescription medications, and they only spend \$9 billion more on research and development, and the taxpayer spends \$30 billion at NIH alone, as I indicated; but even, comparatively speaking, it is 14.4 percent of their gross revenues that are invested in research and development—if you compare that to, as I said, Intel, Microsoft, Lucent, and other companies, which is 14.3 percent, you find more competitive products in the technology arena. Their prices are coming down. The American consumer is not benefiting from the investments that are being made by the pharmaceuticals, yet it is a highly profitable industry. So we are not seeing the same benefits that would yield lower prices for the American consumer.

Now, in conclusion, let me say, I hope this Senate will adopt this amendment that creates the kind of safety regime that would ensure drug importation will become a reality. Simply certifying safety on the part of the Secretary of Health and Human Services has been tried and yet has never accomplished that goal. It has been an impediment to drug importation. It has occurred twice in the last 10 years, and for whatever reasons the Secretaries in the previous administration and this administration have concluded they will not certify the safety regime because there has been no safety regime. It could be done, but it has not been done through the agencies. FDA could do it. It has not accomplished it. It has not implemented it. It has not had the impetus to pursue it. That is why we have taken it a step further. This legislation has been examined, reexamined, based on the concerns that have been expressed by those who have been opposed to it in the past saying they have concern about safety.

We understand that. So we have gone a step further and incorporated every safety-related measure possible that is achievable, measurable, and provide the FDA with the resources to accomplish it.

The Senate has voiced its view to provide market access on this issue on many occasions, even by virtue of passing the certification standard. Obviously, I think there has been an indication on the part of the Senate to support some type of initiative that allows for drug importation. But we want to mitigate the concerns that have been expressed repeatedly about the issues of safety by incorporating all of those measures in this amendment that is pending before the Senate.

In fact, 68 Members of this body voted to adopt the amendment that was offered by the Senator from Louisiana, Mr. VITTER, to the Homeland Security appropriations bill. But we need more than to simply allow importation. We must provide an effective framework that will address the concerns that will ultimately ensure the safety of our consumers.

Sixty-eight Members of this body supported blocking the Customs agency from banning drug importation, so it is obvious Members of this Senate truly want to pass a measure that will allow for drug importation. That is why I think this legislation logically affords us the ability to provide the safety and, at the same time, allow consumers in America to benefit from competition, from lower prices, based on the track record and the experience of other countries that have been adopting this approach for many decades.

Competition is what is missing in this process. It will work for the consumer. To date, the process has not worked for the consumer where they have benefited from lower prices for medications because there has been no

competition. Competition has been virtually absent. I note the comment of the former Pfizer CEO, Hank McKinnell, who wrote:

Competition is good medicine for economies. . . . Name an industry in which competition is allowed to flourish—computers, telecommunications, small package shipping, retailing, entertainment—and I'll show you lower prices, higher quality, more innovation, and better customer service. There's nary an exception. Okay, there's one. So far the healthcare industry seems immune to the discipline of competition.

Those are the words of the former Pfizer CEO, Hank McKinnell.

It is indeed time to make competition work to benefit consumers and taxpayers. Americans deserve and will seek out affordable life-sustaining medications. We must assure that access is safe. That is what we accomplish in this amendment that is pending before the Senate.

Again, I thank my colleague from North Dakota, Senator DORGAN, for his leadership on this question and for all those who are supporting this initiative.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senate majority whip.

AMENDMENT NO. 1022

(Purpose: To ensure the safety of human and pet food.)

Mr. DURBIN. Mr. President, in a brief period of time I will be offering an amendment which I hope to bring to a vote very shortly, perhaps in the next 15 or 20 minutes, depending on the wishes of the chairman of the committee and the ranking member, Senator ENZI.

This amendment relates to the issue of food safety. This has been one of my concerns for a long time as a Member of the House and the Senate. I know everyone across America trusts that the food they buy for their families and everyone in their house is safe, that they can eat it and not get sick.

We all know what has happened over the last several months. Whether we are talking about contaminated *E. coli* in spinach, salmonella in peanut butter, or the latest pet food contamination, people are asking questions of Members of Congress and this Government: Are we doing our job? What is happening here? Why are so many dangerous food products showing up so frequently? How can we protect ourselves?

For many years I have thought the real answer is to tackle the whole issue. I have said it before on the floor, 12 to 15 different Federal agencies inspect our food—imagine that—and they all have different standards. Some inspect food every single day. Go to a meatpacking plant, poultry processing plant; the food is inspected every single day, every minute of every day, as it passes along those lines by the U.S. Department of Agriculture.

Fish is another story. Fish is inspected by the Food and Drug Administration. How do they inspect it? By

what they call the “sniff test.” They lean over and smell the fish, and if they have what they call a “head snap,” they know they have a bad load of fish. Sounds kind of comical, but it is what we get down to, by and large, in terms of inspecting fish.

So when you go throughout our Government and look at different products and how they are inspected, it makes no sense why different agencies are doing different parts of the food chain. From a consumer’s point of view, I do not want to know there are 12 or 15 different agencies at work, with their lights on, in Washington, with a lot of different employees. I want to know there is one good agency, scientifically driven, that is making the right call as to whether there should be an inspection every day, every month, every year—whenever.

They do not have that today, and the system breaks down. What we have seen happen over the last several months is a clear indication that our food safety system—as good as it may be—needs to be a lot better. So I am offering this amendment on food safety.

I thank the Senator from Wyoming who has been very cooperative and helpful in making certain this is a bipartisan amendment. There is nothing partisan about food safety. We should all agree that the goal is one both parties share, all Americans share. Senator KENNEDY has given me the time to offer this amendment on this important bill early on, and I certainly appreciate it. Senator ALLARD from Colorado, a veterinarian, has been involved in this negotiation, as has Senator HARKIN, the chairman of the Agriculture Committee. Many people have come together to take a look at this and make sure it is moving in the right direction.

There was an early warning. The early warning came a few weeks ago when we had a pet food crisis. People who own dogs and cats know what I am talking about. All of a sudden there was a suspicion that the food you were giving your dog—that animal you love, an animal that is part of your family—could be poisoning that animal. Well, for 90 million Americans that is a big deal, and they were concerned about it. So we started looking into why this pet food was contaminated.

That crisis was an early warning signal to America. It was a warning signal that we came to learn had a lot to do with the imports coming into America. More and more imports of food products are coming in from overseas. If you believe we have inspectors sitting in China and France and Germany and Brazil taking a look at these things as they come off the assembly line, taking a little test sample and running it to the lab, you are wrong. It does not happen. In fact, once the shipment is on the boat, or on the plane, coming to America, the odds are 99 to 1 no inspector will ever look at it before it is put into a food product—99 to 1. Only 1 to 1.5 percent of food products sent to

America is actually inspected by our Government.

Now, we look at what came over from the Chinese and find out they were adding a chemical to wheat gluten, a protein product called melamine. Melamine is a chemical derived from coal, which is used in the manufacturing of plastic. It has no business in anything that is edible. It was put into the shipment of protein, this wheat gluten, in order to enhance its value because when they tested this wheat gluten on its arrival, this melamine chemical indicated the presence of nitrogen, therefore, more protein, and, therefore, it was worth more. They would sprinkle in the melamine and make more money off the shipment. If this were the end of the story, you would say: Well, that was a pretty nice move; they just made a bigger profit off the shipment. It wasn’t the end of the story. It turns out that wheat gluten, when used for pet foods, is toxic. Over 4,000 animals died across America because of melamine and possibly other contaminants. We are still investigating.

So we went to find out how it got into the shipment, and the Chinese did not cooperate. They have started to. I am glad they have. They have agreed to visas for our inspectors. But this pet food crisis was a warning sign, a signal to us in America that this dramatic increase in imports of food products leaves us vulnerable. Today, it was your cat or your dog. Tomorrow, it could be someone in your family whom you love. So we address part of this in this bill.

Secondly, it is an indication that the Food and Drug Administration doesn’t have the authority or the resources to do their job as well as they should. This is a great agency. They have an awesome responsibility. We heap more and more responsibility on them each year, we provide them very little by way of additional resources, and they are being stretched to the absolute limit. Of course, this pet food crisis is an early warning that the whole food safety system has to be investigated and honestly looked at. So this is a start. It is an effort to try to make a difference.

I wish to thank Senator KOHL from Wisconsin and Senator BENNETT from Utah. When the pet food crisis came out, they called a timely hearing after our Easter recess, and we started working on this amendment just at that moment, and thanks to them for realizing the importance of this issue.

I also thank those who helped us draft this legislation—the Center for Science and the Public Interest, the Humane Society, which has been terrific from start to finish, the American Veterinary Medical Association, and the Coalition for a Stronger FDA.

Special thanks, while I am giving out bouquets here, to my staffer David Lazarus. This young staffer has really put his heart and soul into this effort. It is his first major legislative undertaking, and I commend him for the very fine job he has done.

Let me say very briefly what this amendment will do. First, it deals with pet food because we have just come off of a pet food crisis, but it doesn’t stop there because this contamination doesn’t stop with pet food. Sure, we found it in the cans of dog food and cat food, but guess what. It ended up in livestock feed. It ended up moving into the feedlots for hogs, turning into pork products we buy in the store. It ended up in poultry plants, being fed to chickens. We are naive to believe that any problem in the pet food industry can’t possibly make it to the human food side of the equation. It can. God forbid that it ever does. We hope we have stopped it in this instance, but it is pure luck if we were able to save ourselves from that calamity this time. We don’t want it to happen again.

There are provisions in this amendment which go directly to the pet food issue, provisions which require the FDA to update their labeling standards for pet food, including nutritional and ingredient information, working closely with the American Association of Feed Control so that the representations on the labels of these cans of pet food are honest representations about what is good for your animal and what is safe. Also, it requires that the Secretary of Health and Human Services establish an enhanced system capable of detecting food contamination and outbreaks of pet illness and death.

This amendment also requires the FDA to develop an efficient, effective communication plan to coordinate with veterinarians and consumers, owners across America, so that we can find out if we are dealing with a need for a recall. Recall data would be consolidated and presented in a searchable format. They were recalling pet food so quickly that if you went to the FDA Web site, you had to plow through all of the corporate press releases to figure out just exactly what was a dangerous product. When I mentioned this to the FDA, they changed their Web site, and we put it into law, to make sure they are consumer friendly and have up-to-date information consumers can understand.

We work with the Secretary as well and the States on activities and programs to improve the safety of raw agricultural commodities. We go beyond just pet food into all edible products, agricultural products. What we attempt to do is to have the Secretary share resources with the States to improve State food programs and help States establish standards for inspection. Fifty States, 50 standards, is unacceptable. There should be one scientific matrix we follow so we know that whether the product comes from Oregon or Illinois or New Hampshire, that it is safe.

We also establish something that I think is historic. It applies to pet and human food as well. It is an adulterated food register, to collect information on cases of food adulteration and suspected adulteration that are potentially dangerous and improve the speed

by which consumers learn about them. We want an early-warning system, and in this age of computers and the Internet, we can achieve it.

I believe this is critically important. In this case, there was a Canadian company called Menu which made dog food. Menu discovered in the middle of February that the cats and dogs were turning up their noses at their product, and then they found those that were eating their products started to show signs of illness, and then some of the animals died. Do you know how long it took them to report this to the Food and Drug Administration? Three weeks. Three weeks, while their products spread across Canada and North America, on the shelves of stores, and unsuspecting customers were buying them, they weren't reporting them. Our law now requires reporting within 2 days, and if they fail to report, they face civil penalties, which I hope will be imposed on a timely basis so that we let all companies know this kind of delay is intolerable.

We also do something here that is important. If we find evidence of adulterated food, we report it as well to Homeland Security. Why? Well, Governor Tommy Thompson told us why. When he left as Secretary of Health and Human Services under this administration, he said: I find it unimaginable that someone hasn't tried to use our food supply—the terrorists haven't turned to our food supply to cause injury and death. He understood, as I do, and everyone should at this moment, it is a vulnerability for America we need to avoid. So this food registry will move us into a notification phase so the Department of Homeland Security can at least have notice if there is a problem.

We also require better access to business records for the investigation to get to the bottom of it. Where did it come from? How is it used? How can we contain the need?

We talk about a sense of the Senate in this amendment that points in another direction, maybe going beyond this current crisis into looking at an overhaul of our whole food safety system, and we require the Secretary of Health and Human Services to report annually to Congress with information about their inspections and enforcement.

I am going to yield the floor at this point, and I again thank Senators KENNEDY and ENZI for their help on this important legislation.

I wish to tell my colleagues that there were things I wanted to add in with this amendment, but in the interest of avoiding political conflict and in the interest of not slowing down this important legislation and in the interest of making certain we did achieve something today, I am saving those arguments for another day.

One of them is the issue of mandatory recall, which I think our Government should have the power to do and currently does not. Our Government

and its agencies do not have the power to recall contaminated food from the shelves. I believe that law needs to be changed. It is not included in this amendment. We will save that debate for another day.

Again, my thanks to my colleagues.

Madam President, I ask unanimous consent that the pending amendment be set aside, and I send an amendment to the desk and ask for its immediate consideration.

The PRESIDING OFFICER (Mrs. MCCASKILL). Without objection, it is so ordered.

The clerk will report the amendment.

The legislative clerk read as follows:

The Senator from Illinois [Mr. DURBIN], for himself and Mr. ENZI, Mr. KENNEDY, Mr. ALLARD, and Mr. NELSON of Florida, proposes an amendment numbered 1022.

Mr. DURBIN. I ask unanimous consent that the reading of the amendment be dispensed with.

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

(The amendment is printed in today's RECORD under "Text of Amendments.")

Mr. DURBIN. Madam President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second? There appears to be a sufficient second.

The yeas and nays are ordered.

Mr. DURBIN. Madam President, before yielding the floor, of course I will leave it to Senator ENZI and Senator KENNEDY for the timing of this rollcall, but I am ready at any time for it to be called after they have had a chance to make a statement.

I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Madam President, I thank the Senator from Illinois, Mr. DURBIN, for his tremendous work and creativity and willingness to make revisions to his amendment so that we can clear up outstanding concerns or clarify outstanding concerns people might have had with it. I think we are at the point where that is the case. I would like to make a few comments on it myself.

Food safety is an issue that affects us all. It is not a partisan issue. We all want the safest food supply possible. It is, instead, our shared goal, a goal that requires cooperation and teamwork through a complicated process, and we have had that.

For many of us, the safety and reliability of our food system is something we all too often take for granted. Day by day, we consume our favorite beverages, enjoy a quick snack, or sit down to a meal at a local restaurant. We rely on a system of checks and balances that takes place behind the scenes that we are often unaware of until something goes wrong. Then and only then do we realize how dependent we are on the food safety system that is supported by the activities carried out by the Federal, State, and local government agencies, as well as by the food industry itself. Together, they inspect, test, research, and monitor our

food supply from the farm or ranch where it is produced to the family dinner table where it is consumed. The type and amount of oversight they exercise depends on the food product, and the degree of regulatory scrutiny they demand is commensurate with the degree of risk.

In addition to these longstanding authorities and the activities of food safety, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 required the Food and Drug Administration to register food processors, inspect their records, and detain adulterated food. It also requires the Food and Drug Administration to issue regulations to ensure the safety of imported foods.

Food safety has been making news lately. From E. coli in fresh spinach to salmonella in peanut butter to melamine-contaminated pet food, we hear a constant drumbeat of food safety problems.

The United States has one of the best food safety systems in the world, but even in the best of systems, there is room for improvement. Those improvements can take many forms. For example, we can address how food becomes contaminated in the first place, and we can make advances in the processing and handling of food. Our surveillance, testing, and reporting systems represent areas we should evaluate, as well as internal and external communications. Interagency cooperation and coordination between Federal and State officials is critical in identifying, tracking, and responding to outbreaks of foodborne illness.

The amendment offered by my colleague, Senator DURBIN, contains several important elements in that response, but it is the beginning, not the end, of the process of food safety. This amendment does a number of important things. It establishes standards for pet food and sets up early-warning systems for any problems with pet food. The amendment improves communications systems about all food recalls, and it coordinates State and Federal activities on fresh and processed produce. Finally, the amendment creates a database of instances of adulterated food so that the FDA can better track patterns of problems and target its limited resources where they are most needed.

I am pleased we are able to work across party lines to develop an amendment today that we can all support, and I ask unanimous consent to be a cosponsor, along with Senator ALLARD.

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

Mr. ENZI. However, there is much more work to be done. This amendment is a good first step on the road to a comprehensive response to food safety.

In March 2005, Senator KENNEDY and I announced that we were working to develop a comprehensive response on another FDA issue, which is drug safety. The bill on the floor this week is a direct result of that announcement and

that pledge to work together. So when I pledge today to work to develop a comprehensive response on food safety, you can have some sense that I do mean that. I want my colleagues to work quickly and diligently to get this amendment to the point where we can accept it. I know we have it scheduled for a vote at the moment, too.

Madam President, I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

Mr. KENNEDY. Madam President, I wish to join with Senator ENZI and thank our friend and colleague, Senator DURBIN, for his strong leadership on this issue. This is an issue of enormous importance to families across the country.

As Senator ENZI just mentioned, over a year ago we made a strong commitment to the Senate that we were going to work on this drug safety issue, and we have come here in a bipartisan way to put forward a very strong bill that will ensure greater safety for American families in the area of prescription drugs. I think we are here to say that we will join with our friend and colleague from Illinois to build on what is an enormously important amendment and commitment to ensuring that we are going to have food safety as well as pet food safety in this country.

I think this amendment, as has been outlined by Senator DURBIN and Senator ENZI, reaches the heart of the challenges we face. One is on the issue of surveillance. We understand that is an essential aspect, whether it is food safety or prescription drugs, or whether it is in the area of avian flu, bioterrorism—whatever the challenge that is out there, surveillance is the first thing that needs to be done. We know that today the system is grossly inadequate.

Second, we know the information about food and food safety is scattered through a number of agencies and through a number of different kinds of delivery systems, and that the coordination between the Federal and State is loose. In all of these areas, this amendment addresses these issues and questions in a very effective way, to bring common sense to and put real teeth into the safety provisions.

The pet food standards that are in this legislation are strong and effective and would be very much appreciated by all Americans who are concerned about this issue. The standards are variable at the present time. The reporting is not good today, and this particular amendment is particularly responsive to that kind of challenge.

Finally, this addresses the central concern all of us have read about and are concerned about, which the Senator has spoken to, and that is the issue of importation. When you add up all of those kinds of elements, we find this is a very solid and meaningful amendment. I think it strengthens the legislation immensely. We have every purpose, as we move forward, to find ways we can provide even a greater

kind of protection and safety to the food supply for American families.

I commend the Senator from Illinois. I think we will be ready to have a vote on this at the earliest time.

The PRESIDING OFFICER. The Senator from Illinois.

Mr. DURBIN. Madam President, I ask unanimous consent that Senators KOHL, CANTWELL, SCHUMER, and BIDEN be added as cosponsors of this amendment.

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

Mr. DURBIN. Madam President, I ask unanimous consent that the Senate proceed to vote in relation to the Durbin amendment No. 1022; that no other amendments be in order prior to the vote; that the time until then be equally divided and controlled between Senators KENNEDY and ENZI; and that the vote be scheduled for 4:30 p.m.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. DURBIN. Madam President, I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

Mr. KENNEDY. Madam President, we expect the vote at 4:30, for our colleagues. After that, we are going to have a conversation with those who have been primarily interested and concerned about the whole issue of biologics. So I give the assurance we are going to address that issue in a timely way. That will ultimately be part of this legislation.

We also will be able to report on progress we have made on several other amendments. There are a few items that are going to necessitate our attention through the evening. We had a very good debate earlier today on the children's provisions; we had an important vote and discussion on that.

This addition this afternoon is enormously important, and I think the time that has been taken to work through this legislation has made it even stronger and better than I think it otherwise might have been. I am grateful to all of our colleagues who are working with us on both sides of the aisle, and particularly the staffs. We are moving forward. We are going to be busy this evening trying to work through some of the items, and we will have the cloture vote tomorrow and the follow-on Cochran amendment.

There is a glimmer in sight about reaching a conclusion to this legislation. Again, we are very appreciative of all who have helped us up to this point. 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.

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

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

MODIFICATION TO AMENDMENT NO. 1022

Mr. DURBIN. Madam President, we found a typo on page 5 in the amend-

ment that we want to clear up before the amendment is considered.

I ask unanimous consent to modify the amendment as submitted to the Senate. I send the modification to the desk.

The PRESIDING OFFICER. Without objection, the amendment is so modified.

The modification is as follows:

(3) post information regarding recalled products on the Internet website of the Food and Drug Administration in a consolidated, searchable form that is easily accessed and understood by the public.

SEC. 4. STATE AND FEDERAL COOPERATION.

(a) IN GENERAL.—The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of fresh and processed produce so that State food safety programs involving the safety of fresh and processed produce and activities conducted by the Secretaries function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—

(1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of the State food safety programs is not unsafe for human consumption.

(b) ASSISTANCE.—The Secretary may provide to a State, for planning, developing, and implementing such a food safety program—

(1) advisory assistance;

Mr. DURBIN. Madam President, 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.

Mr. KOHL. Madam President, I rise today and would like to briefly speak about Senator DURBIN's amendment regarding food safety. I was happy to cosponsor this amendment, and I agree with all of the sentiments expressed by the Senator earlier today.

This amendment deals with many of the underlying problems that allow food safety issues, such as the ones we have dealt with in recent months that have affected not only humans, but their pets as well.

It requires the FDA to set standards for pet food and to update them as necessary, and it directs the Secretary of Health and Human Services to establish a system capable of detecting pet food contamination and outbreaks of pet illnesses and death—this will prevent the type of confusion that continues to surround the recent melamine outbreak, and will help detect these problems much earlier. It requires FDA to develop effective communication plans to coordinate with stakeholders during outbreaks of both pet and human foods, so people know what is going on—quickly—and know what to do. It directs the Secretary to work with States to collaborate on activities and programs that assist in improving the safety of raw agricultural products such as spinach, which was the cause of a major food safety recall last fall. Importantly, it requires FDA

to establish a registry to collect information on cases of potentially dangerous food adulteration to help get any dangerous food off of the shelves more quickly and to allow FDA to target inspection resources where most needed.

This amendment does many important things—and takes many important first steps. I know that Senator DURBIN would have liked this amendment to go a little further, and I agree with his sentiments, but it is important to at least take the first step.

In March of this year, I held a hearing in Madison, WI, on food safety issues at the FDA. The Commissioner of FDA attended, as well as the Director of the FDA's Center for Food Safety. At that time, I pointed out that outbreaks of foodborne illness caused by produce have doubled since 1998. During this same time, the FDA's food budget has suffered. The number of people getting sick is going up, but the number of inspections and food safety tests being conducted is dwindling. So too are the number of food inspectors and overall staff at the FDA's Center for Food Safety. Imports have risen dramatically over the years, but the FDA is only able to inspect less than 1 percent of them.

Events after that hearing seemed to exacerbate what I pointed out. The recent pet food scare, and the ongoing melamine investigation, serve as constant reminders that we have been taking this issue for granted, assuming that the FDA has the authority and funding necessary to do its job, when that is clearly not the case.

Senator DURBIN's amendment begins to take care of some of the problems with FDA authority and actions.

As the chairman of the Agriculture Appropriations Subcommittee, which has jurisdiction over the FDA's budget, it is my job to make certain that the FDA has the money to carry out its vital role of protecting our food. The Food Center at FDA doesn't have user fees from industry to boost its funding—it all comes from the Congress, and has been stagnant for far too long.

I have been working diligently to make sure that when the fiscal year 2008 Agriculture Appropriations bill is written, food safety will be one of its highlights. I do not believe the administration has ever requested enough funding for food safety at the FDA, this year notwithstanding. I plan to correct that. It may not happen all in the first year being fiscally responsible can be tough—but it will happen. We will provide a significant increase to the FDA this year, so they can implement some of what Senator DURBIN's amendment proposes, and quite simply, so they can hire inspectors where they are needed, to do the necessary research to prevent outbreaks from occurring wherever possible, and so we don't continue to see large recall notices in our newspapers every day. It is not a problem that can be fixed immediately, but I fully intend to meet my

end of the obligation in making sure that FDA has the money that it needs, and can use responsibly, to tackle this problem head on.

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

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

Mr. DURBIN. Madam President, pursuant to the unanimous consent request, I ask that the roll be called on amendment No. 1022.

The PRESIDING OFFICER. Under the previous order, the question is on agreeing to amendment No. 1022, as modified, offered by the Senator from Illinois.

The yeas and nays have been ordered. 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 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), and the Senator from Arizona (Mr. MCCAIN).

The result was announced—yeas 94, nays 0, as follows:

[Rollcall Vote No. 149 Leg.]

YEAS—94

Akaka	Durbin	Murkowski
Alexander	Ensign	Murray
Allard	Enzi	Nelson (FL)
Baucus	Feingold	Nelson (NE)
Bayh	Feinstein	Obama
Bennett	Grassley	Pryor
Bingaman	Gregg	Reed
Bond	Hagel	Reid
Boxer	Harkin	Roberts
Brown	Hatch	Rockefeller
Bunning	Hutchison	Salazar
Burr	Inhofe	Sanders
Byrd	Inouye	Schumer
Cantwell	Isakson	Sessions
Cardin	Kennedy	Shelby
Carper	Kerry	Smith
Casey	Klobuchar	Snowe
Chambliss	Kohl	Specter
Clinton	Kyl	Stabenow
Coburn	Landrieu	Stevens
Cochran	Lautenberg	Sununu
Coleman	Leahy	Tester
Collins	Levin	Thomas
Conrad	Lieberman	Thune
Corker	Lincoln	Vitter
Cornyn	Lott	Wainwright
Craig	Lugar	Voinovich
Crapo	Martinez	Warner
DeMint	McCaskill	Webb
Dole	McConnell	Whitehouse
Domenici	Menendez	Wyden
Dorgan	Mikulski	

NOT VOTING—6

Biden	Dodd	Johnson
Brownback	Graham	McCain

The amendment (No. 1022), as modified, was agreed to.

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

The motion to lay on the table was agreed to.

Mr. VITTER. Madam President, I ask unanimous consent that the pending

amendment be set aside and that I may call up amendment No. 983.

The PRESIDING OFFICER. Is there objection to setting aside the pending amendment?

Mr. KENNEDY. Reserving the right to object, I suggest the absence of a quorum.

The PRESIDING OFFICER. The Senator from Louisiana has the floor.

Mr. KENNEDY. I object to the unanimous consent request.

The PRESIDING OFFICER. Objection is heard.

Mr. KENNEDY. Madam President, 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.

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

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

AMENDMENT NO. 983

Mr. VITTER. Madam President, I renew my unanimous consent request that any pending amendment be set aside and that amendment No. 983 be called up.

The PRESIDING OFFICER. Is there objection?

Without objection, the amendment is set aside, and the clerk will report.

The assistant legislative clerk read as follows:

The Senator from Louisiana [Mr. VITTER] proposes amendment numbered 983.

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

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

The amendment is as follows:

(Purpose: To require counterfeit-resistant technologies for prescription drugs)

At the end of subtitle E of title II, insert the following:

SEC. —. COUNTERFEIT-RESISTANT TECHNOLOGIES FOR PRESCRIPTION DRUGS.

(a) REQUIRED TECHNOLOGIES.—The Secretary of Health and Human Services shall require that the packaging of any prescription drug incorporate—

(1) radio frequency identification (RFID) tagging technology, or similar trace and track technologies that have an equivalent function;

(2) tamper-indicating technologies; and

(3) blister security packaging when possible.

(b) USE OF TECHNOLOGIES.—

(1) AUTHORIZED USES.—The Secretary shall require that technologies described in subsection (a)(1) be used exclusively to authenticate the pedigree of prescription drugs, including by—

(A) implementing inventory control;

(B) tracking and tracing prescription drugs;

(C) verifying shipment or receipt of prescription drugs;

(D) authenticating finished prescription drugs; and

(E) electronically authenticating the pedigree of prescription drugs.

(2) PRIVACY PROTECTION.—The Secretary shall prohibit technologies required by subsection (a)(1) from containing or transmitting any information that may be used to

identify a health care practitioner or the prescription drug consumer.

(3) **PROHIBITION AGAINST ADVERTISING.**—The Secretary shall prohibit technologies required by subsection (a)(1) from containing or transmitting any advertisement or information about prescription drug indications or off-label prescription drug uses.

(c) **RECOMMENDED TECHNOLOGIES.**—The Secretary shall encourage the manufacturers and distributors of prescription drugs to incorporate into the packaging of such drugs, in addition to the technologies required under subsection (a), overt optically variable counterfeit-resistant technologies that—

(1) are visible to the naked eye, providing for visual identification of prescription drug authenticity without the need for readers, microscopes, lighting devices, or scanners;

(2) are similar to technologies used by the Bureau of Engraving and Printing to secure United States currency;

(3) are manufactured and distributed in a highly secure, tightly controlled environment; and

(4) incorporate additional layers of non-visible covert security features up to and including forensic capability.

(d) **STANDARDS FOR PACKAGING.**—

(1) **MULTIPLE ELEMENTS.**—For the purpose of making it more difficult to counterfeit the packaging of prescription drugs, the Secretary shall require manufacturers of prescription drugs to incorporate the technologies described in paragraphs (1), (2), and (3) of subsection (a), and shall encourage manufacturers and distributors of prescription drugs to incorporate the technologies described in subsection (c), into multiple elements of the physical packaging of the drugs, including—

(A) blister packs, shrink wrap, package labels, package seals, bottles, and boxes; and

(B) at the item level.

(2) **LABELING OF SHIPPING CONTAINER.**—Shipments of prescription drugs shall include a label on the shipping container that incorporates the technologies described in subsection (a)(1), so that members of the supply chain inspecting the packages will be able to determine the authenticity of the shipment. Chain of custody procedures shall apply to such labels and shall include procedures applicable to contractual agreements for the use and distribution of the labels, methods to audit the use of the labels, and database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.

(e) **PENALTY.**—A prescription drug is deemed to be misbranded for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) if the packaging or labeling of the drug is in violation of a requirement or prohibition applicable to the drug under subsection (a), (b), or (d).

(f) **TRANSITIONAL PROVISIONS; EFFECTIVE DATES.**—

(1) **NATIONAL SPECIFIED LIST OF SUSCEPTIBLE PRESCRIPTION DRUGS.**—

(A) **INITIAL PUBLICATION.**—Not later than 180 days after the date of the enactment of this Act, the Secretary shall publish in the Federal Register a list, to be known as the National Specified List of Susceptible Prescription Drugs, consisting of not less than 30 of the prescription drugs that are most frequently subject to counterfeiting in the United States (as determined by the Secretary).

(B) **REVISION.**—Not less than annually through the end of calendar year 2010, the Secretary shall review and, as appropriate, revise the National Specified List of Susceptible Prescription Drugs. The Secretary may not revise the List to include fewer than 30 prescription drugs.

(2) **EFFECTIVE DATES.**—The Secretary shall implement the requirements and prohibitions of subsections (a), (b), and (d)—

(A) with respect to prescription drugs on the National Specified List of Susceptible Prescription Drugs, beginning not later than the earlier of—

(i) 1 year after the initial publication of such List; or

(ii) December 31, 2008; and

(B) with respect to all prescription drugs, beginning not later than December 31, 2011.

(3) **AUTHORIZED USES DURING TRANSITIONAL PERIOD.**—In lieu of the requirements specified in subsection (b)(1), for the period beginning on the effective date applicable under paragraph (2)(A) and ending on the commencement of the effective date applicable under paragraph (2)(B), the Secretary shall require that technologies described in subsection (a)(1) be used exclusively to verify the authenticity of prescription drugs.

(g) **DEFINITIONS.**—In this Act:

(1) The term “pedigree”—

(A) means the history of each prior sale, purchase, or trade of the prescription drug involved to a distributor or retailer of the drug (including the date of the transaction and the names and addresses of all parties to the transaction); and

(B) excludes information about the sale, purchase, or trade of the drug to the drug consumer.

(2) The term “prescription drug” means a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

(3) The term “Secretary” means the Secretary of Health and Human Services.

Mr. VITTER. Madam President, first, in terms of laying the groundwork for this amendment, let me speak very briefly about the broader reimportation debate. I commend my colleagues who have brought this issue to the floor, and I certainly join them in pushing strongly for reimportation language in this bill. I have worked with many Members of this body, Republican and Democrat, on this issue since I was elected, including the primary authors of the reimportation amendment that we will be voting on later under this bill. I certainly want to join many voices, again, on both sides of the aisle, in terms of the need for this sort of important legislation that helps stabilize and bring down the price of prescription drugs.

My amendment, No. 983, to which I will now turn, is very directly related to that. It is not a reimportation amendment per se, but it goes directly to one of the primary issues that opponents of reimportation regularly bring up, which is safety. My amendment, No. 983, is about tamper-resistant technology—packaging technology—which can go a long way in meeting all of those safety concerns. I think there are many legitimate ways we can meet them, but this is a very effective and a very economical way to help meet any of those concerns.

This amendment, No. 983, would require the incorporation of counterfeit resistant technologies into the packaging of prescription drugs. Not just reimported prescription drugs, but all prescription drugs because counterfeit prescription drugs is an issue not simply with regard to reimportation. Spe-

cifically, wholesale prescription drugs would contain RFID radio-tagging technology, tamper-resistant packaging, and blister security packaging, when possible.

This is language directly from my legislation of the last Congress, the Reducing Fraudulent and Imitation Drugs Act. Of course, the purpose of that bill and this amendment is to address that safety concern, which comes up in a number of contexts, but certainly including reimportation. By ensuring that prescription drugs are authentic, this amendment would ensure the drug supply within the United States, as well as prescriptions reimported from Canada and other industrialized nations, are indeed safe.

Again, the amendment would require that such technologies be used exclusively to authenticate the pedigree of prescription drugs. It would actually prohibit such technologies from containing or transmitting any identifying information of a health care practitioner or consumer or any advertisement or information about indications or off-label uses. So it is specifically for authentication. This is what you are getting. It cannot be used for any other purpose that might bring up privacy or other concerns.

It would also require prescription drug shipments to include a label on the shipper container that incorporates similar packaging technologies.

Finally, the amendment would require the Secretary to publish a national specified list of susceptible prescription drugs consisting of not less than 30 of the most frequently counterfeited prescription drugs in the United States. This would provide significant assistance to efforts by U.S. law enforcement and the FDA to deal with this issue.

I hope all of us can join together around this very promising new technology that can help meet any legitimate safety concerns out there. Much more broadly speaking, of course, I certainly hope we come together to pass broad-based reimportation language in this bill, which I have supported well before coming to the Senate and, being in the Senate, certainly support in this context.

Mr. NELSON of Florida. Will the Senator yield?

Mr. VITTER. Certainly I yield.

Mr. NELSON of Florida. Certainly the Senator remembers when he and this Senator from Florida introduced an amendment a year ago to allow the importation of drugs from Canada for a limited supply, stated as 90 days or less, for personal use, and how we passed that here in the Senate. It was watered down once it got into conference in the House. It only allowed Americans going to and from Canada to carry drugs in that capacity—personal use, limited supply.

Now we are going to be approaching this, and I ask the Senator, he is joining on the Dorgan amendment on the reimportation as one of the cosponsors of this amendment, is that correct?

Mr. VITTER. I honestly do not know if I am technically a cosponsor. I am certainly supporting it. I supported our common efforts for several years. Many of the elements of my separate bill have been incorporated into the Dorgan-Snowe language, going back to last year. So we are certainly all working in concert.

I again recognize and thank the Senator from Florida for our common work on the amendment last year, which he referenced.

Mr. NELSON of Florida. If the Senator will further yield, does he remember in the debate we had when we agreed to that amendment, that Customs had even gotten into the act and was seizing thousands and thousands of these pharmaceutical packages for individual use and limited supply? Of course, in my State of Florida that happened with great frequency since a number of our senior citizens, in fact, do that. Finally we got Customs to come out and say they were no longer going to do that, they were going to defer it to the Food and Drug Administration. The Acting Administrator of the FDA had actually said no, they didn't have an objection to a limited supply for personal use, whether it was ordered by phone or Internet or by the mail, or someone walking across the border.

Isn't it interesting that after all of that—and we finally agreed to the amendment—we still come to the year 2007 and we are having to address this issue again?

Mr. VITTER. I agree with the Senator, absolutely. We should have taken care of this a long time ago. But we are where we are, and I certainly urge my colleagues on both sides of the aisle to address this in a full and comprehensive way.

Mr. NELSON of Florida. The Congressional Budget Office is estimating that this legislation is going to save consumers in this country \$50 billion over the next 10 years because so often the price they get it for at the retail outlet here is twice what they can get it for from a Canadian pharmacy.

It has been a pleasure for me to work with the Senator. I look forward to working with Senator DORGAN on his amendment.

Mr. VITTER. I thank the Senator from Florida. I certainly have similar beliefs.

I urge adoption of this amendment I presented and certainly urge my colleagues to also support the broader reimportation language, as will I.

I yield the floor.

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

Mr. ENZI. I thank the Senator from Louisiana for his patience on this amendment, and also his understanding that he would work with my staff and the staff of Senator KENNEDY to see what can be done to make our drug supply safer. I appreciate that.

I also thank him for all the efforts he has made on behalf of the Louisiana

turtle farmers, which was a new industry to me—although they have been exporting turtles all over the world for years—for the work he did drafting and putting together a mechanism for eliminating salmonella in turtles so they can be, once again, pets in the United States.

The PRESIDING OFFICER. The Senator from New York.

Mr. SCHUMER. Mr. President, I rise to engage in a colloquy with my colleagues from Utah, New York, Massachusetts, and Wyoming on biologics. I thank every one of them for their cooperation and help as we move forward.

Mr. President, I rise today with my colleagues to speak about biologic drugs, a large and growing sector of the drug market. Biologic drugs can cost tens of thousands of dollars a year for a single patient, and treat devastating diseases such as cancer and its complications. There is currently no clear pathway for lower cost competitors to biologic drugs to enter the market, as there is for generic versions of traditional chemical drugs. I have introduced a bill to create such a pathway. I am glad to see my friends Senator KENNEDY, Senator ENZI, and Senator HATCH on the floor to discuss this issue with us. I yield to my colleague from Utah.

Mr. HATCH. I am happy to discuss this issue with my colleagues. As they are aware, this has been my high priority for a number of years, given that I am the author with Representative HENRY WAXMAN of the Drug Price Competition and Patent Term Restoration Act—or “Hatch-Waxman”. The Schumer-Clinton bill, which I know has been introduced by Representative WAXMAN in the House, is an important contribution to this dialogue. I want to work to reach an acceptable compromise on an expedited basis, and it is clear to me it must be a bipartisan effort.

Mrs. CLINTON. I thank the Senator for his leadership on generic drugs and for his presence here today. In 1984 when the Hatch-Waxman generic drug law was written, very few biologic drugs existed and there was no need to empower the FDA to approve lower cost versions of existing biologic drugs. This is no longer the case and it is time to enact legislation that will allow the FDA to approve safe and effective follow-on versions of biotech drugs.

Mr. KENNEDY. I thank my colleagues and I agree that creating a pathway for follow-on biologics is an important issue worthy of our consideration.

Mr. SCHUMER. I say to Chairman KENNEDY, the junior Senator from New York and I stand ready to offer a bipartisan amendment to this bill that would establish a pathway for follow-on biologic drugs. We would prefer to work with you, and with the distinguished Senators from Wyoming and Utah. To that end, we would like to work together to discuss a pathway that protects patient safety, enables

consumer access to more affordable biologic drugs, and provides appropriate incentives for continued innovation of lifesaving drugs.

Mrs. CLINTON. I agree with my friend Senator SCHUMER, and note with gratitude that the HELP Committee began bipartisan discussions on how to accomplish this goal. And while I was disappointed that follow-on biologic legislation was not included during committee consideration of S. 1082, it was in good faith that I did not offer an amendment with the understanding that our bipartisan efforts would continue.

As my colleagues and I move forward on this important effort, I think it is important to identify the key principles that must be contained in the legislation: We must provide the FDA with the authority and flexibility to approve biopharmaceuticals subject to a workable, abbreviated approval pathway that is efficient, effective and scientifically grounded. We must also include measures to ensure timely resolution of patent disputes, as well as adequate incentives for continued innovation.

Mr. KENNEDY. I assure the Senators from New York that the conference report on the FDA Revitalization Act will include a pathway to follow-on biologics that has been reported out of the HELP Committee and that is acceptable to the Senators from New York. I plan to hold a markup on this issue on June 13.

Mr. ENZI. The heart of the debate is how to construct a regulatory framework so that biologic drugs can be safely available under an accelerated pathway. It is more difficult to approve biosimilars than to approve generic versions of typical drugs. The balance we are trying to find is a compromise that promotes access with innovation, while also maintaining the high standards of safety at the Food and Drug Administration.

Biologics are complex molecules modeled after key processes occurring daily within the human body. One analogy is that if a typical drug was a 3 bedroom, 2 bath starter home, a biologic would be a skyscraper. The size, scope and complexity are completely different. The nomenclature is, too. As key scientists stated at our HELP Committee hearing on this topic, these are not generic biologics but biosimilars.

With many drugs, we can describe their structure with a high degree of precision—but not with follow-on biologics. You can't make an exact “copy” of a biologic, like you can for most typical generic drugs. For example, if I was to try to build the skyscraper of a biologic without the blueprints, as any generic company would need to do to create a follow-on biologic, I would have to ensure that every copy was identical or there could be fatal results.

Because of this, science must be an essential part of any safety standard.

One piece out of place would cause the entire structure to fall.

But to be clear, a safe pathway for an accelerated approval process for biologics, that also preserves innovation, is possible. It is not just me who believes it—the FDA, generic and pharmaceutical industries have all said so as well. I have been working across party lines with Senators HATCH, KENNEDY and CLINTON to develop legislation that does just that. Our staffs have been working tirelessly on this topic: individually meeting with experts and stakeholders; and as a group, talking with experts from the United States and global leaders. After all, we want the same end result—legislation that ensures medicines are safe and affordable, and that medical innovation continues to flourish.

I have a track record of working across party lines to build consensus and find common ground on tricky legislative issues. I know that with a little more time, and through regular order, we will develop a bipartisan package that accomplishes our common goals.

I concur with the chairman and am committed to moving a bipartisan bill through the HELP Committee in the near future with the goal that it can be joined with the conference on the FDA Revitalization Act.

Mr. HATCH. I look forward to working with my colleagues to include bipartisan follow-on biologics legislation in the conference agreement on the FDA Revitalization Act. It is clear that consumers would benefit tremendously from an abbreviated pathway for consideration of biosimilar products. Any effort, though, must be based on a sound understanding of the science involved and it must contain incentives for development of the innovator products which will be copied.

Mr. SCHUMER. I thank my colleagues for these commitments. I look forward to working together with Chairman KENNEDY, Senator ENZI, Senator CLINTON, and Senator HATCH to develop workable legislative language that can be scheduled for a June 13 markup in the HELP Committee and included in the FDA Revitalization Act conference report.

AMENDMENT NO. 1025

With that, I ask unanimous consent to set aside the pending amendment and send my amendment, a sense of the Senate, to the desk.

The PRESIDING OFFICER. Without objection, it is so ordered. The pending amendment is set aside. The clerk will report the amendment.

The bill clerk read as follows.

The Senator from New York [Mr. SCHUMER], for himself, Mrs. CLINTON, Mr. ENZI, Mr. HATCH, and Mr. KENNEDY, proposes an amendment numbered 1025.

Mr. SCHUMER. I ask unanimous consent the reading of the amendment be dispensed with.

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

The amendment is as follows:

(Purpose: To express the sense of the Senate with respect to follow-on biologics)

At the end of the bill, add the following:

SEC. ____ SENSE OF THE SENATE WITH RESPECT TO FOLLOW-ON BIOLOGICS.

(a) FINDINGS.—The Senate finds the following:

(1) The Food and Drug Administration has stated that it requires legislative authority to review follow-on biologics.

(2) Business, consumer, and government purchasers require competition and choice to ensure more affordable prescription drug options.

(3) Well-constructed policies that balance the needs of innovation and affordability have broad bipartisan support.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) legislation should be enacted to—

(A) provide the Food and Drug Administration with the authority and flexibility to approve biopharmaceuticals subject to an abbreviated approval pathway;

(B) ensure that patient safety remains paramount in the system;

(C) establish a regulatory pathway that is efficient, effective, and scientifically-grounded and that also includes measures to ensure timely resolution of patent disputes; and

(D) provide appropriate incentives to facilitate the research and development of innovative biopharmaceuticals.

Mr. SCHUMER. Mr. President, I ask that the amendment be adopted.

The PRESIDING OFFICER. Is there further debate on the amendment?

If not, the question is agreeing to the amendment of the Senator from New York.

The amendment (No. 1025) was agreed to.

Mr. KENNEDY. Mr. President, I move to reconsider the vote by which the amendment was agreed to.

Mr. ENZI. Mr. President, I move to lay that motion on the table.

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

Mr. KENNEDY. Mr. President, I thank all of our colleagues for their cooperation and their help on this particular subject matter. It is a matter of enormous importance, incredible consequence, and enormous complexity. We thank them for all of their help and assistance in bringing us to where we are so that the Members understand better where we are. We are absolutely committed to having that hearing and having the results of that go into our conference.

I am enormously appreciative of the patience and the cooperation we have received. I am grateful again to all of those here, colleagues on both sides, for their cooperation in helping us move this forward.

I thank the Senator from Utah. I want to congratulate him. He is receiving an honorary degree tomorrow from a great university in his State. We were talking about biologics. We think of the Hatch-Waxman proposal and acknowledge his work, attention, and help in the fashioning of that important piece of legislation, particularly when we are thinking about his in-

volvement in the biologics, a clear indication we are going to have some good bipartisan support and we are going to have a team that has a breadth of knowledge and understanding of these kinds of subject matters. We wish him well on his trip to Utah and congratulate him on his degree tomorrow.

Mr. HATCH. Will the Senator yield?

Mr. KENNEDY. I will yield.

Mr. HATCH. Mr. President, I thank my dear friend and colleague. It is so nice of him to say that. I take tremendous interest in this bill, as I do every piece of legislation, but this bill in particular.

I congratulate the chairman and the ranking member for the way they have conducted not only the committee through this process but this bill itself. I hope this bill will pass and that we can correct whatever needs to be corrected, and that we will be able to do this follow-on biological work together. If we can do that, this will be a major breakthrough bill, and will do a great deal of good for the FDA. If that happens, then I think the chairman and the ranking member deserve a great deal of credit. I am very grateful my friend from Massachusetts has been so kind to me today.

The PRESIDING OFFICER. The Senator from New York is recognized.

Mr. SCHUMER. I add my thanks to the chairman and ranking member of the HELP Committee for all of their help and constructive resolution of this. It allows us to pass a very important FDA bill and at the same time move on the biologics.

I join my colleague from Massachusetts in congratulating my friend from Utah on his honorary degree. He will get a doctorate, I imagine, and perhaps after he will not only get an honorary degree and be a doctor but maybe he can even create a few biologics after we pass the law.

The PRESIDING OFFICER. The Senator from Utah is recognized.

Mr. HATCH. Mr. President, to say the distinguished Senator from New York knows how to stick it to a person on the floor is all I can say.

I am grateful for this friendship and grateful for his and Senator CLINTON's work on this as well, and willingness to work together in a bipartisan way. This is big-time stuff. If we get it right, it will surely do a lot of good, as Hatch-Waxman has done over the last 23 years.

The PRESIDING OFFICER. The Senator from New Mexico is recognized.

Mr. DOMENICI. Mr. President, I ask unanimous consent that I be permitted to speak for up to 10 minutes as in morning business.

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

HONORING JACK VALENTI

Mr. DOMENICI. Mr. President, I was present yesterday at the funeral mass at St. Matthew's for Jack Joseph Valenti. I did not know he had a middle name, Joseph, but I am learning more

and more about him now after his passing. I was a friend of his. I thought I knew much about him. But the more I read, the more I find out what a spectacular man and a marvelous life he lived.

I thought I would share with the Senate, since somebody said at the mass, as they were permitted to speak—they were one of the few who were selected—I would bet that everybody in this church would like to come up here and be given 10 minutes to say something about their friend Jack Valenti.

That person who said that was absolutely right. That is exactly how I felt sitting there: Wouldn't it be nice if I could walk up there and tell all of these people and whoever else was listening, share what I knew about him. Of course, that was not to be.

But today I am going to do that in the Senate for a few minutes, and tell the Senate about how this man, who was known to try to help everybody in very different circumstances, how he came to know me and how I came to know him.

I was elected in 1972, and of course right now it sort of goes by easy; my last name is Italian. You know it was pretty well understood when I was elected that I was Italian—DOMENICI from out in the West, when all of the Italians who are in politics are from out here in the East, from New York, New Jersey. People wondered: Where did that guy come from?

Well, the truth is, Jack Valenti also wondered. He called me on the telephone and said: Are you PETE DOMENICI, the new Senator?

I said: Yes, sir. He told me who he was. He said: You know, I don't know you, you don't know me, but you probably could easily find out who I am. All I want to tell you is: I would like to help you.

Now, we are thousands of miles away. I have never seen him. I was elected. He is telling me on the phone: I would sure like to help you if I can.

Of course, I said: Give me your phone number and let me get ahold of you. By the time I asked a few people, they said: You are lucky. He is one of the people in Washington who knows more about what is going on here, than the man who called you.

I quickly arranged a meeting at the Willard Hotel. It was prior to its remodeling so it wasn't as nice as it is today. But I didn't know better. I made arrangements there. Then I invited him to come and visit. Here comes Mr. Valenti to come and meet me there at the Willard Hotel. I mean, it was a joyous occasion. You would have thought I was a long-lost relative. It was all because he was glad to see a young Italian boy get elected to the Senate. He came from an immigrant Italian family himself.

So we talked. He said: Well, let me try to help you. I would like to tell you what his first offer was. Let's go meet some people and see what we can do about talking about the committee assignments you might get.

I told him: Here is the one I want. I want the Joint Committee on Atomic Energy, because that has a lot to do with my State. So we talked and we worked. Sure enough, we were making a little headway and we read that the House had had a meeting of leadership and they had decided there would no longer be a Joint Committee on Atomic Energy so they abolished it. So all of my work and all of his work was for naught, because we decided we were not going to do business in a joint manner on atomic energy.

But what a joy it was, the first meeting—not successful in terms of our mission but greatly successful in terms of establishing our friendship.

I will mention two things in my life and then yield to the Senator.

Years later, one of my sons was working here in Washington. Some people know him. His name is David. He had established and built a charter school here, a school in town that ended up being called Maya Angelou School, a school named after the great poet laureate. And, of course, as you would guess from the name of the school, it was sort of a special school. It was a charter school my son started with the help of another man, and it was for the purpose of taking the troubled young teenagers, who were either going to jail, because they had already done enough bad things, criminal things, they were going to jail, or the judge would assign them to this school.

This son of mine built this charter school. It got to be a pretty good size. At a point in time he was opening a new building, and he called me and talked to me and said: You know, maybe I could get some help from somebody for some computers for these students.

This is my second meeting with my friend. I called him up and said: I would like you to meet my son David. I told him why. He said: Of course. They met, talked on the telephone. Within a very short period of time, the charter school I am describing to you, which was a very difficult thing for my son and his friend to run—had a great success. He opened two of them; two of them exist in Washington now. But, lo and behold, shortly after this meeting and our discussion with Mr. Valenti, the computers that were needed for the school to totally fill out all of the computer needs arrived as a special donation from somebody.

Well, of course, we know the somebody. We found out later our friend Mr. Valenti worked to get in touch with those who could help donate to these students' needs.

He is gone now, but we do not know how many thousands of things like this he did during his life, along with the other things that are more notorious that he did in his job, which was a very open and public job for many years of his life, and a hard one when he worked for the motion picture industry. So we do not know how many people he helped. But I thought maybe I would

borrow this few minutes of the Senate's time to put down my thoughts for his wife, who I obviously did not know as well as I knew him. But I did get to know her. I saw her at the funeral. Of course, she is having a difficult time. I do not know their children. I did have a chance to talk to his wife and say I hope that everything went well. I think it will. With this, I say maybe no one else in the Senate will do this, but as part of my day, I salute Mr. Jack Valenti for all he did, and I am very grateful I had the chance to say a few words about him.

I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

Mr. KENNEDY. Mr. President, I thank my friend from New Mexico. I had the good opportunity to attend that service as well. I will include my comments about Jack Valenti. He was a dear and valued friend of the Kennedys. We went back a long time with Jack, to the 1960 campaign. It was a long friendship, that endured a lot of very glorious times and difficult and challenging ones as well. He was a person of great purpose, with a love for his country, devotion to his industry, which he represented so effectively, and a wonderful friend to many of us. I thank the Senator for his comments.

Mr. President, for the benefit of our Members here, we are going to recess shortly and go over to 9:30 tomorrow morning. The hour before the cloture vote will run from 9:30 to 10:30, and we will yield a half hour on our side to the proponent of the amendment, Senator DORGAN. Then at 10:30 or just about 10:30 we expect we will have a roll call vote on the Dorgan amendment, or the motion to invoke cloture on the Dorgan amendment. Then, depending on how that comes out, we will move ahead to hopefully conclude work on some of the items we have had good discussions about today—the Stabenow amendment. I am grateful to Senator STABENOW. We spoke about this earlier in the day. We have worked with her and made some very important progress and are grateful to her for her cooperation.

We indicated now to the membership how we are going to proceed on the extremely important item of biologics. We now have the drug safety. We have enhanced this bill with food safety. We are going to address in our conference the issue of biologics. This is going to be an extremely important pathway. We have been working with Senator ROBERTS and Senator HARKIN on the direct consumer advertising issue. There are some very important constitutional issues. I am grateful to Senator ROBERTS for his cooperation and help. Senator KOHL has an amendment on reverse payments. There is Senator VITTER's amendment and potentially one or two others that Members have indicated they are giving thought to offering, but haven't decided whether they would.

We are getting close to the end of this, but we still have important matters to do. We are going to try to work with our colleagues. We have made great strides in the evenings. I am very grateful to Senator ENZI and particularly to our staffs who have, each evening, including through the weekend, worked tirelessly to try and ease the differences on many of these amendments and have done a brilliant job. This legislation is extraordinarily important. We have had several amendments, important amendments, but we have also worked out some others that have strengthened the legislation.

In a few moments, we will go into adjournment until tomorrow. But Senators should look forward to the debate at 9:30 and vote at 10:30 on the cloture petition relative to the Dorgan amendment.

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. KENNEDY. 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, for the information of the Members, there will be no further votes this evening.

The PRESIDING OFFICER. The Senator from Oklahoma.

Mr. INHOFE. Mr. President, I ask unanimous consent that the pending amendment be set aside for the consideration of amendment 988.

Mr. KENNEDY. If the Senator would withhold, we have a pending amendment. I will have to object until we clarify exactly where we are. Would the Senator give us 30 seconds?

Mr. INHOFE. That would be fine. My intention was to set aside the pending amendment so I could consider this. Then set this aside and go back to the pending amendment.

Mr. KENNEDY. I have no objection to that.

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

AMENDMENT NO. 988

Mr. INHOFE. I thank the Senator from Massachusetts for his tolerance.

Mr. President, I introduced last year a bill I called the Child Medication Safety Act. We are offering it as an amendment to this underlying bill. It is my anticipation that we will get a vote on it ultimately. This is to protect children and their parents from being coerced into administering a controlled substance or psychotropic drug in order to attend school. The House passed their version of H.R. 1790 by 407 to 12 under suspension of the rules in November of 2005.

Parents today face many challenges when raising their children, one of which is ensuring that their children receive the best education possible. My views on education come from a somewhat unique perspective in that my wife Kay was a teacher at Edison High

School. My daughters are both teachers. I can assure my colleagues that I am one of the strongest supporters of quality education. However, it has come to my attention that schools have been acting as physicians or psychologists by strongly suggesting that children with behavioral problems be put immediately on some form of psychotropic drugs. Schools and teachers are not equipped to make these diagnoses and should make it mandatory for the student to continue attending the school. This is clearly beyond their area of expertise. Therefore, I am introducing this legislation to ensure that parents are not required by school personnel to medicate their children.

The Child Medication Safety Act requires, as a condition of receiving funds from the Department of Education, that States develop and implement policies and procedures prohibiting school personnel from requiring a child to obtain a prescription as a condition of attending school. It should be noted that this bill does not prevent teachers or other school personnel from sharing with parents or guardians classroom-based observations regarding a student's academic performance or regarding the need for evaluation of for special education.

Additionally, this bill calls for a study by the Comptroller General of the United States reviewing: No. 1, the variation among States in the definition of psychotropic medication as used in public education; No. 2, the prescription rates of medication used in public schools to treat children with attention deficit disorders and other such disorders; No. 3, which medications listed under the Controlled Substances Act are being prescribed to such children; and, No. 4, which medications not listed under the Controlled Substances Act are being used to treat these children and their properties and effects. This GAO report is due no later than 1 year after enactment of this act.

I believe it is an extremely important amendment. It protects the rights of our children against improper intrusion regarding health issues by those not qualified. If a parent or guardian believes their child is in need of medication, then they ought to have the right to make that decision and consult with a licensed medical practitioner who is qualified to prescribe an appropriate drug. I am hoping others will join me in support of the amendment. It is a parental rights amendment that should be supported by all.

With that, it is my intention that we will be putting this in line to get a vote. I ask unanimous consent now to return to the previous pending amendment.

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

Mr. KENNEDY. I thank the Senator for his cooperation. 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. 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. I understand the Senator from Oklahoma wants to go into morning business to make a statement. I ask unanimous consent that after he has completed his statement, that I be recognized for purposes of offering my Internet pharmacy protection and safety bill to the underlying bill.

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

Mr. INHOFE. Mr. President, may I ask a point of inquiry of the Senator from Massachusetts. Apparently the desk is not in agreement with what we did. We set aside the pending amendment for consideration of my amendment which I brought up and presented. Then we returned to that amendment. I would like to ask the Chair if that is accurate.

The PRESIDING OFFICER. The Senator did not offer his amendment. The Senator may offer his amendment, but it was not offered.

Mr. KENNEDY. I ask unanimous consent that his amendment be at the desk and be subject to being called up.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows: The Senator from Oklahoma [Mr. INHOFE] proposes an amendment numbered 988.

Mr. INHOFE. I ask unanimous consent that reading of the amendment be dispensed with.

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

The amendment is as follows:

(Purpose: To protect children and their parents from being coerced into administering a controlled substance in order to attend school, and for other purposes)

SEC. . CHILD MEDICATION SAFETY.

(a) REQUIRED POLICIES AND PROCEDURES.—

(1) IN GENERAL.—As a condition of receiving funds under any program or activity administered by the Secretary of Education, not later than 1 year after the date of enactment of this section, each State shall develop and implement policies and procedures prohibiting school personnel from requiring a child to obtain a prescription for substances covered by section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) or a psychotropic drug as a condition of attending school or receiving services.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed to create a Federal prohibition against teachers and other school personnel consulting or sharing classroom-based observations with parents or guardians regarding a student's academic performance or behavior in the classroom or school, or regarding the need for evaluation for special education or related services under section 612(a)(3) of the Individuals with Disabilities Education Act (20 U.S.C. 1412(a)(3)).

(3) PROHIBITION OF PAYMENT OF FUNDS.—No Federal education funds may be paid to any local educational agency or other instrument of government that uses the refusal of a parent or legal guardian to provide a substance covered by section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) or a psychotropic drug for such individual's child

as the basis of a charge of child abuse, child neglect, education neglect, or medical neglect until the agency or instrument demonstrates that it is no longer using such refusal as a basis of a child abuse, child neglect, education neglect, or medical neglect charge.

(b) DEFINITIONS.—In this section:

(1) CHILD.—The term “child” means any person within the age limits for which the State provides free public education.

(2) PSYCHOTROPIC DRUG.—The term “psychotropic drug” means a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is not a substance covered by section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) but is—

(A) used in the diagnosis, treatment, or prevention of a disease; and

(B) intended to have an altering effect on perception, emotion, or behavior.

(3) STATE.—The term “State” means each of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.

(c) GAO STUDY AND REVIEW.—

(1) REVIEW.—The Comptroller General of the United States shall conduct a review of—

(A) the variation among States in definitions of psychotropic medications as used in regard to State jurisdiction over public education;

(B) the prescription rates of medications used in public schools to treat children diagnosed with attention deficit disorder, attention deficit hyperactivity disorder, and other disorders or illnesses;

(C) which medications used to treat such children in public schools are listed under the Controlled Substances Act; and

(D) which medications used to treat such children in public schools are not listed under the Controlled Substances Act, including the properties and effects of any such medications, including the incidence of hallucinations, psychosis, violence, suicide, heart problems, significant weight gain, or diabetes that students may experience while on these medications.

(2) REPORT.—Not later than 1 year after the date of enactment of this section, the Comptroller General of the United States shall prepare and submit a report that contains the results of the review under paragraph (1).

Mr. INHOFE. I do apologize to the managers of the bill as well as to the Chair. It was my understanding that I actually had that done previously. With that, if it is proper form now to get into the mix, I ask unanimous consent that I be permitted to speak as in morning business for up to 12 minutes.

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

(The remarks of Mr. INHOFE pertaining to the introduction of S. 1269 are located in today's RECORD under “Statements on Introduced Bills and Joint Resolutions.”)

Mr. INHOFE. I thank the managers of this bill for giving me this time to make this presentation.

I yield the floor.

The PRESIDING OFFICER (Ms. CANTWELL). The Senator from New Hampshire.

Mr. GREGG. Madam President, I understand that I may go forward. I appreciate the courtesy of the Senator from Massachusetts.

AMENDMENT NO. 993

(Purpose: To provide for the regulation of Internet pharmacies)

Madam President, today we have been discussing, at some depth, and ap-

propriately so, how to protect American citizens who purchase drugs overseas—from overseas pharmacies or from Canadian pharmacies—or purchase drugs on the Internet. This is a very significant issue for Americans, especially as more and more Americans use the Internet for the purposes of buying all sorts of items, including pharmaceuticals.

So we need to be sure this extraordinary regime we have set up in this country stays intact that allows a person, when he or she goes into an American drugstore or goes into an American supermarket, to be fairly confident the product they buy is not adulterated and the product they buy is what it says it is and that in the instance of a pharmaceutical or a medication, it is going to be what the doctor told them to take. That has been one of the great successes of American Government. It is because the Food and Drug Administration is overseeing this effort to protect the food supply and the pharmaceutical supply.

Whether the Food and Drug Administration has the wherewithal, the legal ability, and the technical and physical ability to protect an American who buys an overseas product, a medicine, and imports it into the United States is very much an issue. The FDA is very concerned about their capacity to police effectively drugs coming into this country, especially over the Internet.

So I have an amendment to this bill which basically is the Safe Internet Pharmaceutical Act, the purpose of which is to give the FDA the authority necessary to protect people who are buying pharmaceutical products over the Internet. This is, in my opinion, very important.

The importance of this has only been further stressed and exemplified by a warning that came out today, fortuitously, from the FDA on the issue of Internet pharmacies. I want to read extensively from this warning because it goes to the essence of the debate we have heard on the floor, especially from Senators supporting the proposal from the Senator from North Dakota relative to reimportation and safety and their representation that it is safe to buy over the Internet and that their amendment will make it legal to buy drugs from outside the United States over the Internet through their reimportation language.

This warning from the FDA states as follows: “FDA Warns Consumers about Counterfeit Drugs from Multiple Internet Sellers.” I am going to read quite a bit of the text because I think, first, it is so on point and it is so important:

The Food and Drug Administration (FDA) is cautioning U.S. consumers about dangers associated with buying prescription drugs over the internet. This alert is being issued based on information the agency received showing that 24 apparently related Web sites may be involved in the distribution of counterfeit prescription drugs.

On three occasions during recent months, FDA received information that counterfeit versions of—

I may not get all these medical terms correct, but I hope I do.

On three occasions during recent months, FDA received information that counterfeit versions of Xenical 120 mg capsules, a drug manufactured by Hoffmann-LaRoche Inc. (Roche), were obtained by three consumers from two different Web sites. Xenical is an FDA-approved drug used to help obese individuals who meet certain weight and height requirements lose weight and maintain weight loss.

None of the capsules ordered off the Web sites contained orlistat, the active ingredient in authentic Xenical. In fact, laboratory analysis conducted by Roche and submitted to the FDA confirmed that one capsule contained sibutramine, which is the active ingredient in Meridia, an FDA-approved prescription drug manufactured by Abbott Laboratories.

While this product is also used to help people lose weight and maintain that loss, it should not be used in certain patient populations and therefore is not a substitute for other weight loss products. In addition the drug interactions profile is different between Xenical and sibutramine, as is the dosing frequency; sibutramine is administered once daily while Xenical is dosed three times a day.

Other samples of drug product obtained from two of the Internet orders were composed of only talc and starch. According to Roche, these two samples displayed a valid Roche lot number of B2306 and were labeled with an expiration date of April 2007. The correct expiration date for this lot number is actually March 2005.

Pictures of the counterfeit Xenical capsules can be seen on the Web site at FDA. I would note they look exactly like the Xenical that is legitimate. We had a Senator here earlier holding up two prescription bottles of, I think it was Lipitor, saying: These two bottles are exactly the same, and one could be bought in Canada for about a third of what it costs in the United States. Well, you can buy this Xenical over the Internet for probably about a third of what it costs in the United States. The only problem is it might kill you. I am going to read further:

Roche identified the two Web sites involved in this incident as brandpills.com and pillspharm.com. Further investigation by FDA disclosed that these Web sites are two of 24 Web sites that appear on the pharmacycall365.com home page under the “Our Websites” heading. Four of these Web sites previously have been identified by FDA's Office of Criminal Investigations as being associated with the distribution of counterfeit Tamiflu and counterfeit Cialis.

At this point, it appears that these Web sites are operated from outside of the United States. Consumers should be wary, if there is no way to contact the Web site pharmacy by phone, if prices are dramatically lower than the competition, or if no prescription from your doctor is required. As a result, FDA strongly cautions consumers about purchasing drugs from any of these Web sites which may be involved in the distribution of counterfeit drugs and reiterates previous public warnings about buying prescription drugs online.

Then it lists the 24 Web sites, and some of them have very seductive

names: "Pharmacea.org," "MensHealthDrugs.net," "MediClub.md"—very seductive names, in order to draw people into purchasing drugs on these sites.

Madam President, I ask unanimous consent that this press release from the FDA be printed in the RECORD.

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

[From the FDA News, May 1, 2007]

FDA WARNS CONSUMERS ABOUT COUNTERFEIT DRUGS FROM MULTIPLE INTERNET SELLERS

The Food and Drug Administration (FDA) is cautioning U.S. consumers about dangers associated with buying prescription drugs over the Internet. This alert is being issued based on information the agency received showing that 24 apparently related Web sites may be involved in the distribution of counterfeit prescription drugs.

On three occasions during recent months, FDA received information that counterfeit versions of Xenical 120 mg capsules, a drug manufactured by Hoffmann-La Roche Inc. (Roche), were obtained by three consumers from two different Web sites. Xenical is an FDA-approved drug used to help obese individuals who meet certain weight and height requirements lose weight and maintain weight loss.

None of the capsules ordered off the Web sites contained orlistat, the active ingredient in authentic Xenical. In fact, laboratory analysis conducted by Roche and submitted to the FDA confirmed that one capsule contained sibutramine, which is the active ingredient in Meridia, an FDA-approved prescription drug manufactured by Abbott Laboratories.

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Other samples of drug product obtained from two of the Internet orders were composed of only talc and starch. According to Roche, these two samples displayed a valid Roche lot number of B2306 and were labeled with an expiration date of April 2007. The correct expiration date for this lot number is actually March 2005. (Pictures of the counterfeit Xenical capsules provided by Roche can be viewed at <http://www.fda.gov/bbs/topics/news/photos/xenical.html>.)

Roche identified the two Web sites involved in this incident as brandpills.com and pillspharm.com. Further investigation by FDA disclosed that these Web sites are two of 24 Web sites that appear on the pharmacycall365.com home page under the "Our Websites" heading. Four of these Web sites previously have been identified by FDA's Office of Criminal Investigations as being associated with the distribution of counterfeit Tamiflu and counterfeit Cialis.

At this point, it appears that these Web sites are operated from outside of the United States. Consumers should be wary, if there is no way to contact the Web site pharmacy by phone, if prices are dramatically lower than the competition, or if no prescription from your doctor is required. As a result, FDA strongly cautions consumers about purchasing drugs from any of these Web sites which may be involved in the distribution of counterfeit drugs and reiterates previous public warnings about buying prescription drugs online [Consumers are urged to review

the FDA Web page at www.fda.gov/buyonline/ for additional information prior to making purchases of prescription drugs over the Internet.]

The 24 Web sites appear on pharmacycall365.com: AllPills.net, Pharmacy-4U.net, DirectMedsMall.com, Brandpills.com, Emediline.com, RX-ed.com, RXePharm.com, Pharmacea.org, PillsPharm.com, MensHealthDrugs.net, BigXplus.net, MediClub.md, InterTab.de, Pillenpharm.com, Bigger-X.com, PillsLand.com, EZMEDZ.com, UnitedMedicals.com, Best-Medz.com, USAPillsrx.net, USAMedz.com, BluePillsRx.com, Genericpharmacy.us and I-Kusui.jp.

Mr. GREGG. It is, of course, ironic that in the middle of this debate over how you make safe drugs that Americans are purchasing, and assure that the FDA has the proper oversight, that the FDA would be issuing this warning. It is a coincidence. The FDA did not do it because we are in the middle of this debate. They did it because they had received the necessary information to fairly well substantiate that at least in three incidents the medication that was purchased was not the medication that was approved by the FDA, even though it was represented as that medication, even though it came in a bottle that looked exactly like that medication, even though it had a tamperproof seal, and it had a label and a date as to when that medication would expire and a lot number. So it certainly looked legitimate. So this just confirms the concern which many of us have that we have to set up a regime where the FDA can properly review what is happening relative to drugs that are being purchased over the Internet, especially. It is not impossible to do that. In fact, it is very doable. That is why I will offer this amendment.

The amendment I will offer basically sets up a system whereby the FDA will require that pharmaceutical products sold over the Internet be subject to the jurisdiction of the United States and that they get an FDA seal of approval which is tamper-proof. So if a citizen wants to use a pharmaceutical site, he or she can go on line and call up a pharmaceutical site, such as drugs.com or whatever—that may actually be a site, so I probably shouldn't use that term—but a site where you think you can purchase drugs at a better price than what you are going to have to pay for them somewhere else, they will see on that Web site a seal like the Good Housekeeping Seal of Approval, only it will be a tamper-proof seal which will reflect the fact that the FDA monitors that site, monitors that pharmacy.

Also, the pharmacy has subjected itself to American jurisdiction, so that if there is an illegal act, they can be prosecuted, or if there are issues of liability, they can be sued; also, that there is contact information which is based in America relative to that and that there is a searchable database where you can go in and find out what that pharmacy has done in the past relative to its prescription-filling activity.

This would all be supported by a fee system which gives the FDA the resources to accomplish this type of monitoring. It really seems like the most logical thing to do.

There is no way you can stop the imagination and desire of the American people to get the best price. That is part of the essence of our character. So it is reasonable that Americans are going to use online pharmacies, but we have to make sure we have a system where we do not have one approval process for legitimate purchasing of drugs through pharmaceutical activity at your local pharmacy and then another process for purchasing drugs which has absolutely no oversight from the FDA if you purchase on the Internet. We have to make sure that if you are using an Internet site, the site has been subject to the same review as the local pharmacy down at the corner is subject to, relative to the quality and management of that pharmaceutical product they are selling. That is what this amendment does.

I hope no one will object to it, but I know other people will. But they shouldn't because this is really something whose time has come. So I am going to offer this amendment tonight. It is timely, of course, in light of this FDA warning which says there are potentially 24 Web sites they have identified, at least 3 of which are selling adulterated drugs, that they know of, which could seriously harm and possibly, if taken in the wrong dosage, since they aren't the proper drug, actually do more than just harm you, they could permanently injure you.

In light of that warning which came out today, it is totally reasonable and appropriate that the Congress should certainly, if it is going to do a drug safety bill relative to the FDA, include in it an Internet pharmacy safety regime which will give the American people some confidence that when they go on line to purchase a drug on line, the site, the portal they are purchasing it through, is subject to FDA review and the drug they are purchasing is an FDA-approved drug, which is made clear by having this tamper-proof seal of approval. It would also reflect the fact that the FDA actually has physical oversight over that pharmacy, that online pharmacy, and gives the FDA the resources to do that oversight. You can't just say: Go and do it, if they don't have the money to do it; you have to give them the resources to do it.

In addition, it sets up a one-stop shopping site at the FDA where people can go on line to the FDA site, check out that Internet pharmacy, if they wish, and make sure the Internet pharmacy does qualify and does carry FDA-approved drugs.

I think it is a very proper approach. It is something, as I mentioned, which is clearly timely in light of this FDA warning.

Madam President, at this time, I ask unanimous consent that the pending

amendment be set aside and that I may call up amendment No. 993 and ask for its immediate consideration.

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

The clerk will report the amendment.

The legislative clerk read as follows:

The Senator from New Hampshire [Mr. GREGG], for himself and Mr. COLEMAN, proposes an amendment numbered 993.

Mr. GREGG. I ask unanimous consent that the reading of the amendment be dispensed with.

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

(The amendment is printed in the RECORD of Tuesday, May 1, 2007, under "Text of Amendments.")

Mr. GREGG. I thank my colleagues for allowing me to go forward at this time.

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

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

AMENDMENT NO. 1011

Mr. MENENDEZ. Madam President, I rise today to talk about an issue of great importance but also of great concern: the importation of prescription drugs.

In their search for more affordable prescription drugs, many Americans have turned to pharmacies in other countries, either via the Internet or trips across the border. While I certainly understand their need for affordable drugs, I do have concerns about this particular solution. We must find a way to ensure that the drugs Americans are buying are safe.

I believe the Cochran amendment will do just that. Senator COCHRAN's amendment allows importation to take effect only if the Health and Human Services Secretary can ensure that it will pose no additional risk to the public health and result in a significant reduction in the cost of prescription drugs. So with this amendment, we get safe drugs at a reduced price, and our ultimate objective is achieved.

Looking closely at the issue of safety, I am also concerned about the importation of counterfeit drugs. Americans deserve to know the label on the bottle—we have seen colleagues put bottles up and show differences. Well, Americans deserve to know the label on the bottle matches the pills inside they are taking. The only way to ensure that is to provide strong protections. We have all heard horror stories about innocent Americans, starved for cheaper prescription drugs, going online or getting in their cars to go to foreign pharmacies to buy their medications. They are coming back home with what they think is their usual medication, but the reality might be quite different.

A recent New York Times article talked about the increasing number of counterfeit drugs. While in the past we may have noticed a misspelled label or off-color pill, today's counterfeit drugs are largely undetectable. The pills look correct, the cardboard boxes are the same, even the blister packaging and foil backing are all normal. But this is not your grandmother's forged medication. These are modern, scary, life-threatening tactics that place American lives in great danger.

While the supporters of the underlying amendment believe their proposal addresses some of these concerns, there are a number of safety concerns that I believe must be addressed by the Secretary of Health and Human Services, and that is why the Cochran amendment is so important.

The underlying proposal would undo current safety protections that ensure Americans are getting products that are essentially the same substance and quantity as what their doctor has prescribed.

While the proposal requires an importer to retain samples of products, it does not require that those be tested to ensure the drugs are the same as what the doctor ordered.

The proposal does not require that imported drugs be approved in their country of origin. It relies only on a paper trail to enforce chain-of-custody requirements, leaving consumers susceptible to unscrupulous dealers who can simply forge documents or copy anticounterfeit technology.

While supporters of the proposal claim that they give FDA the authority to conduct inspections of foreign manufacturing plants, the reality is that the United States would actually have to get permission for those inspections from foreign countries, and that is assuming we can even trace the purchase of those products to their country of origin in the first place.

Importers are not required to disclose the origin of the products they sell, so consumers would have no way to opt out if they wanted to ensure they were getting Food and Drug Administration-approved products.

Finally, the underlying amendment allows importation from far more than just Canada. Written into the proposal is permission to import from Canada and other countries, including certain countries in the EU, even if the drugs leave the chain of custody of the manufacturer or fall outside of the Food and Drug Administration's jurisdiction. Because of the EU structure, we would actually be opening ourselves to drugs from countries such as Latvia, Estonia, and other recent additions to the EU. Some of these countries from the former Soviet Union have counterfeit rates up to 20 percent.

The Cochran amendment would ensure these safety concerns are resolved and that the Government provides for the protection of the public's health and safety.

Now, in my mind, as we have this debate, the real problem is affordability

of prescription drugs, and the real solution to that problem is expanding access to affordable drugs in the United States. In that effort, I take a back seat to no one. But at the same time, I strongly believe we must also protect the health and safety of those we represent.

These two goals are not mutually exclusive. We can and must do both. I believe this amendment—the Cochran amendment—accomplishes what we all want, which is expanding access to safe, affordable drugs. I encourage my colleagues to support the Cochran amendment.

AMENDMENT NO. 1011

Mr. KOHL. Madam President, I rise today to join Senators STABENOW, LOTT, BROWN, and THUNE in offering amendment No. 1011. This amendment will help speed the introduction of cost-saving generic drugs by preventing abuses of the Food and Drug Administration citizen petition process.

Consumers continue to suffer all across our country from the high—and ever rising—cost of prescription drugs. A recent independent study found that prescription drug spending has more than quadrupled since 1990, and now accounts for 11 percent of all health care spending. At the same time, the pharmaceutical industry is one of the most profitable industries in the world, returning more than 15 percent on their investments.

One key method to bring prescription drug prices down is to promote the introduction of generic alternatives to expensive brand name drugs. Consumers realize substantial savings once generic drugs enter the market. Generic drugs cost on average of 63 percent less than their brandname equivalents. One study estimates that every 1 percent increase in the use of generic drugs could save as much as \$4 billion in health care costs.

This is why I have been so active in pursuing legislation designed to combat practices which impede the introduction of generic drugs. The amendment offered today, includes provisions based on legislation that I first introduced with Senator LEAHY in the last Congress, and targets one particularly pernicious practice by brandname drug companies to impede or block the marketing of generic drugs—abuse of the FDA citizen petition process.

FDA rules permit any person to file a so-called citizen petition to raise concerns about the safety or efficacy of a generic drug that a manufacturer is seeking FDA approval to bring to market. While this citizen petition process was put in place for a laudable purpose, unfortunately in recent years it has been abused by frivolous petitions submitted by brandname drug manufacturers, or individuals acting at their behest, whose only purpose is to delay the introduction of generic competition. The FDA has a policy of not granting any new generic manufacturer's drug application until after it has

considered and evaluated any citizen petitions regarding that drug. The process of resolving a citizen petition, even if ultimately found to be groundless, can delay the approval by months or years. Indeed, brandname drug manufacturers often wait to file citizen petitions until just before the FDA is about to grant the application to market the new generic drug manufacturer's solely for the purpose of delaying the introduction of the generic competitor for the maximum amount of time possible. This gaming of the system should not be tolerated.

In recent years, FDA officials have expressed serious concerns about the abuse of the citizen petition process. In 2005, FDA Chief Counsel Sheldon Bradshaw noted that "[t]he citizen petition process is in some cases being abused. Sometimes, stakeholders try to use this mechanism to unnecessarily delay approval of a competitor's products." He added that he found it "particularly troublesome" that he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application, but rather to delay approval by compelling the agency to take the time to consider the arguments raised in the petition, regardless of their merits, and regardless of whether the petitioner could have made those very arguments months and months before."

And a simple look at the statistics gives credence to these concerns. Of the 21 citizen petitions for which the FDA has reached a decision since 2003, 20—or 95 percent of them—have been found to be without merit. Of these, 10 were identified as "eleventh hour petitions"—defined as those filed less than 6 months prior to the estimated entry date of the generic drug. None of these 10 "eleventh hour petitions" were found to have merit, but each caused unnecessary delays in the marketing of the generic drug by months or over a year, causing consumers to spend millions and millions of dollars for their prescription drugs than they would have spent without these abusive filings.

Among other things, our amendment will, for the first time, require all those who file citizen petitions to affirm certain basic facts about the truthfulness and good faith of the petition, similar to what is required of every litigant who makes a filing in court. Our amendment also includes a provision from my bill that directs the HHS that all citizen petitions on generic drug applications be adjudicated within 6 months of filing, which will put an end to excessive delays in bringing needed generic drugs to market because of the filings of these petitions.

While I strongly support this amendment and I am pleased that many of my provisions were included, I do wish the amendment could have gone even farther and include my provision to allow the Department of Health and

Human Services—the FDA's parent agency—the power to sanction those who abuse the process. While this proposal would not have an effect on any person filing a truly meritorious citizen petition, this provision would serve as a strong deterrent to attempts by brand name drug manufacturers or any other party that seeks to abuse the citizen petition process to thwart competition. Having said that, I do believe our amendment today is an important step in the right direction to remove a significant obstacle exploited by brand name drug companies to prevent or delay the introduction of generic drugs. I urge my colleagues to support this amendment.

AMENDMENT NO. 1016

Mr. SPECTER. Madam President, the Food and Drug Administration Revitalization Act is an important step toward protecting American consumers and patients and ensuring the safety of prescription drugs. To increase the safety and efficacy of prescription drug approval, I will offer an amendment to establish the National Centers of Pharmaceutical Innovation. These Centers, in consultation with the Food and Drug Administration, FDA, Commissioner, will modernize medical product development and enhance product safety.

I am very concerned about long delays and the safety of bringing new drugs to patients. The FDA has been faced with the withdrawal of prescription drugs from the market due to concerns about increased health risks. This situation illustrates the difficulty in achieving the right balance in investigating new drugs that, while intended to help patients, can also come with very serious risks. Furthermore, such incidents could lead to the erosion of public confidence in the safety of medicines developed by drug companies. Drug companies spend enormous sums of money to test potential new candidate medicines. Not only is the process of developing and testing a new drug costly, it is lengthy as well. As a result of delays in the clinical trials process, there are fewer drug discoveries each passing year, ultimately hindering our Nation's competitiveness in this field.

According to Ernst R. Berndt, Ph.D., Adrian H. B. Gottschalk, S.M., Matthew W. Strobeck, Ph.D., Massachusetts Institute of Technology, MIT, Sloan School of Management, "scientific advances and enhanced [research and development] efforts, the number of average annual new drug applications, NDAs, and new biologic license applications, BLAs, approved by the U.S. Food and Drug Administration has been smaller after 2000 than in the mid-1990s. Moreover, recent estimates suggest the average costs of bringing a new medicine to market have increased sharply to between \$800 million and \$1.7 billion, with the lower estimate being 2½ times higher than similar inflation-adjusted estimates published a dozen years earlier." Clearly, there is great

need to improve the methods and science that are used to approve prescription drugs.

I am further concerned that new technologies, including genomics, proteomics, and bioinformatics are not being fully incorporated into the drug approval process. Using these new technologies as part of the clinical drug approval process has the potential to substantially reduce costs and the time needed to develop and test new drugs. Additionally, we must improve the workforce available to pharmaceutical companies, which is not well trained in the modern tools needed for sophisticated drug development. The FDA does not have a structured research program to bridge this knowledge and workforce gap and has few extramural research activities in place to tap the expertise available in our Nation's university health programs.

This amendment will establish the National Centers for Pharmaceutical Innovation to improve the development and testing of new drugs so that they make it to market more quickly and remain there. Up to five centers will be operated by universities in partnership with the FDA to develop methods to utilize new technology to improve the drug approval system. They will also expand the quality and number of professionals trained to work in this field. The centers will introduce new technologies to improve the manufacture of pharmaceutical and biotechnology products.

I believe these centers can provide a significant part of the solution to this complex problem. These centers will be established from qualified universities that have graduate training programs with extensive experience in the development and evaluation of medicines; and proficiencies in pharmaceutical and biotechnology science and engineering. It is the expectation that the work completed by these centers and the FDA would lead to an increased number of drugs brought to market by industry, at a decreased cost. Another effect will be an enormous gain to the public's health, while decreasing the chance of unintentional harm and costs of medical care.

The National Centers for Pharmaceutical Innovation hold a promising solution to the problems in drug discovery and safety facing our Nation today. I encourage my colleagues to support this important amendment.

OVERTURNING DSHEA

Mr. HATCH. My office has been inundated by calls from people throughout the country who believe that this legislation, specifically the provision establishing a Reagan-Udall Institute, will overturn the Dietary Supplement Health and Education Act of 1994. That has not been my reading of the bill, but I wonder if other Senators have heard similar concerns?

Mr. HARKIN. Yes, I have received a good many calls as well. And, I have to say that I would be very concerned, as I know the Senator from Utah is, if

Mr. HARKIN. Yes, I have received a good many calls as well. And, I have to say that I would be very concerned, as I know the Senator from Utah is, if anything in the bill we are considering, S. 1082, would overturn DSHEA, a law we fought side-by-side to see enacted.

Mr. ENZI. It might be helpful if I explained the provision you are discussing, as my office has received many calls as well and I believe the callers are not informed about this matter. Subtitle B of title II of S. 1028 establishes the Reagan-Udall Foundation for the Food and Drug Administration. That simple purpose of that non-profit Foundation is to lead collaborations among the FDA, academic research institutions and industry designed to bolster research and development productivity, provide new tools for improving safety in regulated product evaluation, and in the long term make the development of those products more predictable and manageable.

Mr. KENNEDY. That is exactly the purpose of the Foundation, which was included in the drug safety legislation Senator ENZI and I introduced last year. The Foundation will be financially supported by industry and philanthropic donated funds. A chief scientist at FDA will promote intramural research and coordinate it with efforts at the Foundation.

Mr. HATCH. That explanation is very helpful. What, specifically, would the role of the Foundation be with respect to dietary supplements?

Mr. KENNEDY. Let me make absolutely clear that the Reagan-Udall Foundation will in no way override, overturn or conflict with the Dietary Supplement Health and Education Act. Nothing in this bill would have that effect.

Mr. ENZI. Yes, we took great pains to make certain there would be no conflict with DSHEA. Regarding foods, and dietary supplements are generally regulated as foods, the general directive of the Foundation is to identify holes in the evaluation of food safety and identify ways to address those deficiencies through collaborative research with industry.

Mr. HARKIN. So to make this absolutely clear, what you are saying is that the bill we are debating would in no way interfere with consumers' access to dietary supplements?

Mr. HATCH. To add to that point, it seems that the language could, in fact, help dietary supplement consumers, because it would allow collaboration between government and industry to conduct research on issues that might be helpful to supplement consumers?

Mr. KENNEDY. Yes, that is the case.

Mr. ENZI. I agree with Chairman KENNEDY's assessment.

Mr. HATCH. I thank you for those assurances and that clarification.

Mr. HARKIN. This has been a very helpful discussion, because Senator HATCH and I could never support legislation that would interfere with DSHEA and we are glad to receive the

assurances of the chairman and the ranking Republican on the committee.

MORNING BUSINESS

Mr. MENENDEZ. Madam President, I ask unanimous consent that there now be a period of morning business with Senators permitted to speak therein for up to 10 minutes each.

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

DEPARTMENT OF JUSTICE

Mr. LEAHY. Madam President, when I was a young law student at Georgetown, the event that stands out the most in my memory was a morning that I and a few other young law students working at various agencies for the summer had with the then Attorney General. It was Attorney General Robert Kennedy. In that meeting, he stressed to us over and over again the professionalism of the Department of Justice and how the professionals had to stay out of any kind of partisan politics and that he would insist upon it.

I was inspired by that meeting. I think it probably shaped my decision to go into public life more than any other single meeting I had.

I ask unanimous consent that an article in today's USA Today by Ronald Goldfarb entitled "Crossing the Line at Justice" be printed in the RECORD.

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

[From USA Today, Wednesday, May 2, 2007]

CROSSING A LINE AT JUSTICE

(By Ronald Goldfarb)

The current agonies of Attorney General Alberto Gonzales call to mind a dramatic moment in the Robert F. Kennedy Justice Department. Members of his organized crime section were in RFK's office reviewing our pending investigations and cases. One of our group advised Kennedy that his grand jury investigations were about to lead to the indictment of the then-mayor of a large Midwestern city, one that had voted for his brother John Kennedy in the close presidential election of 1960.

When my colleague completed his report about the big scalp about to be added to our list of political corruption cases, RFK was quiet. It happened that the scalp in question belonged to President Kennedy's ambassador-designate to Greece. The attorney general smiled slightly and facetiously remarked: "Well, that's nice. Now my brother's going to have to put me on the Supreme Court." The indictment went forward and included others in the city's political (Democratic) machine. All were convicted.

That anecdote is relevant today as the Senate Judiciary Committee considers the attorney general's recent dismissals of several U.S. attorneys. When it comes to the proper administration of justice in the Department of Justice, there are politics and there are politics.

THE TWO P'S

Capital "P" politics—that is, party politics, such as the partisan personal shenanigans of Gonzales meddling with the independence of competent prosecutors' discretion in response to political pressures—are improper and have no place in the justice

system. Small "p" politics, the imposition of discretionary preferences, policies and priorities in the focus of prosecutorial discretion, generally are proper. Partisans must accept them, like it or not. They are not the basis for replacing attorneys general.

The distinction is important. When the Justice Department that I served in during the Kennedy administration came to office, "political" priorities changed. The internal security division, active and robust during the Eisenhower administration when loyalty was a major concern, was de-emphasized and eventually was deactivated. The organized crime and the civil rights sections, small and quiet in earlier years, grew into major centers of departmental work and were the centerpiece of RFK's regime. That kind of priority setting is proper.

Administrations come to office offering change. Like these changes or not, people cannot claim they involve improper politics. Critics have the right to change administrations with their votes in subsequent elections. Had Al Gore been elected, no doubt environmental prosecutions would have taken front and center in the department's efforts.

After Sept. 11, 2001, homeland security would have been any attorney general's special interest, RFK's included. So if one deplores the values and priorities of the John Ashcroft and Gonzales administrations at Justice, USA Patriot Act excesses and the like, the recourse will be at the 2008 voting machines.

On the other hand, capital "P" party politics have no place in any Justice Department. That is the unique indictment of Gonzales, and one that should lead to his replacement. All attorneys general face political pressure to act against their parties' political enemies and to protect their friends. Those are the moments of truth for all attorneys general, the one that Gonzales failed, to the embarrassment of even his own party representatives.

RFK'S TESTS

When RFK was attorney general, two comparable moments stand out in my memory. In one, his notorious father's long-time attorney—James Landis, "a virtual member of the immediate family," according to one biography—was charged with failing to file his tax returns for five years. Immense pressures were put on Kennedy to find an excuse not to indict the aging and prestigious former Harvard law dean. RFK stayed out of the decision-making process, and Landis pleaded guilty and received a brief incarceration. But for his close association with the Kennedys, Landis probably would not have suffered so. Everyone wanted to help Landis, but they were super self-conscious about the propriety of doing so.

A similar moment arose when an investigation showed that the brother of the influential congressman from New York, Eugene Keogh, had abused his office as a New York state supreme court judge. Kennedy agonized over the political pressures on him; he worried that the not open-and-shut case might not be winnable, after major political embarrassment to Kennedy loyalists. To his credit, Keogh told Kennedy he knew he'd do the right and fair thing. The attorney general's aides pressed him to do what he'd do in any other non-political case. Judge J. Vincent Keogh was indicted and convicted. That is the only way an attorney general can keep the balance of justice even and credible.

Gonzales needed aides who spoke to him with comparable candor and rectitude. Instead, he is falling on his sword over the U.S. attorney firings that he administered without knowing, as he has testified, much about them at the time. Like former vice presidential aide Lewis "Scooter" Libby in the