and a kind word for anyone who crossed his path.

My predecessor in the Senate, Warren Magnuson, had a phrase for someone like that— ''a workhorse not a showhorse.''

PAUL COVERDELL was a workhorse in the finest sense.

PAUL earned the respect of everyone here because he treated everyone else with respect and dignity.

PAUL's work here in the United States Senate was really just an extension of a lifetime of service. Whether it was serving his country in the U.S. Army, serving the people of Georgia as a state senator, or helping people around the world through his work as director of the United States Peace Corps, PAUL brought his generous spirit and his determination to everything he undertook.

Mr. President, the people of Georgia are fortunate to have been served by a person of PAUL's character and skills.

Those of us who worked with him here in the U.S. Senate were fortunate to have him as a friend and colleague. His passing is a loss to our Senate, to Georgia and to the Nation. I will miss him as a friend and colleague.

Mr. SARBANES. Mr. President, I rise today to join my colleagues in honoring a distinguished public servant and a valued Member of the United States Senate, Senator PAUL COVERDELL, who died Tuesday evening at the Piedmont Hospital in Atlanta, Georgia.

Senator COVERDELL was elected to the United States Senate in 1992 and served as the Republican Conference Secretary since December, 1996. He was a member of the Senate Finance, Foreign Relations, and Small Business Committees and chaired the Agriculture Committee's Subcommittee on Marketing, Inspection and Product Promotion.

Before entering public life, Senator COVERDELL served in the U.S. Army in Okinawa, Taiwan and Korea. He earned a Bachelor's degree in journalism from the University of Missouri before returning to Georgia to work in his family's business.

PAUL COVERDELL's political career began in 1970 when he was elected to the Georgia State Senate serving as Minority Leader for 14 years. In 1989, he accepted President Bush's appointment as Director of the Peace Corps, where he refined the agency's mission to serve the emerging democracies of Eastern Europe.

While Senator COVERDELL and I rarely agreed on the many issues that came before the Senate for consideration, I greatly respected his hard work and his unfailing courtesy and civility. He was a modest man who valued results more than he valued headlines. Indeed, PAUL COVERDELL was well-respected by every member of this body, engendering the affection of all those with whom he served.

Senator COVERDELL served the citizens of Georgia and the Nation well and we are all deeply saddened by his untimely death. I would like to take this opportunity to pay tribute to him and to extend my deepest and heartfelt sympathies to his family.

AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS ACT, 2001—Continued

AMENDMENT NO. 3925

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. I thank Senators for their eloquent words about the passing of PAUL COVERDELL. I see no one else seeking recognition for that purpose, so at this time I move back to the bill. If there is anything PAUL COVERDELL disliked, it was quorum calls and delaying the process. We worked together on the education bill, and I know he was proud when it moved expeditiously and the debate was lively.

In that spirit, I think we must return to the business before the Senate.

Therefore, I call up amendment 3925.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Vermont [Mr. JEFFORDS], for himself, Mr. WELLSTONE, Mr. DORGAN, Ms. SNOWE, Mr. GORTON, Mr. JOHNSON, Mr. LEVIN, and Mr. BRYAN, proposes an amendment numbered 3925.

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

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

The amendment is as follows:

(Purpose: To amend the Federal Food, Drug, and Cosmetic Act to allow importation of covered products)

At the end of title VII, add the following:

SEC. . AMENDMENT TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) SHORT TITLE.—This section may be cited as the ''Medicine Equity and Drug Safety Act of 2000''.

(b) FINDINGS.—Congress makes the following findings:

(1) The cost of prescription drugs for Americans continues to rise at an alarming rate.

(2) Millions of Americans, including medicare beneficiaries on fixed incomes, face a daily choice between purchasing life-sustaining prescription drugs, or paying for other necessities, such as food and housing.

(3) Many life-saving prescription drugs are available in countries other than the United States at substantially lower prices, even though such drugs were developed and are approved for use by patients in the United States.

(4) Many Americans travel to other countries to purchase prescription drugs because the medicines that they need are unaffordable in the United States.

(5) Americans should be able to purchase medicines at prices that are comparable to prices for such medicines in other countries, but efforts to enable such purchases should not endanger the gold standard for safety and effectiveness that has been established and maintained in the United States.

(c) AMENDMENT.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended—

(1) in section 801(d)(1), by inserting ''and section 804'' after ''paragraph (2)''; and

(2) by adding at the end the following:

''SEC. 804. IMPORTATION OF COVERED PRODUCTS.

''(a) REGULATIONS.—

''(1) IN GENERAL.—Notwithstanding sections 301(d), 301(t), and 801(a), the Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting importation into the United States of covered products.

''(2) LIMITATION.—Regulations promulgated under paragraph (1) shall—

''(A) require that safeguards are in place that provide a reasonable assurance to the Secretary that each covered product that is imported is safe and effective for its intended use;

''(B) require that the pharmacist or wholesaler importing a covered product complies with the provisions of subsection (b); and

''(C) contain such additional safeguards as the Secretary may specify in order to ensure the protection of the public health of patients in the United States.

''(3) RECORDS.—Regulations promulgated under paragraph (1) shall require that records regarding such importation described in subsection (b) be provided to and maintained by the Secretary for a period of time determined to be necessary by the Secretary.

''(b) IMPORTATION.—

''(1) IN GENERAL.—The Secretary shall promulgate regulations permitting a pharmacist or wholesaler to import into the United States a covered product.

''(2) REGULATIONS.—Regulations promulgated under paragraph (1) shall require such pharmacist or wholesaler to provide information and records to the Secretary, including—

''(A) the name and amount of the active ingredient of the product and description of the dosage form;

''(B) the date that such product is shipped and the quantity of such product that is shipped, points of origin and destination for such product, the price paid for such product, and the resale price for such product;

''(C) documentation from the foreign seller specifying the original source of the product and the amount of each lot of the product originally received;

''(D) the manufacturer's lot or control number of the product imported;

''(E) the name, address, and telephone number of the importer, including the professional license number of the importer, if the importer is a pharmacist or pharmaceutical wholesaler;

''(F) for a product that is—

''(i) coming from the first foreign recipient of the product who received such product from the manufacturer—

''(I) documentation demonstrating that such product came from such recipient and was received by such recipient from such manufacturer;

''(II) documentation of the amount of each lot of the product received by such recipient to demonstrate that the amount being imported into the United States is not more than the amount that was received by such recipient;

''(III) documentation that each lot of the initial imported shipment was statistically sampled and tested for authenticity and degradation by the importer or manufacturer of such product;

''(IV) documentation demonstrating that a statistically valid sample of all subsequent shipments from such recipient was tested at an appropriate United States laboratory for authenticity and degradation by the importer or manufacturer of such product; and

''(V) certification from the importer or manufacturer of such product that the product is approved for marketing in the United States and meets all labeling requirements under this Act; and

''(ii) not coming from the first foreign recipient of the product, documentation that each lot in all shipments offered for importation into the United States was statistically sampled and tested for authenticity and degradation by the importer or manufacturer of such product, and meets all labeling requirements under this Act;

''(G) laboratory records, including complete data derived from all tests necessary to assure that the product is in compliance with established specifications and standards; and

''(H) any other information that the Secretary determines is necessary to ensure the protection of the public health of patients in the United States.

''(c) TESTING.—Testing referred to in subparagraphs (F) and (G) of subsection (b)(2) shall be done by the pharmacist or wholesaler importing such product, or the manufacturer of the product. If such tests are conducted by the pharmacist or wholesaler, information needed to authenticate the product being tested and confirm that the labeling of such product complies with labeling requirements under this Act shall be supplied by the manufacturer of such product to the pharmacist or wholesaler, and as a condition of maintaining approval by the Food and Drug Administration of the product, such information shall be kept in strict confidence and used only for purposes of testing under this Act.

''(d) STUDY AND REPORT.—

''(1) STUDY.—The Secretary shall conduct, or contract with an entity to conduct, a study on the imports permitted under this section, taking into consideration the information received under subsections (a) and (b). In conducting such study, the Secretary or entity shall—

''(A) evaluate importers' compliance with regulations, and the number of shipments, if any, permitted under this section that have been determined to be counterfeit, misbranded, or adulterated; and

''(B) consult with the United States Trade Representative and United States Patent and Trademark Office to evaluate the effect of importations permitted under this Act on trade and patent rights under Federal law.

''(2) REPORT.—Not later than 5 years after the effective date of final regulations issued pursuant to this section, the Secretary shall prepare and submit to Congress a report containing the study described in paragraph (1).

''(e) CONSTRUCTION.—Nothing in this section shall be construed to limit the statutory, regulatory, or enforcement authority of the Secretary relating to importation of covered products, other than the importation described in subsections (a) and (b).

''(f) DEFINITIONS.—In this section:

''(1) COVERED PRODUCT.—The term 'covered product' means a prescription drug under section 503(b)(1) that meets the applicable requirements of section 505, and is approved by the Food and Drug Administration and manufactured in a facility identified in the approved application and is not adulterated under section 501 or misbranded under section 502.

''(2) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice pharmacy in the United States, including the dispensing and selling of prescription drugs.

''(3) WHOLESALER.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States.''.

Mr. JEFFORDS. Mr. President, I also ask unanimous consent that Senator BRYAN be added as a cosponsor to the amendment.

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

Mr. JEFFORDS. Mr. President, I will now discuss a problem we have relative to the cost of prescription drugs.

I am joining several of my colleagues from both sides of the aisle in offering an amendment that will take a giant step toward providing access to affordable prescription drugs for Vermonters, and all Americans.

Our amendment will allow pharmacists and wholesalers to import safe, U.S.-made, FDA-approved lower-cost prescription drugs from other countries. We maintain the gold standard of safety in this country, but hope to rein in the platinum standard we have for prices.

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

Americans pay by far the highest prices in the world for prescription drugs, and for many the price is just too high.

What's worse is that those Americans who can least afford it are the ones paying the highest prices. Americans who don't have health insurance that covers drugs are forced to pay the ''sticker price'' off the pharmacist's shelf.

In short, the practice of price discrimination hits the uninsured and low-income Medicare beneficiaries the hardest.

It is sad that during a time when the United States is experiencing unprecedented economic growth, it is not uncommon to hear of patients, like we heard in my committee's hearing yesterday, who cut pills in half, or skip dosages in order to make prescriptions last longer, because they can't afford the refill.

The question that we must ask is, can we put politics aside and work in a bipartisan manner to deal with this national crisis? I say we must. And I am hopeful that today we can.

This bipartisan amendment I am offering is based on legislation I introduced, S. 2520, the Medicine Equity and Drug Safety Act, or the MEDS Act. Joining me in introducing that legislation were Senators WELLSTONE, SNOWE, and COLLINS and joining as cosponsors are Senators DORGAN and GORTON. The hearing I held yesterday allowed all of the parties to fully examine and articulate their views on this legislation.

Our bill, which we have revised and are offering as an amendment, gives pharmacists and wholesalers the ability to negotiate more favorable prices with manufacturers. They can do so because they will have the ability to purchase in other countries—this is important—where exactly the same drugs are sold for far less. These are areas that have been approved by the FDA. There is no question about that aspect.

The drug industry has argued that this amendment compromises safety. As chairman of the Committee on Health, Education, Labor, and Pensions, safety is my first concern. That is why these imports will be limited to FDA-approved drugs that are made in the United States or FDA inspected facilities. And that is why this amendment reflects weeks of discussions with the people who enforce our drug safety laws.

The amendment before us is a revision of the MEDS Act based on input from government experts who raised issues of public health and safety. Specifically, I asked FDA for technical assistance on this bill, and addressed each safety concern that the agency raised.

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

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

I point out this bipartisan amendment also drops a provision in our original bill that would have allowed personal imports, which I would have liked to retain because I think it is important.

We dropped the personal use provision in order to answer concerns that some raised about safety. I was willing to compromise on that point at this time in order to get a bill that raises no safety concerns at all.

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

This amendment will provide equitable treatment of Americans, particularly those who do not have insurance, or access to big discounts for large purchases like HMOs. As I said before, this is not the only solution. I strongly believe we need a prescription drug benefit in the Medicare system for those people who are eligible for Medicare. But it is a commonsense measure that we can enact now to ease the burden of expensive prescription drugs on our people, for those on the borders, and all Americans. I ask for the support of my colleagues.

I yield the floor.

The PRESIDING OFFICER. The Senator from Mississippi.

AMENDMENT NO. 3927 TO AMENDMENT NO. 3925

Mr. COCHRAN. Mr. President, I send a second-degree amendment to the desk.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Mississippi [Mr. COCHRAN], for himself and Mr. KOHL, proposes an amendment numbered 3927.

At the end of the amendment insert the following:

''(g) This section shall become effective only if the Secretary of the Department of Health and Human Services certifies to the Congress that the implementation of this section will: (1) pose no 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.''

Mr. COCHRAN. Mr. President, the purpose of this second-degree amendment is to try to help ensure the result of the change in this law, in the authority for importing drugs into the country or selling drugs to American consumers from Canada, which I think this amendment the Senator has offered is targeted to address, will not result in any new dangers to the consuming public, and would require the Secretary to certify that that would be the case for any new regulatory regime implementing the amendment if it is adopted.

One problem we need to bring to the attention of the Senate in connection with this amendment is the added cost that is going to result from this, in terms of added appropriations for the Food and Drug Administration. It is estimated by that agency that $92 million would have to be appropriated to provide the funding necessary to implement and carry out the obligations of that agency in connection with supervising this amendment.

The distinguished Senator is chairman, as Senators know, of the legislative committee that has jurisdiction over this overall subject area in the law. I regret this is an issue being brought to the Senate as an amendment to the Agriculture Department's appropriations bill. It would be more appropriate, in my view, for the legislative committee which the Senator chairs to deal with this, to report out legislation, and in the usual way of managing changes in the law, have the Senate address it on a freestanding bill. The body is put at a disadvantage to try to understand all the nuances, the implications of the legislation, what the practical results will be. It has become very controversial. I think the Senator from North Dakota, in opening remarks as we brought this legislation up yesterday or the day before, talked about the advertising that was being run in the newspapers by the pharmaceutical industry. I think that is on this subject. It is related to this subject.

So there is a great deal of attention being focused on this highly controversial issue. All the States along the northern tier that border on Canada have a great interest in this. It has become a hot button political subject for debate in senatorial campaigns and, I guess, all the congressional elections and the Presidential campaign. So this is a big political item here we are called upon to understand, to sort through, and then to make sure we legislate in a fashion that serves the public interest—not somebody's private political interest, not somebody's private financial interest, but the broad public interests of the United States. That is our responsibility.

So what I am seeking to do with this second-degree amendment is ensure that is the result; that we are not putting in jeopardy, by changing this law, if this survives the process here in the Senate and conference with the House—we are not putting in jeopardy the well-being of American consumers and we also prepare to add to the funding requirements of the Food and Drug Administration to enable them to carry out their obligations under the law.

With those words of explanation as to where I see this and how I see this playing out, I am not going to prolong the debate.

Let me point out one other thing. Some might say this is legislation on an appropriations bill; Why don't you just raise the issue in that way? Make a point of order under rule XVI.

The point is the House has included language in its Agriculture appropriations bill and this amendment, as it is drafted—as I am advised by the Parliamentarian—is not subject to a rule XVI point of order but, rather, it is germane and would not fall if a point of order is made. That may be tested by somebody if they want to argue with the Parliamentarian about it, but that is what my staff advises me.

With that information about this situation I am prepared to let others talk about it. Let me say, before I yield the floor, just as a matter of general information now that we are on the bill, Senator KOHL is the cosponsor of this second-degree amendment. I have offered the amendment with him.

Also, as we began consideration of the appropriations bill, he did not have an opportunity to make his opening remarks. At some point this afternoon, we will give him that opportunity or he can take that opportunity when he gains recognition from the Chair.

I hope this will not be a long, drawn-out debate. It is not necessary. We have heard a lot of speeches about this. We have had a lot of information sent to our offices on this issue of reimportation and selling drugs and pharmaceutical products across the borders, importing from manufacturers, the rights of pharmacists—all the other related issues. It is a serious matter. But we do not need to have a long, drawn-out filibuster of it in my view. We need to vote on it. If the votes are here to adopt this amendment, so be it. We will take it to conference and try to resolve the issue in the way we always do, give and take, trying to understand what is best for the country.

Also in connection with the broader picture of the bill itself, we do not have a lot of troublesome issues in this bill, in my view. I have not heard from Senators. We have asked Senators to let us know if they have amendments, to bring them to the floor and offer them, and let's dispose of them and complete action on this bill. I was heartened today by conversation, as we were getting started, from the Senator from Nevada, the assistant Democratic leader, Mr. REID, who suggested we could finish this bill today. He saw no reason why we could not. I see no reason why we could not finish it today.

I hope as we proceed we will keep that goal in mind. Let's finish this bill today. I hope we can have third reading at about 6 o'clock. I do not see any reason why we cannot.

There are some Senators who want to offer amendments. We want to hear them. We want to consider them and consider them fully and fairly, but it should not take an unnecessarily long amount of time to do that. So I encourage the Senate to act with dispatch, deliberation, but all deliberate speed. That is a Supreme Court phrase that has been used from time to time.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, I respectfully disagree with my distinguished chairman and also the ranking member on the amendment they have proposed. This amendment is worded in such a way as to prevent the proposal from ever taking effect because they know it will be impossible, certainly so difficult as to be unworkable, to prove prospectively that all savings will be passed on to the patients. There is no way that can happen. This is just in there to clean this bill up. I strongly oppose this amendment.

I yield the floor.

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. DORGAN. Mr. President, I rise to support the legislation offered by the Senator from Vermont. But before I speak on that let me just mention to the Senator from Mississippi and the Senator from Wisconsin who have brought this bill to the floor, I am a member of their subcommittee on appropriations. I certainly respect the work they have done. They do an outstanding job, they and their staffs, putting together the Agriculture appropriations bill. It is not an easy bill to construct and to bring to the floor.

One amendment that I will offer at a later time will deal with the disaster now facing farmers who have flooded lands and especially those farmers whose crops are burning up day after day in the deep South.

Last Friday morning, as we were taking a series of votes, I talked with Senator COVERDELL. He and I were prepared to offer an amendment to assist farmers dealing with flooded lands in my part of the country and drought-stricken lands in Georgia. Georgia is the hardest hit State with drought

problems, and family farmers there are suffering substantially. Senator COVERDELL intended to join me in offering an amendment offering them some emergency assistance. I will want to address this issue on this legislation. I will certainly talk with the chairman and the ranking member to do so in a way that relates to the needs of the Senate, but especially in a way that meets the needs of those family farmers who, through no fault of theirs but through natural disasters, have seen their crops disappear and are suffering some very significant problems.

I will save further discussion of this problem for a later time in this debate.

With regard to the amendment offered by the Senator from Vermont, I strongly support this amendment. Several bills have been introduced in Congress on this subject. I introduced a piece of similar legislation along with Senator WELLSTONE and Senator SNOWE. I am also pleased to join as a cosponsor of the legislation authored by the Senator from Vermont.

All of these bills relate to the same issue. That issue is very important and one we should address. The reason it is being addressed here and now is that the House of Representatives has already addressed it on its Agriculture appropriations bill, and it is important that the Senate also weigh in on this issue. The Senator from Vermont certainly has a right, and is protected with respect to germaneness, to offer this amendment to this bill.

Let me describe the issue before us in terms that people can better understand, using a couple of different medicines as examples.

I ask unanimous consent that I be allowed to use these medicine bottles in my presentation.

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

Mr. DORGAN. I have here bottles of 3 different prescription drugs that are ranked among the top 20 in the United States in the number of prescriptions filled and sales volume. All of these drugs, incidentally, are approved by the U.S. Food and Drug Administration.

I have here the actual bottles for these medicines. This one happens to be Zoloft, which is used to treat depression. The company that produces these pills and puts them in different size bottles then sells them all around the world. It is exactly the same medicine produced by the same company, sold in different places. Buy it, for example, in Emerson, Canada, and you will pay $1.28 for a pill. Buy it 5 miles south of there in Pembina, ND, and you will not pay $1.28 for the same pill. Instead you will pay $2.34. It is the same pill in the same bottle, made by the same company in the same manufacturing plant. The only thing different is the price. The pill costs $1.28 in Canada, and $2.34 for an American consumer.

Or what about Zocor? Zocor is a very popular prescription drug. Pick up any Newsweek or Time magazine and see the multipage ads for this drug. I have here two bottles of Zocor made by the same company, with the identical manufacturing process. One bottle is sent to Canada where it costs $1.82 per tablet; the other is sent to a U.S. consumer who is charged $3.82: $1.82 for someone living in Winnipeg, $3.82 for someone living in Montpelier.

Norvasc is a prescription drug that is used to lower blood pressure. The bottles are almost identical—again, both bottles are by the same manufacturer, and contain the same pill. Norvasc costs the Canadian consumer 90 cents. It costs the U.S. consumer $1.25 per pill.

Or to look at this price disparity another way, the cost of a 1-month supply of Zocor—the same pill, by the same company, in the same bottle—is $54 when it is sent to a Canadian. When it is sent to an American, it costs $114.

Or Zoloft—again the same pill, by the same company, made in the same manufacturing plant—costs the Canadian $38 for a 1-month supply; the American pays $70.

Norvasc costs Canadians $27 for a one month supply and the same quantity costs Americans $37. I can show you medicine where the price inequity is 10 to 1.

The question our constituents in the States of Vermont, North Dakota, Minnesota, and Washington ask is: How can this be justified? This is the same product. If this is a global economy, why must I go to Canada to try to buy a prescription drug that was manufactured in the United States in the first place in order to buy it for half the price? That is what Americans all across this country are asking.

The companies that produce these medicines are able to access all of the ingredients they need to produce prescription drugs from all around the world in order to get the lowest prices. If the pharmaceutical manufacturers are able to benefit from the global economy, why then can the consumer not also access that same drug made in a plant approved by the FDA when it is being sold in Winnipeg for half the price?

What is the answer to that? Many of us believe American consumers should be able to also benefit from the global economy. My colleague from the State of Washington, Mr. GORTON, has sponsored his own legislation to address this issue and he is also a cosponsor of this amendment. All of us have to respond to our constituents.

This is not just a Canada-United States issue. Americans pay higher prices than anywhere else in the world. How much more do we pay? If Americans pay an average of $1 for a pharmaceutical product, that same product has a much lower average cost in every other industrialized nation. We pay $1; the Canadians pay 64 cents. We pay $1; the English pay 65 cents. We pay $1; the Swedes pay 68 cents. We pay $1; the Italians pay 51 cents. We are charged the highest prices for prescription drugs of any country in the world. The American people ask the question: Why?

Senior citizens are 12 percent of our population, but they consume one-third of the prescription drugs in America. I come from a State with a lot of senior citizens. They have reached the years of their lives where, in most cases, they are no longer working and are living on a fixed income. Last year, they saw, as all Americans did, prescription drug spending in this country go up 16 percent in 1 year. Part of that is price inflation, part is driven by increased utilization. Nonetheless, older Americans saw a 16-percent increase in prescription drug spending in this country in 1 year.

Those of us who have held hearings on this issue and who have heard from senior citizens know what they say. They tell us they are forced to go to the back of the grocery store first, where the pharmacy is, to buy their prescription medicines because only then will they know how much money they have left to pay for food. Only then will they know whether they are going to get to eat after they have purchased their prescription drugs.

This is an issue for all Americans, not just senior citizens, but it is an especially acute problem for senior citizens.

In January on one cold, snowy day, I traveled with a group of North Dakota senior citizens to Emerson, Canada.

First we visited the doctor's office—because it is required in Canada—where the North Dakotans who wanted to buy prescription drugs in the Canadian pharmacy showed the doctor their prescription from a U.S. doctor, and the Canadian doctor wrote a prescription for them. Then we went to a very small, one-room pharmacy just off the main street of Emerson, Canada, a tiny little town of not more than 300 or 400 people. Emerson is 5 miles north of the North Dakota border.

I stood in that pharmacy and I watched the North Dakota senior citizens purchase their prescription drugs, and I saw how much money they were saving on the prescription drugs they were buying.

As is often the case, senior citizens will take 2, 3, 4, or 8 different prescription drugs. It is not at all unusual to see that.

I watched these North Dakotans compare what they were paying in the United States to what they were paying at this little one-room pharmacy in Emerson, Canada. It was staggering.

They asked me the question: Why do we have to come to Canada to do this? Why can't our pharmacists come up here and access this same supply of drugs and pass the savings along to us?

The answer is that there is a Federal law in this country that says that only the manufacturer can import prescription drugs into the United States.

The amendment we are considering, offered by the Senator from Vermont,

proposes to change that. He does not propose to do so in any way that would jeopardize the safety of medicines that are available in this country. He does not propose to in any way suggest that we should not maintain the chain of custody needed to assure a safe supply of prescription drugs.

But he does propose that we amend that law and replace it with a system that assures the safety of the medicine supply, while allowing pharmacists and drug wholesalers to go to Canada and go to other countries and access that same prescription drug, provided that it was produced in a plant that was approved by the FDA. This amendment assures not only the safety of the manufacturing process but also the chain of custody of the supply. In this way we will allow U.S. consumers the full flow and benefit of the global economy.

Why can't American pharmacists and drug wholesalers shop globally for prescription drugs, provided it is the same pill, put in the same bottle, manufactured by the same company in a plant that is approved by the FDA?

The answer is that they ought to be able to do that. There is no excuse any longer for preventing them from doing that.

Zocor, Prilosec, Zoloft, Vasotec, Norvasc, Cardizem—you can go right on down the list of the medicines most frequently used by senior citizens and compare what they cost here with what they cost in Canada and Mexico. Then ask the question: Why? Why are we in America charged so much more for the identical prescription drug?

The answer is simple: It is because the big drug companies can do it here. The pharmaceutical industry charges what the market will bear in the United States. The U.S. consumers are prevented from being a global consumer.

Let me say this about the pharmaceutical industry. I want them to do well. I support them on a range of things. I want them to be profitable, and I want them to be able to do substantial research. I do not wish them ill. I applaud them and thank them for the research they do to create lifesaving, miracle drugs. They only do part of the research, of course. A substantial part is also done through the National Institutes of Health, through publicly funded research. And we are dramatically increasing our investment in NIH.

But some will say to the Senator from Vermont: What you are doing will dramatically reduce research and development by the drug companies. These prices are what support research and development.

Hogwash. Nonsense. The fact is, a larger percentage of the research and development is done by the drug companies in Europe than is done in the United States. Let me say that again. More research and development is done in Europe than in the United States. And that comes from the pharmaceutical industry's own figures.

Take a look at the billions and billions of dollars the drug industry spends on promotion and compare that to what they spend on research and development.

In fact, if you pick up a weekly magazine, such as Newsweek, you will see the multipage ads for prescription medicine. They are spending billions of dollars on direct-to-consumer advertising. They are going directly to the consumer and saying: We want you to go to your doctor to demand that he or she write a prescription for this medication for you.

That just started a few years ago. It is now rampant. Doctors will tell you that patients come to their offices, saying: I read about this medicine in an ad in Newsweek. I want you to prescribe that. That is what is happening.

Billions of dollars are spent to try to induce consumers to demand medicine that can only be given to them by a doctor who believes it is necessary.

While all of this is going on, the Senator from Vermont offers a piece of legislation that I fully support. If I were writing the legislation offered by the Senator from Vermont, I would prefer that it not leave out the provision that allows personal use importation. I hope at some point we can allow for that.

But I just say this. I know that literally $60 or $70 million has been spent by the pharmaceutical industry because it is scared stiff that we are going to pass this legislation.

In fact, in the Washington Post the pharmaceutical industry has been running a full-page ad for the last several days. I do not know what a full-page ad costs in the Washington Post, but I know it is not cheap. How many citizens, who support our bill, have the ability to go to the Washington Post and buy a full-page ad?

This full-page ad is just totally bogus. It says: One of these pills is a counterfeit. Can you guess which one? Congress is about to permit wholesale importation of drugs from Mexico and Canada. The personal health of American consumers is unquestionably at risk. Counterfeit prescription drugs will inevitably make their way across our borders and into our medicine cabinets. Counterfeit prescription drugs can kill. Counterfeit prescription drugs have killed.

This is from the pharmaceutical industry, which wants to scare people into believing the legislation that we are now debating is somehow bad for our country's consumers. That is totally bogus. We are proposing an amendment that assures the safety of the drug supply but finally assures the American consumer that they can access drugs that are priced reasonably.

If someone in another country is paying half the price or a third or a tenth of the price being charged the American consumer for the same drug that is produced in a manufacturing plant approved by the FDA, why can't the American consumer have access to those drugs in a global economy?

The answer is: They ought to be able to do it.

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

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

Mr. JOHNSON. I commend the Senator for his work and commend Senator JEFFORDS for his work on this issue. In relation to the advertisement in the Washington Post, I wonder if the Senator from North Dakota would share with us the sponsor of that advertisement as it appears on the ad?

Mr. DORGAN. Yes. The sponsor is Pharmaceutical Research and Manufacturers of America. The drug industry obviously wants to keep things as they are.

Let me just make one additional point. It is not my intention to have the American people go to another country for their prescription drugs. It is my intention to force the pharmaceutical industry to reprice their drugs here in the United States. If our pharmacists and our drug wholesalers are able to access the same drugs at a much lesser price in Canada or England or elsewhere, and bring them back and sell them at a savings to our consumers, it will force the industry to reprice their drugs in this country.

That is my goal. It is not my goal to put people in minivans and send them outside this country to access prescription drugs. I want pressures brought through the global economy to equalize prescription drug prices in this country vis-a-vis what they are being sold at in other countries.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Washington.

Mr. GORTON. Mr. President, let's paint a picture, or set the stage, for this debate.

Most of the research and development and manufacture of prescription drugs goes on here in the United States, in a highly constructive fashion. Drug companies, and their research and development staffs, here in this country experiment and work, literally for years, to develop new and effective prescription drugs.

They are magnificently successful in that quest. And at least one of the reasons we are debating this issue today is that they are so successful that every year the share of our health care dollar that goes to prescription drugs increases because we now have conditions that can be treated by prescriptions that previously required hospitalization, if indeed they could be treated at all.

The process of taking an idea through its basic and applied research, its testing and its development to licensing by the Food and Drug Administration is long and arduous and is aimed both at safety and effectiveness. During that period of time, these companies spend a great deal of money with no return. It is clear, both to the proponents and opponents of both the first- and second-degree amendments,

that these companies are entitled to recoup those long and large costs of research and development. They are not only allowed, properly, to recoup the costs of those drugs that are actually brought to market, but the cost of all of the dead-end streets they run into with some of this research and development. To that point, there is agreement.

We are also dealing with a business, as any other in the United States, that spends a good deal of its time and effort in developing new products. Even at the early stage, there are some factors that favor the pharmaceutical industry because of its importance to the United States. It, as other companies, is entitled to a research and development tax credit, but it, unlike most other industries, also benefits hugely from research conducted by the National Institutes of Health, as the primary sponsor of this amendment well knows. So approximately half of all of these research and development costs are already underwritten by the taxpayers of the United States, either through tax credits or through our direct appropriations to the National Institutes of Health.

It is at this point that the wonderful line from ''Alice in Wonderland'' comes to mind, and the situation becomes ''curiouser and curiouser.'' At the point at which these pharmaceutical products have been licensed, the actual manufacturing cost for that pill is, generally speaking, not very high. And so much of the price structure is to cover the research and development, the very large advertising costs to which the Senator from North Dakota referred, other marketing costs, the lobbying those companies do in the Congress, and a reasonable and, I may say, in most cases generous profit. But these U.S.-based, often U.S.-owned, pharmaceutical manufacturing companies consistently charge their American customers—not the individual patient in this case but the huge regional drugstore chains as well as individual pharmacies—far higher prices than they charge for the identical product overseas or across our northern and southern borders.

One would think in a normal market that prices would be nondiscriminatory or, if anything, the manufacturers would be grateful enough for the tremendous aid and assistance they receive from the taxpayers of the United States perhaps to give at least a small price break to American purchasers. But, no, as has been pointed out, they charge Americans pretty close to twice as much as they charge anyone else. These wholesale prices, obviously, are reflected in retail prices for the drugs.

My experience in the State of Washington is very much similar to that outlined both by the Senator from Vermont and the Senator from North Dakota. We ran a little test; we went up to Canada, priced identical drugs in the State of Washington and in British Columbia, and found a 62-percent difference. In other words, it was way less expensive to buy them in Canada. So busloads of Americans go from Seattle and other parts of the State of Washington across the border to buy drugs and bring them back.

Why, one asks oneself, would American companies do this? Why would they discriminate against Americans?

They say: There is a simple answer to that. The Canadian Government, the Mexican Government, the Government of the United Kingdom, fix the prices of drugs. They want their citizens to get these pharmaceutical products less expensively than Americans do. So they, by government fiat, set the prices. And so we sell them, the drugs, for a lower price for a simple reason: We have already manufactured and sold lots of them in the United States. And when you go from the ten-millionth pill to the twenty-millionth pill, it doesn't cost you very much to manufacture those new pills, so we can still make a profit, even though we are selling them at half price in other countries.

Gee, isn't that unfair? Yes, I guess so, but that is the way the world is.

Now, that particular argument that price-fixing countries do much better for their consumers than a free market does in the United States is really a two-edged sword. It is one heck of an argument for price fixing in the United States. The junior Senator from Minnesota, a couple weeks ago, put up a proposal that would do exactly that, fix the price of drugs in the United States. This is a point at which I agree with the drug companies. They say: You fix prices and you will dry up research and development. I am not sure how far down we look for the validity of that argument, given the great excess of advertising costs over research and development costs, but let us assume that it is totally and completely valid as an argument. Then under those circumstances, we shouldn't be fixing prices here in the United States. But that doesn't mean we should continue to allow Americans to suffer the immense discrimination that goes on consistently year after year, product after product in this country.

When I discovered the extent of this problem, basically out of a cover story in Time magazine—I believe it was last November—it seemed to me, as a former State attorney general who for an extended period of time was in charge of consumer protection, fine, you just tell them by law to stop discriminating. Don't charge Americans any more than you are willing to charge Canadians or Italians or citizens of the United Kingdom.

That is price fixing, the companies say. That is a terrible thing.

Well, it is not price fixing to say you don't discriminate. If you can't make a profit at a given price, you don't have to sell the drug in Canada or in any other place.

But they have a lot of money to spend trying to sell that bill of goods to people. So we discovered—again, I think this was as a result of my history as a State attorney general—that we have a statute in the United States that prevents price discrimination. It is called the Robinson-Patman Act. It was passed in 1936. It was a sweeping antidiscrimination bill. It prevents price discrimination in the sale of any commodity in interstate commerce, with certain exceptions for actual cost savings from quantity sales and the like. So we said, fine, and the bill we introduced just said interstate and foreign commerce, with respect to prescription drugs.

It is interesting; the drug companies paid no attention to that distinction at all, and they still use these millions of dollars to say it is price fixing. Well, if so, then we have fixed the price of every commodity in the United States for 64 years, which I think surprises most people who believe in and have benefited from the truly free economy in the United States.

The argument that this is price fixing is fraudulent—purely and totally fraudulent. But I am not wedded or married to one solution to this problem of excessive prices imposed on American consumers for their prescription drugs because while we ban importation by law—by custom at least—we have permitted for an extended period of time American citizens to cross our borders—northern or southern or, for that matter, across the ocean to Europe—and to return to the United States with a 3-month supply of any prescription drug they are using, without being bothered by any of the governmental agencies of the United States. Both of my other Senate colleagues in this regard have pointed out that that happens in their State, and I have already pointed out that it happens in mine.

So the Senator from Vermont and the Senator from North Dakota came up with the idea that if an individual can do it for himself or herself, why not let our pharmacists do it and bring these prescription drugs back to the United States, which are often manufactured in the United States and then shipped north or south of the border—bring them back and offer them for sale, presumably at a lower price.

I am sure the Senator from Vermont doesn't mind my saying, in a sense, this solution is truly bizarre—that somehow or another it should be less expensive for a pharmacist to buy from a middleman than it should be from a manufacturer in the first place, and then have to ship the product across a national border twice in order to get the lower price. But the bizarre nature of the proposal is a simple and direct result of the outrageous discrimination that is practiced in the first place, and nothing else.

So the Senator from Vermont has written a bill and proposed an amendment to allow the retail seller, or the wholesaler, to engage in this reimportation. But concerned as he and the FDA are about making sure you

get the real thing, most of the words in his amendment have to do with the safety of the product, of making certain you are getting what it is that you thought you purchased. In fact, it doesn't allow this reimportation unless the Secretary of Health and Human Services promulgates regulations permitting that reimportation that meet necessary safeguards.

OK, that is where we are at this point. And then, instead of simply opposing the proposal, my good friend from Mississippi puts up a second-degree amendment that says the Secretary has to certify to Congress that it would pose no risk to public health and safety and will result in a significant reduction in the cost. It is either absolutely unnecessary, because we are talking about something the Secretary has already done, and the price part of it is unnecessary because if there isn't a significant savings in the price, nobody is going to go up and buy them in the first place or it is an attempt—and I regret to say this—to kill the amendment of the Senator from Vermont in its entirety and see to it that it doesn't happen. The drug companies and their sponsors are not really wanting to justify the situation that exists in the United States today because it can't be justified, so they use an argument for safety that is already far more adequately covered by the amendment proposed by the Senator from Vermont in any event.

Now we are able to deal with this issue as part of this appropriations bill, of course, because the House of Representatives did. So it is properly before us. But the other matter that I find extraordinarily odd with respect to the second-degree amendment is just this: The distinguished chairman of the subcommittee, the manager of the bill, knows perfectly well that individuals can go across our borders and come back with a 3-month supply of prescription drugs. If he and the Senator from Wisconsin are so concerned about safety that they have to pile on with a second-degree amendment, why aren't they banning totally and completely personal reimportation? The Senator from Vermont isn't even touching that subject in his amendment. I wish he did. The House of Representatives did. He is setting up a way for reimportation to take place at the wholesale level, where safety is far more protected than it is with respect to these individual purchases.

But the individual purchases have not created a great problem. If they had, people would stop engaging in those policies. Whatever else we may say about Canadians, they are not in the business of poisoning their own citizens.

This reimportation can take place with perfect safety under the amendment as proposed by the Senator from Vermont, and anything added to it is simply an attempt to kill it and to maintain the status quo.

Let me go back to the stage I have set and simply say this: The status quo is American manufacturers using American taxpayers' money to produce products in the United States of America, which they then sell at prices that discriminate outrageously against American purchasers. That is really all there is on the stage today—discrimination by American companies against American purchasers, in spite of the support of American taxpayers.

The first-degree amendment takes at least a modest step toward curing that situation. The second-degree amendment is designed to keep it in place forever.

I have one final point, Mr. President. I agree with each of the Senators who have previously spoken on the desirability and the importance of a Medicare drug benefit. There is some debate over to whom it should apply, how much it should cost. But Medicare covers about 40 million Americans. We have 250 million Americans altogether. None of the rest of them will be helped at all by even the most generous Medicare drug benefit. All of them will be helped by this amendment, to the extent that it is actually effective, because it will in fact end up lowering the price of prescription drugs in the United States of America. That is why the first-degree amendment should be adopted and the second-degree amendment that attempts to gut it should be rejected.

Mr. COCHRAN. Mr. President, I am pleased to announce to the Senate that we have been able to secure an agreement on a unanimous consent request to limit debate on the pending Cochran amendment and the underlying Jeffords amendment. I understand it has been cleared.

I ask unanimous consent that the Senate proceed to vote in relation to the pending Cochran amendment, No. 3927, at 5 o'clock p.m., and the time between now and then be equally divided in the usual form. I further ask unanimous consent that following that vote, the Senate proceed to vote immediately in relation to amendment No. 3925, as amended, if amended, the Jeffords amendment.

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

Mr. COCHRAN. I thank the Chair. I remind Senators that this doesn't mean we have to use all the time between now and 5. I encourage Members to make brief statements. We can vote before 5 and then move on to another subject.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that Senator GREGG be added as cosponsor to amendment No. 3925.

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

Who yields time?

Mr. KENNEDY. Mr. President, will the Senator from Vermont be good enough to yield 12 minutes?

Mr. JEFFORDS. Mr. President, I yield 12 minutes to the Senator from Massachusetts.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized for 12 minutes.

Mr. KENNEDY. Mr. President, I support this amendment and I commend the sponsors for their efforts to address the high cost of prescription drugs.

I support this amendment, and I commend its sponsors for their efforts to address the high cost of prescription drugs. The American public wants affordable medicines, and I believe we should do all we can to reduce the financial burden imposed on our citizens by high drug costs.

It is worth emphasizing that imports of prescription drugs from other countries must be accompanied by strict precautions to protect the public. Federal standards require that all prescriptions sold in the United States must be safe and effective. The public health protections guaranteed by the Food, Drug, and Cosmetic Act do not end at the gates of the manufacturer's plant but extend all the way to the doorstep of the consumer. Congress has promised the American people that the medications they use will be effective and be free of contaminants.

In 1988, President Reagan signed into law the Prescription Drug Marketing Act to protect Americans from counterfeit, contaminated, and other unsafe medications. Today counterfeit drugs continue to plague the citizens of many countries, including our own. In 2000, at least 30 people in Cambodia died from fake malaria medications. 60,000 people in Niger were vaccinated against a deadly epidemic of meningitis with counterfeit vaccines, and received water injections instead of real medicines. This past year the United Kingdom broke up a smuggling ring to import counterfeit drugs into the U.K. from India. According to a DEA official, 25% of the prescription drugs brought by consumers into the U.S. from Mexico are fake. From 1989 to 1994 a counterfeit antibiotic from China was sold in the U.S. through legal distribution channels resulting in almost 2,000 adverse events, including 49 deaths. In spite of an Import Alert issued by the FDA in September 1999, the fake medication may still be entering the U.S.

I raise these problems to emphasize that without adequate protections, legalizing importation by pharmacists and wholesalers will increase the risks already posed by fake and contaminated drugs. This amendment deals with these safety concerns primarily by placing the responsibility for assuring the quality of imported products on the importer, subject to FDA oversight—and it gives FDA broad authority to impose additional requirements necessary to protect public health.

The FDA needs adequate tools to combat counterfeit or adulterated drugs. Adequate funding for the FDA is essential to ensure the safety of imported prescription drugs. FDA currently inspects less than 1% of all drug shipments from other countries. Clearly, additional resources will be necessary to implement this amendment.

As we all know, the real issue is providing an effective and affordable prescription drug benefit to senior citizens and the disabled under Medicare.

That is the basic and fundamental issue. We wouldn't be having this debate if we were providing an effective prescription drug program to the seniors under the Medicare program. It wouldn't be necessary. We wouldn't have to be taking these additional risks. This is not a substitute for the Senate taking action on that important measure.

The President has reiterated the fact that he would be glad in working with our Republican friends to sign their marriage penalty legislation if it included a prescription drug program. It is absolutely essential. This legislation is no substitute for it.

The cost of the drugs these patients needed far exceeded their ability to pay, even if the cost was deeply discounted. A patient with high blood pressure, irregular heartbeat, and an enlarged prostate would pay $3,100 annually for drugs.

This particular chart indicates the general patient profile for some of the most common kinds of concerns, particularly for the elderly. They are the ones who have the highest utilization of the prescription drugs. They are the ones who need the protections under Medicare. They are the ones who, hopefully, we are going to take action on in this Congress to protect.

We are talking about osteoporosis, or heart trouble with a typical cost of $2,412—that is 20 percent of the pretax income; high blood pressure, irregular heartbeat, enlarged prostate, $3,100, 26 percent of pretax income; severe arthritis, ulcers, gastric reflux, depression, $3,696, 31 percent; ulcers, high blood pressure, heart disease, asthma, $4,800, 40 percent.

This basically shows not only the access but the enormous costs of the prescription drugs to address these particular items.

A patient with heart disease and severe anemia, $26,500, and 22 percent.

If we look at this chart, most senior citizens have very moderate incomes. Look at this. Fifty-seven percent are under $15,000; 21 percent are under $24,000. We have virtually 80 percent below $24,000.

We are talking about a handful of senior citizens in the upper areas. Eighty percent of our seniors are people of extremely modest means. The cost of these drugs are going absolutely out of sight.

That is why we have to have a program that is going to provide coverage, and that is going to be universally affordable for our seniors and for the Federal Government as well.

This is a drug crisis for our seniors. The coverage is going down, and the costs are going up.

I will take just a moment of the Senate's time to point out what is happening to our senior citizens.

Twelve million—effectively a third—of our seniors have no coverage whatsoever. Eleven million of them have employer-sponsored coverage. We are going to show a chart in just a moment that shows employer-sponsored drug coverage is collapsing.

Some three million have Medicare-HMO, and we will find what is happening in the HMOs where they are putting limitations of what they are going to be prepared to reimburse under prescription drugs.

The next is Medigap costs which are going right up through the ceiling and becoming less and less affordable.

The only group of Americans who have dependable, reliable, affordable prescription drugs are the 4 million Americans under Medicaid.

It is a national disgrace when we know the commitment that was made here in the Congress in 1964 and in 1956 that said to our senior citizens, work hard, we will pass Medicare, and you will not have to worry about your health care needs in your golden years. We didn't include a prescription drug program because the private sector didn't have it then. Only 3 cents out of every dollar was expended on prescription drugs. Now it is up 20 cents, and in some places even 30 cents, in terms of the costs of the health care dollars. Health benefits have dropped by 25 percent. That is between 1994 and 1997. This arrow is continuing to go right down.

The other chart showed where you have 11 million seniors getting covered by employer-based programs. This chart indicates that they are rapidly losing coverage at the present time.

We have 11 million who do not have any coverage, and 12 million who have employer-sponsored coverage. But that is going down.

This shows what is happening if they get Medicare HMO drug coverage. We see 75 percent will limit coverage to less than $1,000. They are putting limitations on what they will pay for. The chart shows the five major illnesses affecting and impacting our senior citizens cost vastly higher than $1,000. Therefore, our seniors, even if they have coverage under an HMO, are still paying an unaffordable amount of money if $1,000 is the limitation. Mr. President, 32 percent have imposed caps of less than $500. We are seeing the collapse of coverage that is out there for our senior citizens.

This chart shows what is happening in the medigap coverage—which is effectively becoming unaffordable—in the sample premium for a 75-year-old person in various States. This is virtually unaffordable.

This chart shows the costs of drugs compared to the Consumer Price Index over recent years, 1995, 1996, 1997, 1998, and 1999. In 1995, 2.5 percent; in 1996, 3.3 percent; in 1997, 1.7 percent; in 1999, 2.7.

The top of the chart shows the actual drug costs in terms of the expenditures being made by seniors to get the drugs they need. We see a very modest increase in the Consumer Price Index. Yet for senior citizens who use three times the amount of drugs as the rest of the population, we find out this is continuing to increase, placing extraordinary pressure on seniors. In many instances, they are completely unaffordable.

As mentioned earlier in the debate, the Pharmaceutical Research Manufacturers say:

> Private drug insurance lowers the prices 30 percent to 39 percent.

That says it all. It is saying you could go ahead and have a reduction in the costs of these prescription drugs anywhere from 30 percent to 39 percent, and they can still make an adequate and generous profit. This is from the industry itself. The seniors are hearing this and living it, as pointed out by the Senator from North Dakota and my friend, the Senator from Vermont. They are seeing this. They know this has happened. They have to go abroad in order to try to get these vital prescription drugs.

The unanswered question is, If we can go across and buy them, why can't we do this in a way that is going to be more accessible and available not only to those able to go over but also to our friends and neighbors and fellow senior citizens?

It is out of that enormous frustration and these facts that this amendment comes to the floor. That is why I believe it should be supported. I think it is essential, but it is not going to address the fundamental issue, which is the Medicare program that will cover all of our senior citizens and effectively do it in a way that will see a significant reduction of costs.

I thank the Senator from Vermont.

Mr. COCHRAN. Mr. President, I yield 10 minutes to the distinguished Senator from Louisiana.

The PRESIDING OFFICER (Mr. SESSIONS). The Senator from Louisiana is recognized for 10 minutes.

Mr. BREAUX. Mr. President, I thank the Senator from Mississippi for yielding.

I was thinking about the argument that we had on the Senate floor about importing medical supplies in terms of prescription drugs from foreign countries into the United States because they might be cheaper. I could get open-heart surgery in Mexico for a lot cheaper than at Oschners in New Orleans or at the Mayo Clinic or at Johns Hopkins or any other fine institution in the United States. It would be half as expensive. I doubt many Americans want to put their lives in the hands of people they know are not regulated.

I could buy many items in countries around the world, and many Third World countries, which would be a lot cheaper. I remember one time going to Hong Kong. I saw some of the Lacoste shirts with the little alligator. My wife and I were shopping in Hong Kong and they had all these Lacoste shirts. They were $5. I said: That is incredible, a heck of a deal. I will buy a Lacoste alligator shirt for everyone I know for gifts for Christmas. We bought one

after another. I bought one or two myself. We came home and the first time I washed the shirt, the alligator fell off. The alligator fell off because it was a counterfeit shirt. The shirt nearly dissolved after the first washing and the alligator drowned in the washer. The product was totally worthless. It was a counterfeit product.

It is one thing when you are buying a knit shirt. When someone is sending me drugs that have been either manufactured in a foreign country or even manufactured here and sent to a Third World country and stored in a warehouse, God knows where, under conditions that may be totally contrary to the safety of that drug, who knows who deals with those products in that country in the privacy of that warehouse. Who knows how many times somebody might go into that warehouse and take the product, and instead of saying we will have 100 pills, if I cut it in half, I could have 200 pills. If I could cut it into fourths and end up not with 100 pills but 400 pills, look how much money I can make if I do it that way.

If I can take that type of quality control, which is nonexistent in a foreign country, and say that is how I will make my money, what kind of products will we be giving to the American consumer? This is not a Lacoste shirt that an alligator might fall off of. This is medicine that is important to the safety and the life of our constituents.

Why do we have a ban on the importation of foreign drugs passed by Congress in 1987? In order to protect U.S. consumers, to make sure that the drugs were not improperly stored, or improperly handled, or improperly shipped, or perhaps made to be like my Lacoste shirt, totally, absolutely counterfeit.

How many Federal bureaucrats are we going to put in 150 countries around the world to ensure those products in those countries are safely stored, safely handled, and not diluted? And how many more bureaucracies are we going to create to make sure those problems don't develop?

We can get a lot of things cheaper in a lot of other countries. How about buying cheaper wheat from China? They have a controlled economy where the Government runs everything and sets the prices. Could we not buy a lot of wheat from China and give it to our constituents a lot cheaper? We don't do that because it is not a level playing field. In that sense, we are competing with a micromanaged economy overseas that the Government participates in and helps their farmers. Our people can't compete against that. It is not a good idea.

This is the bottom line—actually two things. No. 1, there is no guarantee we are not going to create a boondoggle with this for all the wholesalers. There is no guarantee, without the Cochran amendment, that anybody who is a consumer is going to have any of the benefit of any of what we are trying to do by importing cheap Third World drugs into this country. Nobody has a guarantee the savings would be passed on to the consumer. I can see a wholesaler who wants to get the drug for $20 selling it for $40 over here and making one heck of a profit. There is no guarantee without the Cochran amendment.

The final point is that this is not the answer to the problem. The answer to the problem is to find a way to guarantee to Medicare beneficiaries that they get the best deal, that we have some ability to provide them with the coverage they need at the price they can afford. That is the real answer.

People say we do not want price controls in this country; that is anti-American. But we are going to buy the price controls from other countries around the world. We will let them impose price controls, and then we will buy from them. Why don't we just put on price controls in this country and call it what it is? We are saying essentially we don't like price controls but we like other countries' price controls and so we will buy it from them with absolutely no ability to guarantee the product coming over here is the product that left this country.

Here is the problem. If a Medicare beneficiary walks into the drugstore and has no insurance because Medicare doesn't cover him, the pharmacist tells him: It is $100 for your prescription. That Medicare beneficiary has to take it out of his pocket or gets his children to pay for it, or, if they are very destitute and poor, Medicare pays for it and they pay $100. If you don't have any coverage, you pay $100 for the prescription.

If, however, you work for the Federal Government, if you are a Senator or one of the staff people here who happens to have the Federal Employees Health Benefits Plan, and you go into the drugstore and buy the same prescription, you don't pay $100, No. 1, because there is volume purchasing because they are purchasing for all the FEHBP people who are covered by FEHBP. The discount by volume purchasers for the insurers gets it down to about $70, a 25-plus-percent discount. That is the average by volume purchasing. But none of us or our staff even pays the $70. We will probably pay a coinsurance of about $35, for some plans even a copayment which could be $15 or $20.

So that is the answer to the problem. The answer is not to import Third World countries' price controls. Talking about Canada is one thing. I guarantee if this passes, we are not going to be importing a lot from Canada. We are going to be buying from countries whose handling of these drugs we have no ability to control. If it were coming from Canada, it would not be a bad deal. We know how they operate. But this amendment is not limited to Canada. Any Third World country will be able to handle the drugs, dilute them, do anything they want, store them where they want, and we will not be able to guarantee the validity of that drug.

This is the answer to the problem: Not importing from other countries, but to try to ensure that all Medicare beneficiaries have some type of coverage that allows them to get the benefits of volume purchasing and also to have some type of insurance where the Federal Government assumes part of the responsibility, part of the risk, and the providers compete and also assume some of the risk to get the price to the Medicare beneficiary down to half or less. That is what we should be working on.

This is a Band-Aid type approach. Really, it is worse than a Band-Aid approach because Band-Aids help; this doesn't help. It puts the American consumer at risk. We passed this law to prevent all the things that are likely to happen if this amendment passes. We should not go back to our constituents and say: We are letting you get cheap drugs from foreign countries because they have price controls. It is the wrong approach, and we should recognize it as such.

I yield the floor.

The PRESIDING OFFICER. The Senator from Mississippi.

Mr. COCHRAN. Mr. President, I yield 15 minutes to the distinguished Senator from Tennessee, Mr. FRIST.

The PRESIDING OFFICER. The Senator from Tennessee.

Mr. FRIST. Mr. President, I rise in opposition to the underlying amendment to allow reimportation of prescription drugs. I have been following the debate for the last couple of hours. I want to bring up a new issue, an issue which I believe is a fundamental issue but which has not been discussed, to the best of my knowledge, at all over the last 2 hours—and that is safety.

The problem has been very clearly identified; and that is, cost. The situation of prescription drugs costing too much in this country, causing people to drive to Mexico and Canada, is a real problem. It has been vividly described. It has been described accurately by almost everybody who has talked today, holding up the bottles and the descriptions on the charts. Today a senior who goes into a drugstore must pay full retail price for a drug because Medicare does not include prescription drug coverage, versus traveling on a bus to Canada, and buying it there for much less.

The answer—and this is absolutely critical—is not reimportation. The answer is not, to my mind, price controls. Price controls get cloaked in all sorts of ways in policy and in various proposals. But the answer is, I believe, not in the amendment we are talking about today but through improved access by offering coverage and utilizing the large purchasing power to provide affordable prescription drugs.

The issue that most bothers me is that fundamentally I believe the underlying amendment puts at risk the safety of these drugs. I say ''puts at risk'' because clearly the authors of this bill

have tried to construct a bill that has safety first and foremost. But let me just say, having read the bill and having a pretty good understanding of the capability of the Food and Drug Administration today, they simply cannot police the world in making absolutely sure these are not counterfeit drugs coming back in and because of this, I find it very hard to support the underlying bill.

If you take a look at the history of reimportation, from 1985 to 1987 in the U.S. Congress, there were a series of nine hearings and three investigative reports regarding this whole concept of reimportation of pharmaceuticals. It is interesting, if you go back and look at what happened and also at what the findings were. As a result of these hearings and investigations, in 1987 the Prescription Drug Marketing Act passed. It was designed to specifically protect Americans' health and safety against the risk of adulterated or counterfeit drugs from being imported into the U.S. Let me quote one of the conclusions from the committee report:

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

I believe, we are obligated to go back and address these two critical concerns, because we are talking about the potential for counterfeit or adulterated drugs. We are talking about life-or-death issues. We are talking about the ability to thin one's blood to prevent a heart attack or a stroke, and if that drug has been altered, if it is counterfeit, it means life or death to the people who are listening to me today.

What they have tried to fashion in this bill is to have the Food and Drug Administration oversee and be responsible for these laboratories which are not in the United States of America. Remember, this is a Food and Drug Administration that, right now, admits they are unable to even inspect the food coming into this country. I argue, whether it is tomatoes or lettuce coming in, the inspection of drugs coming in is much more important to the health of Americans. It is partly because I am a physician, so I deal with patients and I know for the most part patients believe it is much more important as well.

Is the Food and Drug Administration equipped? If you ask the people who have run the FDA you will find the following. Dr. David Kessler, former head of the Food and Drug Administration, in a letter to Representative DINGELL this past year, stated the following when we talk about reimportation. I quote Dr. David Kessler:

> In my view, the dangers of allowing re-importation of prescription drugs may be even greater today than they were in 1986. For example, with the rise of Internet pharmacies, the opportunities of illicit distribution of adulterated and counterfeit products have grown well beyond those available in prior years. Repealing the prohibition on re-importation of drugs would remove one of the principal statutory tools for dealing with this growing issue.

We know the cost of prescription drugs is a problem. But ultimately you don't want to do anything that jeopardizes the safety of these drugs and ultimately the health and welfare of patients.

Let's turn to Dr. Jane Henney, who is the current Commissioner of the Food and Drug Administration. In front of the Senate appropriations committee March 7 of this year, she said, in expressing severe reservations regarding the importation of drugs:

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

Her words—''increased risk.''

It is the risk of this legislation that bothers me in terms of safety for our seniors. The question is whether the FDA is equipped to implement the safety precautions necessary? Right now we are hearing from the leaders they cannot be responsible for the safety and efficacy of reimported pharmaceuticals. Let me point out what is going on today in terms of how effective their inspections are.

Of the 6,030 foreign manufacturers shipping bulk drugs to the United States since 1988, approximately 4,600 were never inspected. When we see people holding up these two bottles and one bottle was reimported from overseas and you are depending on the FDA—which clearly does not have the capability to guarantee the safety of these pills—and then you put that pill in your mouth, I believe, based on at least the leaders at the Food and Drug Administration today and in the past, that pill could very well be unsafe and not only cause severe illness, but even death.

I mentioned the food issue, but as you recall, the Food and Drug Administration is responsible for overseeing the safety of food in this country. In our hearing at the Health, Education, Labor and Pensions Committee last month, some said: We can safely import lettuce from other countries, so why can't we do the same for medicines?

The analogy of lettuce versus medicine is, as a physician, very hard for me. Last year, I joined Senator COLLINS in introducing the Imported Food Safety Improvement Act because of all of the outbreaks of illness associated with imported food products.

We introduced the food safety bill predominantly because of the FDA's own admission—just like I believe the FDA is admitting today in terms of re-importation of drugs—that they cannot insure the complete safety of food coming into this country. If we cannot insure the safety of food coming into this country, as a physician, as someone who has that doctor-patient relationship, who has taken an oath of doing no harm—I cannot promise my patients that the prescription medicines they may be taking are guaranteed to be safe and effective, especially when I have the leadership of the FDA telling me they are ill-equipped and cannot guarantee the drugs have not been altered.

Again, the authors of this legislation basically said it is going to be safe because the FDA can do it. I will take it one step forward and say based on current evidence, I do not believe the FDA can do it.

Former Carter FDA Commissioner Dr. Jere Goyan said it best:

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

The underlying amendment, although well-intended, is inadequate in assuring the safety of potential recipients, beneficiaries, and patients who receive pharmaceuticals that have been reimported. Therefore, I will not vote to repeal the important consumer safety legislation that we put in place over 10 years ago without much further investigation to answer that critical question of safety.

Medicines today are affordable when there is coverage for them. I believe we have to do something to help those unfortunate seniors across the country who do not have good prescription drug coverage today.

Senator BREAUX and I have worked aggressively to develop a bipartisan prescription drug coverage plan and have introduced such a plan.

This plan is above politics and it is above partisanship. It is time to take the very best minds, the very best doctors, the very best health care experts, and elected representatives and bring them together to deal with these challenges facing Medicare in offering affordable prescription drug coverage.

The Breaux-Frist 2000 plan, known as the Medicare Prescription Drug and Modernization Act of 2000, takes the necessary first steps to provide universal outpatient prescription drug coverage and strengthen and improve the Medicare program overall. First, it restructures the 1965 model of Medicare by establishing a competitive Medicare agency to oversee competition under Medicare+Choice and the addition of a new drug benefit.

It establishes voluntary universal outpatient prescription drug coverage which I believe is the answer to the cost issue.

It provides comprehensive prescription drug benefits.

It guarantees catastrophic protections so a senior is protected from paying high drug costs out of their own pocket beyond $6,000.

It guarantees price discounts off prescription drugs so seniors never pay retail prices for prescription medicines again.

It guarantees affordable drug coverage by offering all beneficiaries a 25-percent subsidy off their premiums.

It protects low-income beneficiaries by providing beneficiaries with incomes below 150 percent of poverty subsidies for premiums and copayments for prescription drug benefits.

Finally, it improves benefits and health care delivery under Medicare by stabilizing the Medicare+Choice program and introducing much needed reforms.

The Breaux-Frist 2000 bill addresses the cost issue. Reimportation of drugs does not. I urge my colleagues, for the safety of health care and health care delivery today, to defeat the underlying amendment on reimportation of drugs.

I reserve the remainder of my time.

The PRESIDING OFFICER. The Senator from Mississippi.

Mr. COCHRAN. How much time is remaining on this side of the issue?

The PRESIDING OFFICER. The Senator has 11 minutes remaining.

Mr. COCHRAN. I yield 10 minutes to the distinguished Senator from Utah, Mr. HATCH.

The PRESIDING OFFICER. The Senator from Utah.

Mr. HATCH. Mr. President, this is a very important amendment. There is a lot of sincerity behind it.

I rise today to offer some concerns about the Jeffords-Dorgan Amendment to the Agriculture Appropriations bill and to support the Cochran amendment.

I have many questions about the Jeffords-Dorgan amendment.

Let me make something perfectly clear from the start—I do not question the good intentions of this amendment. I know that my colleague, Senator JEFFORDS, is sincerely seeking to address this difficult matter of high prices for pharmaceuticals in the United States.

As I traveled across my state and around our country this election year, I found that many Utahns and many Americans, particularly our senior citizens, are having difficulty in affording prescription medicines. Some are going across the borders to Canada and Mexico. We have all seen the news broadcasts of those cross-border bus trips to buy the cheaper foreign drugs. And, it may seem obvious, particularly to two Senators who represent States on the Canadian border, that the solution is simply to allow the importation of prescription drugs into our country.

There is something of a cruel dilemma at play here: right at the moment when scientists seem poised to invent an unbelievable new array of diagnostics, therapeutics, and vaccines, many Americans are encountering difficulties in affording these new and sometimes costly medications.

There are many issues at play in this debate.

One issue that policymakers face is to see whether a balance can be constructed whereby we retain the necessary investment to produce the promised wonder cures while at the same time maintain our ability to deliver these new products to the patients at affordable prices.

This is part of what is shaping the debate over the fashioning of a prescription drug benefit for the Medicare program.

This balance between new drugs and affordable drugs is what shaped the debate 16 years ago when the Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984. I am proud to have played a leadership role in this law that helps, according to CBO, consumers save $8 billion to $10 billion annually through the purchase of generic drugs.

But, in our understandable and highly populist zeal to make drugs more accessible, we must not kill the goose that lays the golden eggs. That is to say, we must be able to continue to attract the private sector investment into the biomedical research establishment that has made the American drug development pipeline so promising.

While it is true enough that, at this time, the drug industry is the most profitable sector of the economy, I do not think that success should be a license for us to over-regulate this industry. Sometimes well-intentioned, but ill-advised, governmental policies have hastened the decline of American business to the detriment of American workers and consumers alike.

But, another consideration with respect to the advisability of this amendment is the premium that we place on our citizens receiving safe and effective products, free from adulteration and misbranding.

Dating from the 1906 Pure Food and Drugs Act, through the 1938 Federal Food, Drug and Cosmetic Act, the 1962 efficacy amendments, and the 1988 Prescription Drug Marketing Act, our Nation has devised a more or less closed regulatory system that ensures that drug products will be carefully controlled from the manufacturer to the patient's bedside.

If we are to open up our borders to a new plethora of drug reimports—I am talking about reimports—we need to be absolutely certain that we have not undermined the integrity of this regulatory system by admitting products improperly manufactured, transported, or stored. A pill may look like the real item but not contain the active ingredient in the right concentration, or it may simply not contain the medication at all.

Similarly, we must not allow the American public to fall prey to counterfeit so-called ''gray market'' products. These are products which could be made to look exactly like the real thing and may comply with, or attempt to comply with, the requirements of the actual approved product, but do not comply with the legal requirement of a license from the patent holder—in short, a pirated product.

While there is a clear and obvious health danger in an adulterated, nonconforming pirated product, there is also great detriment to the American public if the unscrupulous are allowed to reimport America's inventions back into America without compensating the inventor. Few will be willing to invest the upfront capital—hundreds of millions of dollars—to develop a drug if another party can make and sell the drug while it is under patent protection.

It takes an average of 15 years and a half a billion dollars to create one of the blockbuster drugs. So we have to be careful. Keep in mind, too, as chairman of the Senate Judiciary Committee, I have a special obligation with respect to our intellectual property laws that we not go down any path that can be seen as inviting the development of a gray market for prescription drugs.

After all, a fake Rolex may be right twice a day, but a bad copy of a good drug can kill you. This is something we have to be more concerned about around here. We can't just do what appears to be good but, in essence, could kill people.

As we move further into the information age, protection of American intellectual property becomes more and more vital to our national interest. For example, if the latest computer software can be taken without proper licensing arrangements, our national leadership in high technology will be threatened.

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

We have had many debates over price controls. I remember those days when Senator Pryor and I were on this floor arguing back and forth about price controls. Fortunately, the Senate, in its wisdom, decided not to go for price controls. This is another step toward price controls that will stultify one of the most important industries in America at a time when we just mapped the human genome, and we are at the point where we can actually create more lifesaving drugs—perhaps at even a greater cost but nevertheless at a greater health care cost savings than ever before.

So that is why intellectual property protections are so necessary.

In fact, one of the great accomplishments of the 1995 GATT Treaty was to put intellectual property protection front and center in our trade relationships with the developing world. Many countries are notorious for the lax policing of patent and copyright violations by their citizens.

When the value of American inventions is expropriated, it is American inventors and American consumers who suffer. The United States cannot and

should not allow free riders around the world essentially to force the American public to underwrite a disproportionate amount of the research and development that results in a next generation breakthrough product.

One has only to read a collection of the section 301 reports the Office of the United States Trade Representative to get a feel of just how prevalent such intellectual property theft is worldwide.

I took the time to present this background because I think the Jeffords-Dorgan amendment requires such analysis.

And I will be the first one to admit that the amendment, at first blush, seems quite simple and appealing. What could be the matter with a rule that essentially says drugs obtained from outside the United States at prices lower than U.S. prices can be resold in the U.S., presumably in a manner that places pressure to lower prevailing U.S. prices? Yet, I recall H.L. Mencken's sage observation, ''There is always an easy solution to every human problem neat—plausible, and wrong.''

I, too, join many of my constituents in Utah and others across the country, in questioning why our citizens are paying higher drug prices than those who live in other countries.

And while I recognize that there are complex economic, political, and social factors at play that partially explain why a drug company would charge less for a drug in a destitute region in sub-Saharan Africa, it is more difficult to understand why drug costs less in Tijuana, Mexico, or Alberta, Canada than in San Diego, California. This is a policy I cannot totally defend. And I do think the pharmaceutical companies need to address this more.

But I can say that where nations impose price controls, a flawed economic theory which we have proven does not work in the U.S., there are negative consequences which among other hazards could imperil the flourishing research and development we count on to bring us miracle cures.

I am very apprehensive about government price controls, particularly on our most cutting-edge technologies like pharmaceuticals. Price controls function in an economic environment the way a lid works on a boiling pot. Price controls may temporarily keep prices down, but they are certainly no long term solution to the problem. As soon as the lid comes off, the pot boils over.

And, why not just keep the lid on indefinitely? Because price controls also have a stifling effect on the incentives to conduct research. Without the prospect of recouping a substantial, multimillion dollar investment, there is little reason for pharmaceutical companies to undertake such research on the next breakthrough drugs. It would not take long for our nation's pharmaceutical industry to atrophy.

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

I support those who wish to instruct the United States Trade Representative to be even more aggressive in promoting and protecting intellectual property rights in all of our bilateral and multilateral trade negotiations.

It seems to me that rather than importing the effects of foreign price controls back into the U.S., a strong case can be made that we should be using our Trade Representative to attack the foreign price controls that many countries have enacted so that a better balance between U.S. research costs and foreign borne research costs might be achieved. Let's stop the free riders and cheap riders overseas while American citizens are paying the full freight of R&D.

I have to confess that one part of me likes the feature of this amendment that creates the challenge to the entrepreneur of bringing goods sold cheaper abroad back to the United States at presumable savings to U.S. citizens. Yet, the amendment provides no guarantee that those wholesalers and pharmacists importing the products would pass their savings on to the consumer. And so, we could be trading public safety for middleman profits, an outcome not contemplated by proponents of the amendment.

Mr. HATCH. I have debated the issue, as I say, of price controls many times, so I will not spend any more time on the issue of price controls. But it does not make sense. That is what we are headed towards.

The greatest industry in our country, that has the greatest potential to do the greatest amount of good to bring health care costs down in the end—even though it is tremendously expensive to develop these drugs—is going to be flattened by this type of legislation which is well meaning, well intentioned, and absolutely destructive to our innovative industries in this particular country.

We have to find a way around this drug price problem in this country without creating a gray market in these particular goods and services. There has not been 1 day of hearings on this particular language. How can we guarantee that foreign government price controllers will not set an artificially low price on some new Alzheimer's drug? And can we be sure this will not have the unintended but real, ripple effect of convincing company officials to forgo research——

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

Mr. HATCH. Mr. President, I ask unanimous consent to take 1 additional minute, with an additional minute given to the other side.

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

Mr. HATCH. Can we be sure this will not have the unintended, but real, ripple effect of convincing company officials to forego research on this new class of drugs for fear that, in conjunction with the new liberal reimport policy, they will not be able to recoup their investment?

Let us hope that the future does not come down to a choice between two lousy alternatives, what economists call a Hobson's Choice: great drugs that are not widely affordable or potentially great drugs abandoned due to minimal projected revenues.

And I can tell you given my work in the area of the AIDS epidemic, as between expensive drugs and no drugs, expensive drugs is a better problem to have.

My conservative instincts are always against government price controls, and I don't think that this principle should be limited to U.S. government price controls if a by-product of this well-intentioned re-import bill is to import some other government's price controls into U.S. market dynamics.

Frankly, this does not seem the type of far reaching legislation that we should rush into without pausing to try to think through all of its ramifications.

It just seems to me that if there are areas where governments world-wide must tread carefully in enacting legislation, if indeed they must tread at all, it is in areas like biotechnology.

It is clear from absolutely stunning developments like the early completion of the mapping of the human genome that there is an incredible synergy taking place between information technology and biotechnology. The high-speed sequencing machines that mapped the genetic code and almost instantaneously made this information available on the Internet represent this confluence of technology.

In our valid and justified quest to help make drugs more affordable to the American public, we should be mindful not to unwittingly retard the development of the next generation of innovation.

Having described the general angst I feel in relation to the possible effect that this legislation may have on the pace of and investment in pharmaceutical research and development as well as challenges it will create in terms of respect for intellectual property rights, I want to focus next on the important concerns that I have about the public safety aspects of the amendment.

I want to commend Senators JEFFORDS and DORGAN for perfecting some of the gaps and shortcomings related to drug safety contained in the House-passed legislation.

But let me say that, as Chairman of the Committee with jurisdiction over the Controlled Substances Act, I am not convinced that the American public is adequately protected by this amendment.

Now, I know that drafting and redrafting is an unglamourous part of the legislative process and that you and your staffs, and if the reports are correct many in the Administration, have been working hard to refine this amendment.

But let's be fair, legislating on an appropriations bill is not the optimum way to change some central provisions of the Food, Drug and Cosmetic Act.

I was involved in redrafting the Import and Export Chapter of the Food, Drug and Cosmetic Act both in 1986 and in 1996.

While I recognize the HELP Committee had a hearing yesterday, I think that everyone would agree with me that it is helpful to have a legislative hearing on legislation when the ink is at least dry.

I would like to see what the FDA, the DEA, General McCaffrey and the Patent and Trademark Office have to say about the bill when they have had time to give thoughtful consideration to a sufficiently finalized draft.

While it is true that the bill is drafted generally to the FDC Act, it will be particularly important to see how this liberalized re-import may affect controlled substances. Can't we take the time to hear from the Drug Enforcement Administration?

Also, I don't know if this is the case, but I have heard second hand reports that the White House has more or less limited FDA to a ''let's make the best of this'' role and is not encouraging the agency to look at this bill more globally.

Also, I cannot help but note that in the latest draft that I have seen, the language covers only drug products and not biologics, which are in the vast majority of cases perceived and used by consumers as drugs in the non-legalistic definition.

And since it is also the case that many times it is precisely these new generation biologics that are the most costly on the market, the question must be asked why Americans should not get the advantage of lower priced biologics as well as drugs?

Frankly, it is evident that each successive draft attempts to address the many shortcomings with respect to assuring the American public that the imported drugs are the safe and effective and unadulterated.

Clearly, this drafting would be better served if it were down in the public forum of a mark-up.

I just don't think that we know enough about this language to be reasonably certain that we could be sowing the seeds of a future tragedy but I certainly don't want to take that chance. I worry that a day will come when either a under-potent or over-potent batch of imported drugs will leave a trail of avoidable carnage.

Yes, we can have certifications and regulations and foreign inspections and every other thing you can think of, but the fact remains we are opening a door that Congress carefully closed in 1988 when it enacted the Prescription Drug Marketing Act. The history of this bill is that it was enacted after a series of serious adverse events due to improperly stored, handled, and transported imported drugs. It also addressed the issue of the import of counterfeit and unapproved drugs such as the presence of counterfeit antibiotics and contraceptives.

These were serious threats to public health and safety. These incidents were the subject of extensive hearings of the House Energy and Commerce Committee. These incidents were the impetus of the 1988 legislation that this amendment would unravel.

Look, I know that there is a certain attractiveness to accept this amendment and that some members may be inclined to vote for this measure with the expectation that the language, which is still in flux, will be cleaned up in Conference.

But I am concerned that opening up this import loophole is either fixable or will do more good than harm.

As interested parties study this measure, objections are beginning to be registered. And they are not only from the big drug companies who are the true, and, to some extent, justified target of this provision.

I am mindful that a similar provision passed the House by a wide margin. But one vote that this legislation did not get was of that the Dean of the House, Representative JOHN DINGELL of Michigan.

Now you would think that if ever there was a group that stood to benefit from legislation it would be the wholesale druggists because they are the natural middlemen in the new, liberalized import system. Instead they call the amendment ''unworkable'' because ''(w)wholesalers do not have the expertise, equipment or personnel to undertake such complicated tasks''.

I will say in public right now that I fully expect that the DEA, FBI, and other components of DOJ will weigh in when this correspondence is answered.

I am particularly interested in learning from the DEA and FBI to what extent importation of counterfeit and adulterated controlled substances is a current problem and to what extent, if any, this legislation, would likely affect the current state of affairs?

But before my colleagues vote on this measure I would ask each of you to review the Dingell correspondence together with any response from the administration. Here are some of the questions that were included in Congressman DINGELL's letter to FDA:

1. Please provide a detailed analysis on how (H.R. 4461 and H.R. 3240) would affect FDA's present operations regarding efforts to prevent misbranded or potentially dangerous drugs from entering the U.S. Specifically, please provide: (a) a description of how the present system now used by FDA works; (b) what the present system is intended to accomplish; and (c) what changes would be required (and the potential effects of those changes) if this legislation passes in its present form.

Please include a discussion of how these amendments would affect the activities of other agencies, such as the U.S. Customs Service, with responsibilities for assuring the safety of imported prescription drugs.

2. Please determine if either of these amendments would have any effect on FDA's ability to enforce good manufacturing practices (GMPs) in any foreign firms that ship drugs to the U.S. If so, please explain any potential effect on consumer health and safety.

3. Please provide a full description regarding what a ''warning letter'' is and how it is typically used by the FDA. Please compare this with correspondence that is sent by Customs.

4. It appears that these amendments would directly affect the ability of FDA to send warning letters to consumers that purchase drugs over the Internet. As you know, some web sites appear to be covertly linked to foreign drug suppliers. When a consumer orders from such a site, it is not always obvious that they are dealing with an offshore supplier, and thus a potentially non-FDA approved facility. Often, warning letters may be the only indication that the Internet-ordered drugs originated from a foreign (and potentially dubious) source. Please indicate how this legislation could affect FDA's ability to protect consumers who purchased drugs in this way.

5. Please detail any other potential effects this legislation could have on FDA's ability to protect consumers from potentially dangerous drugs that originate aboard.

6. Finally, please provide technical assistance in the form of specific suggestions for legislative or regulatory changes that would be needed in order to facilitate the safe importation of prescription drugs by individuals, wholesalers, or retailers.

Only if you are convinced that FDA has the resources and international presence to enforce the myriad of new regulations and procedures required by the amendment should you vote for this measure.

Ask yourself how confident you are that more word-smithing during a closed conference committee meeting is likely to prevent one or more of your constituents from being seriously injured down the road by unsafe drug products brought into the U.S. as a result of this amendment?

Do we really want to turn back the clock and essentially re-open a dangerous door that was closed by the Prescription Drug Marketing Act of 1988?

Why the rush to open a potential Pandora's box of public health problems?

I hope that this well-intentioned amendment, offered by two highly-respected co-sponsors, does not place Congress and the public in the position of the old adage, those who do not understand the past are doomed to repeat it.

I respect the men and good intentions behind this amendment.

We all want to increase access to pharmaceuticals for all Americans. I do not think that the benefits of the Jeffords-Dorgan amendment outweigh its downsides, and that is why I am supportive of the alternative offered by the Senator from Mississippi.

I have to say, when this debate happened in the House, my dear friend, Congressman JOHN DINGELL, who has

played a tremendous role in health care all these years I have been in the Congress, stood up and argued against this. He lost in the House, but he should have won.

During the House debate, Congressman DINGELL said the following, ''We now find ourselves in the regrettable position of confronting the possibility that the easing of the law with regard to food and drug and cosmetics, which is going to be done here under this legislation, will in fact reduce the safety of the American consuming public.''

Mr. DINGELL was Chairman of the House Energy and Commerce Committee when the PDMA passed in 1988. He was a key mover and shaker behind the bill. As the bill was being developed the Energy and Commerce Committee issued a report that concluded that ''the very existence of a market for reimported goods provides the perfect cover for foreign counterfeits.''

Mr. President, I ask unanimous consent that his letter be printed in the RECORD, as well as the National Wholesale Druggists' Association letter, where they beg us not to pass this type of legislation because of the harm it could cause to the American public and to the American consumer.

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

JULY 14, 2000.

Hon. JANE E. HENNEY, M.D.,
Commissioner, Food and Drug Administration, Rockville, MD.

DEAR DR. HENNEY: Recently, the House of Representatives adopted two amendments, one by Rep. Crowley (D-NY) and one by Rep. Coburn (R-OK), to the Agricultural Appropriations bill which could have a profound effect on how the Food and Drug Administration (FDA) protects consumers from imported prescription drugs of uncertain safety and effectiveness. I am concerned that these amendments could seriously undermine the Prescription Drug Marketing Act (PDMA), and thus adversely affect public health.

During the 1980's, the House Energy and Commerce Committee conducted a lengthy investigation into the foreign drug market that ultimately led to enactment of the PDMA. That investigation discovered a potentially dangerous diversion market that prevented effective control over the true sources of merchandise in a significant number of cases. The integrity of the distribution system was found to be insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit pharmaceuticals. As the resulting Committee report stated, ''pharmaceuticals which have been mislabeled, misbranded, improperly stored or shipped, have exceeded their expiration dates, or are bald counterfeits, are injected into the national distribution system for ultimate sale to consumers.''

The PDMA was designed to restore the integrity and control over the pharmaceutical market necessary to eliminate both the actual and potential health and safety problems before injury to the consumer could occur. Again, the Committee report was clear on why the PDMA was needed: ''[R]eimported pharmaceuticals threaten the public health in two ways. First, foreign counterfeits, falsely described as reimported U.S. produced drugs, have entered the distribution system. Second, proper storage and handling of legitimate pharmaceuticals cannot be guaranteed by U.S. law once the drugs have left the boundaries of the United States.''

Alarmingly, I find little now that suggests that the problem with misbranded, adulterated, or even counterfeit foreign drugs has been solved. I reiterated these concerns with respect to the Crowley and Coburn amendments (see enclosed remarks). In fact, the evidence suggests the problem is getting worse. I am concerned that in our haste to find a way to bring cheaper drugs to seniors and other needy Americans—a clearly important and laudable goal—we risk making changes to key health and safety laws we may later regret. I am thus requesting that you quickly provide me with the following information:

(1) Please provide a detailed analysis on how (H.R. 4461 and H.R. 3240) would affect FDA's present operations regarding efforts to prevent misbranded or potentially dangerous drugs from entering the U.S. Specially, please provide: (a) a description of how the present system now used by FDA works; (b) what the present system is intended to accomplish; and (c) what changes would be required (and the potential effects of those changes) if this legislation passes in its present form.

Please include a discussion of how these amendments would affects take activities of other agencies, such as the U.S. Customs Service, with responsibilities for assuring the safety of imported prescription drugs.

(2) Please determine if either of these amendments would have any effect on FDA's ability to enforce good manufacturing practices (GMPs) in any foreign firms that ship drugs to the U.S. If so, please explain any potential effect on consumer health and safety.

(3) Please provide a full description regarding what a ''warning letter'' is and how it is typically used by the FDA. Please compare this with correspondence that is sent by Customs.

(4) It appears that these amendments would directly affect the ability of FDA to send warning letters to consumers that purchase drugs over the Internet. As you know, some web sites appear to be covertly linked to foreign drug suppliers. When a consumer orders from such a site, it is not always obvious that they are dealing with an offshore supplier, and thus a potentially non-FDA approved facility. Often, warning letters may be the only indication that the Internet-ordered drugs originated from a foreign (and potentially dubious) source. Please indicate how this legislation could affect FDA's ability to protect consumers who purchased drugs in this way.

(5) Please detail any other potential effects this legislation could have on FDA's ability to protect consumers from potentially dangerous drugs that originate abroad.

(6) Finally, please provide technical assistance in the form of specific suggestions for legislative or regulatory changes that would be needed in order to facilitate the safe importation of prescription drugs by individuals, wholesalers, or retailers.

I would appreciate a full response to this letter by Friday, July 28, 2000. Please do not delay.

Sincerely,

JOHN D. DINGELL,
Ranking Member.

NATIONAL WHOLESALE
DRUGGISTS' ASSOCIATION,
Reston, VA, July 18, 2000.

DEAR SENATOR: I am writing on behalf of the National Wholesale Druggists' Association (NWDA) to request that you oppose the pharmaceutical importation amendment Senator Jeffords is expected to offer to the Fiscal Year 2001 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill.

NWDA is the national trade association representing distributors of pharmaceuticals and health care products. NWDA active members operate over 200 distribution centers throughout the country, distributing over $77 billion in these products to every state, the District of Columbia and U.S. territories.

From NWDA's perspective, the Jeffords' amendment is unworkable. It would require wholesalers to statistically sample the products, test them for authenticity, develop extensive record keeping and documentation and relabel products from the country of origin to U.S./FDA approved labels. In their new role, wholesalers would also now likely have to also prepare professional package inserts to accompany each bottle or vial. These new requirements may reclassify ''wholesalers'' as ''relabelers'' and/or ''repackagers,'' which, under FDA regulations, would trigger different and significant additional regulatory requirements. I am not aware of any wholesalers who have these capabilities and I strongly doubt that they would undertake them due to the considerable expense.

Wholesalers do not have the experience, equipment or personnel to undertake such complicated tasks. Our expertise is in distributing pharmaceuticals in an efficient, timely and cost-effective manner on a daily basis. An ''average'' NWDA-wholesaler purchases product from over 900 different manufacturers, stores over 25,000 different health care items at any one time and distributes them to its hundreds of customers, including independent pharmacies, chain drug stores, hospitals, HMO's, integrated health systems, clinics, home health providers, physicians and government sites.

The measure also imposes numerous new reporting requirements on wholesalers. While it is questionable if these reports actually will help to ensure the health and safety of Americans, they will be very burdensome and costly for the wholesalers who must compile and maintain them. Furthermore, as a result of the testing and reporting requirements, lability exposure for the wholesaler is increased dramatically. All of these new requirements and liabilities will, in our opinion, add significant costs to imported products.

NWDA-wholesaler members have a razor thin net profit margin of just 0.62%. Operating in a highly competitive marketplace, wholesale drug distributors have passed these savings from lower operating costs through to our customers. All of these additional responsibilities, regulatory burdens and liability exposure will, in our opinion, ultimately be passed along to consumers. Wholesalers simply do not have the margins to absorb these types of added costs. Indeed, the financial viability of some wholesalers could be jeopardized if the Jeffords measure were to be enacted.

In closing, NWDA, as indicated in previous communications, is concerned about the potential threat to the public health posed by the importation of products that have been produced, stored and/or handled in a manner that is inconsistent with U.S. quality standards. Notwithstanding the language in the amendment relating to documentation, the Jeffords amendment does not ensure the safety and integrity of imported prescription drugs. However, NWDA stands ready to work with Senator Jeffords and others to devise an approach that will ensure the safety and integrity of pharmaceutical products as well as provide access to them for all Americans.

If you have any questions, please do not hesitate to contact me or have your staff

contract Robert Falb, NWDA Director of Congressional Affairs, at 703–787–0020 or rfalb@nwda.org.

Sincerely,

RONALD J. STRECK,
President & CEO.

Mr. HATCH. Given the reported White House activity on this bill, I would not be surprised that FDA will quickly respond to and brush aside the questions this letter raises.

Mr. President, in sum, we are in danger of losing a tremendously innovative and effective and productive industry that has made the American Nation the leader in health care throughout the world.

I think this type of an amendment will undermine everything we have decided to do all these years, that has really benefited the whole world.

I yield the floor.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, I point out, we held a hearing on this yesterday. I wanted to correct my good chairman on that.

I yield 5 minutes to the Senator from New York.

The PRESIDING OFFICER. The Senator from New York.

Mr. MOYNIHAN. Mr. President, I very much appreciate the courtesy of my friend from Vermont because I rise to support the views of my friend from Utah, who spoke so carefully about the matter of price controls.

Sir, I do not expect to have any considerable influence on what we do today. But I would like, in a very short order, to try to put what we are doing in a perspective.

This began, for me, during the period of the Finance Committee hearings on the health care legislation submitted to us by the administration in 1993.

At one hearing, a professor, Charles Fahey, of Fordham University, speaking for the Catholic Health Association, said: What we are witnessing in the country is the commodification of medicine.

And down the table, the head of the UCLA hospital said: Can I give you an example? In Southern California, we now have a spot market for bone marrow transplants.

This thought stayed with me, that market forces were beginning to shape decisions in health matters as they had not done before.

It was particularly poignant that the first institutions that would have trouble in this new situation would be the medical schools and the teaching hospitals, which, as economists say, are public goods. Everybody benefits from public goods so no one has an incentive to pay for it—and we are seeing this all over the country in a short 6 years.

Now, today, we are seeing another phenomenon of a market that comes into being as railroads did, as oil refineries did, oil producers, as has been going on through the history of free markets and free enterprise, which is price controls. There is something about our political systems in the West that responds to the creation of new markets and the seeming rise in prices in those markets—when, in fact, quality rises—that says perhaps we could control this by controlling the price.

It always fails, Mr. President. It is the one thing you can say with a large degree of confidence that in the 20th century this effort always fails. Sometimes it fails by producing black markets where the laws are not obeyed; others by simply depressing the quality of the products in the market. That is what we have to watch for here in the main.

We are dealing with thoroughly responsible organizations. The Pfizer Corporation, from my city of New York, began work in Brooklyn in 1849, developed the first treatment for parasitic worms in the mid-19th century when that was a rampant endemic disease. It has since gone on to do other extraordinary things. It was the first major producer of penicillin in the United States, which was a drug of such enormous consequence in the Second World War, the first time we were able to destroy one cell in a body without destroying others.

Today Pfizer has 12,000 researchers with a budget of $4.7 billion, larger than the budget of the National Science Foundation. I say, sir, impose price controls, which always seems like a good idea at the time, and in a short order there will be no such budget. A period of enormous innovation, very recent in the history of medicine, will come to a close.

I see my time has come to a close. I ask unanimous consent to print in the RECORD the paper I gave at the 42nd annual Cartwright Lecture as reprinted in ''Academic Medicine,'' the journal of the Association of American Medical Colleges.

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

[Reprinted from Academic Medicine, 1998 by the Association of American Medical Colleges]

ON THE COMMODIFICATION OF MEDICINE

(By Daniel Patrick Moynihan)

ABSTRACT

The author reviews key themes of medicine and medical education in the 20th century, such as the revolution in therapies and the consequent and continuing changes in the economies of health care; workforce issues, including the controversy over the optimum number of residency slots; and the impact of managed care on teaching hospitals and medical schools. This impact is part of ''the commodification of health care,'' in which health care is beginning to be bought and sold in a market, where prices determine outcomes, and where the not-for-profit, service orientation of health care providers is threatened.

He discusses in detail the pressures this new health care environment places on medical schools and teaching hospitals, and recounts the first Senate Finance Committee hearing in April 1994 on the subject of academic health centers under health care reform. Soon after, the Committee approved legislation to create the Graduate Medical Education and Academic Health Center Trust Fund, to be financed by a 1.5% tax on private health care premiums in addition to Medicare Graduate Medical Education payments. The provision was later dropped from a similar bill that came before the full Senate, but has since been introduced as the Medical Education Trust Fund Act of 1997.

The author concludes by cautioning that matters will grow more difficult in the near future, since the threats to academic medicine's institutions have not yet become part of the national political agenda.

Acad. Med. 1998; 73:453—459.

I must begin by expressing great gratitude to the Dean's Advisory Committee on Honors and Awards for inviting me to be the recipient of the 1997 Cartwright Prize. I will not, however, dissemble my anxiety at being, evidently, the first lay person to receive this prize in its 116-year history. I take comfort in one respect only, which is that I propose to address the same subject, the condition of our medical schools, that Abraham Flexner addressed in 1910, and whilst a historic figure of the first order, Flexner, too, was a layman!

He was, of course, concerned with quality. Yet the text of his celebrated Report to the Carnegie Foundation for the Advancement of Teaching is filled with financial details and economic terms:

''In the entire United States there is already on the average one doctor for every 568 persons . . . in our large cities there is frequently one doctor for every 400 or less.

''Over-production is stamped on the face of these facts.

''A century of reckless over-production of cheap doctors has resulted in general overcrowding.''

Flexner's view was that there were then too many inadequate medical schools producing too many inadequate doctors. He would raise quality by reducing the number of institutions and increasing the quality of the graduates. He had his way.

In 1910, the year of his report, there were 155 medical schools in the United States. By 1932, there were 76, with but a single addition by 1950. In 1910, there were 4,400 medical graduates in a population of 92.2 million, or 4.8 graduates for every 100,000 people. In 1996, there were 15,907 medical graduates in a population of 268.6 million, or 5.9 graduates for every 100,000 people.

I risk speaking beyond my knowledge, but it appears to me that we can see in all this a combination of disinterested behavior not without a trace of self-protection. At the time, all manner of folk were becoming ''professional.'' Lawyers and accountants and engineers, and, heaven forbid, professors of government. Gatekeepers were put in place and access was restricted. The public got the benefits of quality; the professions of, well oligopoly.

It is striking how echoes of this early debate could be heard in the course of the debate over President Clinton's 1993 health care proposal, an exchange which, of course, continues.

The new administration had announced its intention to send Congress a bill that would establish universal health care. The work of drafting the legislation was assigned to a group of some 500 persons. By the time the first session of the 103rd Congress was coming to a close, we still had not received a bill. On November 23, the day before we ''went out,'' as our phrase has it, I finally was able as chairman of the Senate Finance Committee to introduce, ''on request,'' a 1,362 page bill. I suspected it was not quite complete—it was not—but it saved the honor of the task force to have got its work done in one year.

Not incidentally, introducing the bill finally focused my mind. It was time surely

that I got some rudimentary education on this subject. Accordingly, I asked Paul A. Marks of Memorial Sloan—Kettering if he would put on a seminar for me. Just basics. We met in their lovely Laurance S. Rockefeller Board Room at 10 a.m. on the morning of Wednesday, January 19, 1994. At about 10:20 a.m. my education commenced. One of my tutors—a dean of great distinction—remarked that the University of Minnesota might have to close its medical school.

Hold it! Minnesota is where all the Scandinavians went. They don't close medical schools in Minnesota; they open medical schools in Minnesota. This is true, surely, of our whole northern tier of states. It happens I take some pride in having demonstrated in 1992 that while the correlation between per-pupil expenditure on education and average score on the national eighth-grade math exam was a derisory .203, the strongest correlation, a negative .522, was the distance of a state capital from the Canadian border. In the place of all the nostrums being bandied about concerning national education policy, I proposed a simple one-step program: move states closer to Canada. I would tend to assume that some similar relationship obtains as regards health care, and so was the more shocked at the idea of a medical school being closed in Minnesota.

On further enquiry, one learned that, being progressive folk, Minnesotans had been joining health maintenance organizations. HMOs, as we would learn to call them. Paul Ellwood had been trying to tell us this. Being cost-conscious, HMOs do not readily send patients to teaching hospitals; lacking patients, teaching hospitals falter; lacking teaching hospitals, medical schools close.

Clearly, we were in a new age of medicine that had come upon us suddenly. In a wonderful brief essay written in 1984, Lewis Thomas described ''medicine's second revolution.'' The first revolution began with 2nd century A.D. Galen, a Greek physician practicing in Rome who introduced bleeding and blistering, mercury and the like. Also anatomy.

This first revolution persisted—witness the passing of our first president—into the early 19th century, when ''serious questions were raised about this kind of therapy.'' Slowly, but successfully, doctors learned Hippocrates' injunction, primum non nocere. Thomas described a celebrated Victorian painting, The Doctor:

''The picture . . . illustrates what used to be the popular conception of medicine and is, to this day, a romantic version of the way the profession likes to view itself. The scene is a Victorian living room where a young child, stricken by an unspecified mortal illness, lies in a makeshift bed; at her side sits the elderly doctor in an attitude combining, all at once, concern, compassion, intelligence, understanding, and command. He is the painting's centerpiece. The child's parents are in the background, the father looking at the doctor with an expression of total trust.

''The doctor in the painting is engaged in what was, for that period in medicine, the only course available at this stage of serious illness: He is monitoring the patient. He has already, presumably, arrived at the diagnosis. He knows the name of the child's illness, he has a solid working knowledge of the pathology, and from his lifetime of professional experience he is able to predict how the disease will run its course and what will happen at the end. He has explained all this to the parents in language that they can understand, and now, at the moment of the picture, he is engaged in the ancient art of medicine. This means, at its essence, that he is there contributing his presence, providing whatever he can in the way of hope and understanding.

''The illusion of the scene is that he is in control of the situation. He is not, of course. Beyond taking the pulse, examining the tongue, listening to the chest, palpating the abdomen, and making sure that what was then regarded as good nursing care is available, there is nothing whatever that he can do to alter the course of the illness or affect its outcome.''

Thomas records that ''this was the kind of medicine I was taught in Boston 50 years ago, which would have been 1934. (When, come to think, we were treating our president for poliomyelitis by seating him in what Gibbon called ''medicinal waters,'' writing of the therapies of Rome in the Age of Caracalla.) He recalls that the terms medical science and medical research were not much used and the term bio-medical, implying that ''medicine and biology were all of a piece,'' was not yet invented. Then this: ''As I recall, 50 years ago we believed that medicine had just about come its full distance.

Before that decade of the 1930s wound out, antibiotics made their appearance in medical practice and everything changed. Changed utterly. To cite Thomas a last time, ''The news that infectious bacteria could be killed off without harm to the cells of the host came as an astonishment to physicians everywhere. American medicine took off.

The transformation of medical science brought profound changes in the economics of medicine. We would associate this with Say's law, the work of the early-19th-century French economist who reached ''a conclusion that may at first sight seem paradoxical, namely, that it is production which opens a demand for products.'' Supply creates its own demand. Say's law began to take hold in medicine. As the supply of efficacious treatments grew, demand grew. In 1929, real per-capita national health expenditures (1996 dollars) were below $300. By 1989, they exceeded $3,000—a ten-fold increase. In 1940, 4.0% of the Gross Domestic Product went to the health care sector. In 1960, 5.1%. But now the trend took hold. The proportion had more than doubled by 1991, when Richard Darman, Director of the Office of Management and Budget, presented this testimony before the Senate Committee on Finance:

''Total public and private health spending is on a growth path that would take over the Gross National Product—if that were not a practical impossibility. Total health spending has grown from less than 6% of GNP three decades ago to about 12% today. It is currently projected to reach 17% by the year 2000 and 37% of GNP by 2030. [Emphasis in original.]''

In Washington, where health care costs were now assuming an ever-larger portion of the federal budget owing to programs such as Medicare and Medicaid, begun in 1965, the issue was increasingly seen in budgetary terms. This was a profound shift. I was a witness to and something of a participant in the development of the Medicare and Medicaid legislation. Money was the least of our concerns. We had the money. Health care was what we cared about. The venerable Robert J. Myers, who was actuary to the House Committee on Ways and Means at that time, has recently reviewed our subsequent experience. In 1965, it was estimated that the outgo for the hospital insurance (HI) portion of Medicare by 1990 would be $9 billion. As it turned out, the actual figure was $66.9 billion. Thus, he writes, ''the actual HI experience was 639% above the estimate.'' Myers notes that in the interval the program was continually expanded in one way or another such that the comparison is not entirely valid. No matter, the issue succumbed to a fair amount of alarm given what, in Myers's words, ''at first glance . . . seems to be a horrendous variation.'' Political attention turned to the issue of demand.

This was a central theme of President Clinton's 1993 health care proposal. One issue identified was what economist Alain Enthoven had earlier called the question of ''physician oversupply.'' Writing in the Journal of the American Medical Association in 1994, Richard A. Cooper of the Medical College of Wisconsin would state that a ''consensus'' had developed that there needed to be a ''better balance'' in the proportion of primary care physicians to specialists. He was careful, however, to note that where the one was determined by demography, ''the driving force behind much of specialty medicine was science.''

This was not a matter of concern to the Clinton task force. Working in secret, an abomination where science is concerned and no less an offense to democratic governance, the task force came up with this formulation:

''Problem: An increasingly overabundant number of medical graduates are entering specialty fields instead of primary care fields (family practice, general pediatrics, general internal medicine).

''Provide [by Federal law] that at least 50 percent of residency graduates enter primary care practice.

''*Limit Federal funding for first-year residency positions to no more than 110 percent of the size of the graduating class of U.S. medical schools. This would further support the action to limit specialty residency positions.* [Emphasis in original.]''

As I have described elsewhere, a dissenting paper dated April 26, 1993, by ''Workgroup 12'' of ''Tollgate 5,'' [sic] written by a physician in the Veterans' Administration, began:

''FOR OFFICIAL USE ONLY

''Subject: Proposal to cap the total number of graduate physician (resident) entry (PGY–1) training positions in the U.S.A. To 110 percent of the annual number of graduates of U.S. medical schools.

''Issue: Although this proposal has been presented in toll-gate documents as the position of Group 12, it is not supported by the majority of the members of Group 12 (listed below).

''REASONS NOT TO CAP THE TOTAL NUMBER OF U.S. RESIDENCY TRAINING POSITIONS FOR PHYSICIAN GRADUATES.

''1. This proposal has been advanced by several Commissions within the last two years as a measure to control the costs of health care. While ostensibly advanced as a man-power policy, its rationale lies in economic policy. Its advocates believe that each physician in America represents a cost center. he not only receives a high personal salary, but is able to generate health care costs by ordering tests, admitting patients to hospitals and performing technical procedures. This thesis may be summarized as: TO CONTROL COSTS. CONTROL THE NUMBER OF PHYSICIANS.''

It went on the state that the proposal would require ''a vast regulatory apparatus.'' Then this:

''13. To end on a philosophic note, when the proposal to cap training slots was presented to the presidents of the major U.S. universities last weekend, they were incredulous that the U.S. government would advance as sound social policy a proposal to limit access to one of the three learned professions with its millennial history of achieving social good. They further recognized that in America open access to careers in these professions has been a traditional path for immigrant social mobility.''

Leaving aside the politically correct last sentence—No White Protestants Need Apply—this was surely an honorable response. The university presidents were right to have been incredulous at this proposal. It

was, in the words of Walter Reich, a proposal for the ''deliberate dumbing down of medicine.'' And yet, it was all kept too much in the family. The administration hardly drew attention to it. A 136-page White House publication on the health care plan had 11 lines on the subject of ''Doctors in the United States: An Unhealthy Mix.'' The press scarcely mentioned the matter, even here in New York where the 110% limit on residencies would have nearly eliminated foreign medical graduates in our hospitals, with the real possibility of many having to close. (The number of residency slots has for some years now been at about 135% of the number of graduates of American medical schools. Imposing a 110% cap would have resulted in a reduction of almost a fifth in the number of residencies nationwide. In that almost half the medical residents in New York City are graduates of foreign medical schools, it would have been very difficult to staff the city's hospitals if such a supply constraint had become law.)

Nor did the workforce issue emerge in the House and Senate hearings on the health care legislation. However, early on the Finance Committee began to sense that the notion of uncontrollable costs was open to question. Indeed, the interval between 1993, when the administration health care plan was proposed, and 1994, when it failed in the Congress, was something of a break point. Average health insurance costs for large employers, including government, declined from $4,117 in 1993 to $4,040 in 1994. (They have since more or less stabilized.) Something was going on, and in the Finance Committee, at least, we began to sense what could only be described as market forces. This sense, at least for this Senator, was of a sudden brought into focus on April 26, 1994, when Monsignor Charles J. Fahey of Fordham University, testifying on behalf of the Catholic Health Association of the United States, said that what we were seeing was the ''commodification of health care.'' Which is to say that health care was beginning to be bought and sold in a market, where prices would determine outcomes. This was not a development Fahey found altogether congenial.

''We want to alert the committee that the not-for-profit mission in health care is being seriously threatened by the increasing commercial environment in which we find ourselves operating; a real commodification of health care, if you will.''

Still, as we pursued the matter, it became ever more clear that something such was happening.

Again, Paul Ellwood did his best to tell us this. At a March 1, 1994, hearing in the Finance Committee, he was asked about projections that health care spending would reach 20% of GDP by the year 2000.

''Dr. ELLWOOD. The problem with building these models that project costs is, if you are going to go with a model, the more compulsory, the more intrusive the system of determining what the numbers are in there, supposedly the more accurate they are.

''What we are having to do here is speculate about how consumers will behave if they are faced with lower-cost health plans versus how providers will behave if there is a ceiling on it.

''My feeling is—I may come to regret saying things like this—we are never going to hit 20%.

''Senator PACKWOOD. That we are going to get what?

''Dr. ELLWOOD. We are never going to hit 20% of the GDP.

''The CHAIRMAN. Write that down. Everybody take notes.''

What Mr. Darman had described—37% of GNP by the year 2030—was an unsustainable trend. It is years now since Herbert Stein, Chairman of the Council of Economic Advisers under President Nixon, offered the epiphanic observation that ''an unsustainable trend cannot be sustained.'' We should have known, and began to sense.

Here are the numbers. In 1993, health care absorbed 13.6% of GDP. The administration projected that without reform, the proportion would rise to 18.9% by the year 2000. (Pretty much along the Darman trend line.) With reform—1,362 pages of it—we could hope for 17.3% of GDP by said year 2000. For what it is worth, the Congressional Budget Office now projects that by the year 2000 health care costs will be 14.3%. As they would say in the age of Thomist medicine, the crisis has passed.

But another crisis awaited. That of medical schools and teaching hospitals. Slowly, beginning with Fahey's testimony, the connection emerged. And it has been all over the press ever since, if one reads the headlines with this in mind. Here is a sample from the superb reporting of Milt Freudenheim in The New York Times:

''HOSPITALS ARE TEMPTED BUT WARY AS FOR-PROFIT CHAINS WOO THEM

''Richard Scott has made deals to take over 137 hospitals in the last year, and he wants more. Now, his Columbia—HCA Healthcare Corporation has its eye on some Catholic hospitals in Chicago.

''Stay away, says Joseph Cardinal Bernardin of Chicago, one of the most powerful clerics in the nation. The Roman Catholic Church has an obligation to poor people and to the Catholic way of health care, the Cardinal recently warned the 20 hospitals in his archdiocese, and selling to a for-profit chain would be a betrayal. He reminded them that the archdiocese could withdraw its recognition of any hospital defying him.''

For Catholics, of course, read Jewish, Presbyterian, Methodist, what you will. Hospitals once were charities.

''BIG HOSPITAL CHAIN MAKES A BID TO BUY BLUE CROSS OF OHIO

''The nation's largest for-profit hospital chain agreed yesterday to buy the main business of Blue Cross and Blue Shield of Ohio, raising concerns among consumers, employers and providers of health care about the enormous influence that such a combination could exert.

''The $229.5 million purchase by the Columbia—HCA Healthcare Corporation would be the first acquisition of a Blue Cross company by a for-profit hospital chain. If approved by state regulators and the national Blue Cross and Blue Shield association, the takeover could open the door for similar deals by a number of nonprofit Blue Cross plans that are struggling to stay in business.''

Recall that Blue Cross began as a not-for-profit cooperative, an idea much associated with resisting market forces.

A recent lead story of the Business Day section of The Times, by David J. Morrow, began:

''WARNER—LAMBERT SHARES PLUNGE ON GLAXO MOVE

''Shares of the Warner-Lambert Company plunged 18.5% yesterday after Glaxo Wellcome P.L.C. halted British sales of Warner-Lambert's diabetes drug, troglitazone [trade name Rezulin]. . . .

''By day's end, Warner-Lambert's shares had dropped $25.875 each, to $114, with 9.9 million shares traded, the second most active of the day on the New York Stock Exchange. The setback shaved $7 billion off the Morris Plains, N.J., company's market value, prompting analysts at Bear, Stearns & Company to adjust their earnings estimates and Morgan Stanley to lower its rating of Warner-Lambert before noon. At one point, Warner-Lambert's stock tumbled to $112, its lowest point since June 20. . . .

Developed by the Sankyo Company Ltd. in Japan, Rezulin was initially heralded as a wonder drug for type-2 diabetes, a chronic disease that affects about 135 million people world-wide. According to Warner-Lambert data, Rezulin reduces or eliminates the daily use of insulin, which has been the predominant treatment for diabetes. Unlike insulin, administered by injection, Rezulin is taken in tablets.''

There was a time, surely, when the advent of a new ''wonder drug'' would have been approached in terms of health care. Now it becomes an affair of share prices.

But now to our main story. This, once again, by Mr. Freudenheim of The Times, on May 20, 1997:

''TEACHING HOSPITALS UNDER THE KNIFE; LONGTIME MISSIONS PRESSED BY H.M.O.'S

''It began as a charity supported by Paul Revere that sent out doctors to the poor. It evolved into the New England Medical Center at Tufts University, a research powerhouse that ranks among the leaders in New England in liver transplants, breast-cancer research and complex heart procedures.

''But now, the biggest health maintenance organization in Boston threatens to starve New England Medical by refusing to pay for its patients to go there, even though the costs are as low or lower than at other Boston teaching hospitals. . . .

''The squeeze on academic medical centers like New England Medical is particularly brutal in Boston, which has seven prestigious teaching and research hospitals and far too many hospital beds, and where costs per patient are among the nation's highest. But dozens of teaching hospitals across the country face similar challenges, and they are responding by reaching out for business partners.

''Some, like the George Washington University Hospital in Washington, D.C., and state university hospitals in California, Oklahoma and South Carolina, are being sold to for-profit chains; others, like New England Medical, Columbia University's Presbyterian Hospital and the University of Minnesota Academic Medical Center, have merged with stronger, nonprofit local institutions; still others, like Beth Israel and St. Luke's/Roosevelt in New York, are merging into holding companies that will run their finances.''

In April 1994, the Senate Committee on Finance held hearings on the subject of ''Academic Health Centers Under Health Care Reform.'' It would appear that these were the first ever on that subject. The testimony was powerful and dispositive. In response to a question from Senators Bob Packwood, our ranking member, Paul Marks described the situation at Sloan-Kettering:

''I think that a price-driven environment is one in which we will have unintended consequences in terms of rationing and quality. You cannot get something for nothing out of the system. And while we can reduce costs substantially, and I think all of us have tremendous pressures to reduce costs, even in high-cost centers, such as the cancer centers, we know right now from our experience because we are being approached by insurance companies, health plans, managed care, and they say how much does a bone marrow transplant cost. And we will say it is $100,000. Well, we will give you all our marrow transplants for $60,000.

''There are two things. Number one, we cannot survive as a quality provider of care doing bone marrow transplantations alone. Even if we got $100,000, we would not want to do it. And at $60,000 we cannot really provide

a quality care program in bone marrow transplantation.

''So I would say that at least in our environment there has to be some kind of legislation which takes into account that a price-driven system today will compromise the quality of health care and will be associated with rationing. I do not think there is any question in my mind about that because they cannot compete in any other way if you are going to drive down just price.''

It would be fair, I believe, to state that the theme of our hearings was, and here I quote from my opening statement, that ''health insurance is important, but health is more important. It comes out of discovery, and we are in a great age of discovery.'' We were up against the problem of how to provide for what economists call public goods. These are readily described. For most goods and services, if the consumer chooses not to pay, he does not receive the benefit. If he does not buy a ticket, he is excluded from the ballpark. By contrast, consumers are not easily excluded from the benefits of a public good, say national defense or cancer research, because everyone benefits whether or not they pay. As Richard A. Musgrave noted in his classic 1959 text, The Theory of Public Finance, the existence of public goods provides a rationale for the government to intervene on markets and either directly provide the public good—as it does with national defense—or support the provision of the public good through indirect payments.

The Finance Committee resolved to do just this for medical schools and teaching hospitals. The chairman's mark, as is our term, of June 29, 1994, provided for a Graduate Medical Education and Academic Health Center Trust Fund to be financed by a 1.5% tax on all private health care premiums. An additional .25% levy, proposed to us by Senator Mark Hatfield, provided for medical research. In all, this made for an average annual revenue to the Trust Fund of $17 billion over five years. To may knowledge, this was the first such proposal of its kind. It did not go unnoticed in our Committee; a motion to strike the 1.75% premium tax failed by 13 votes to seven.

It would be pleasing to report that there was at least some response to the bipartisan approval by the Senate's tax-writing committee of a trust fund for this purpose. But there was none. The Committee finished its work on Saturday, and there was a long front-page report in The Times. The tone was cool. Our assignment had been to provide universal health care; we had only provided for 95% coverage by 2002. That a bipartisan majority had approved a very considerable measure meant nothing to those who had vowed never to compromise. These included a fair number of journalists, whose disappointment, even distaste, was made plain. In the end, of course, no bill was brought to a vote in either chamber. The Congressional elections that followed were widely understood to mark a repudiation of the whole enterprise, and indeed, the subject has receded, in Congress at least, while health maintenance organizations continue their seeming predestined course.

The one exception is this matter of medical schools and teaching hospitals. In the 104th Congress, four bills were introduced. This time the Senate Finance Committee rejected the trust fund on a tie vote, ten to ten. (Tie votes fail.) By contrast, on the House side, in the Committee on Ways and Means, the new chairman, Representative Bill Archer of Texas, proposed and carried a Teaching Hospital and Graduate Medical Education fund that would receive, among other revenues, $13.5 billion in appropriated general funds over a six-year period. This measure became part of the Balanced Budget Act of 1995. It passed both House and Senate, but was vetoed by President Clinton over other matters. In the current, 105th Congress, I have reintroduced S. 21, the ''Medical Education Trust Fund Act of 1997.'' This was a ''first day'' bill, and accorded some prestige, as the first 20 numbers are reserved for the Majority and Minority leaders. For all that, at the end of the year there are no cosponsors and few prospects. The subject has not made its way onto the national political agenda as a singular public good that has been placed in jeopardy by what Columbia's great seer, Robert K. Merton, described back in 1936 as the ''unintended consequences'' of actions arising in other contexts.

Expect matters to grow more difficult in the near future. There will be all manner of proposals to regulate managed care, much as a century ago we commenced to regulate the railroads and such like commercial activities. This can be helpful; it can be hurtful. James F. Blumstein of the Health Policy Center at Vanderbilt University suggests that the current federal investigation into various health care providers ''is taking its cues from past task forces on the Mafia.'' Or desert warfare, for that matter, given the formal title, ''Operation Restore Trust.'' Again, expect more. But be of good cheer. Some things take a long time, as Lewis Thomas attested. Most importantly, may a layman urge that you physicians be importunate. You are too precious to let your collective well-being be taken for granted. I close with the words with which Dominic P. Purpura, dean of the Albert Einstein College of Medicine here in New York, on October 5th opened the new Jerome and Dawn Greene Medical Arts Pavilion at Montefiore Hospital in the Bronx:

''We are gathered here for several reasons. Most importantly to bear witness to the felicitous marriage of high-spirited philanthropy and good works, now consummated in this . . . Medical Arts Pavilion. We are here for another purpose as well. To dispel the septic rumor oozing from some health policy think tanks to the effect that academic medical centers such as ours are dinosaurs doomed to extinction by the impact of the asteroid of managed care. Look skyward! On this day of noble purpose the sun shines brightly. No ashen clouds obscure the values that have made American medicine a crowning achievement of Western Civilization. And what are these core values? Simply stated: Faith in evidence-based medicine and trust that our superbly trained physicians will translate the basic science of medicine into the art and science of patient care.''

The author thanks Dr. David Podoff, minority chief economist for the Senate Committee on Finance, for assistance with this article.

Mr. JEFFORDS. Mr. President, I yield 4 minutes to the Senator from Minnesota.

The PRESIDING OFFICER. The Senator from Minnesota.

Mr. WELLSTONE. Mr. President, I am very pleased to be involved in working on this legislation with the Senator from Vermont and other legislation with Senator DORGAN.

To my colleague from Utah, if we read the amendment carefully—all colleagues who are going to vote—we are very clear on protections. If safeguards are not in place, the drugs cannot be reimported. That is clear language.

These are some of the protections: strict FDA oversight; proof of FDA approval of imported medicines; only licensed pharmacists and wholesalers can import medicines for retail sale; importers will have to meet requirements for handling as strict as those already in place for manufacturers; lab testing to screen out counterfeits; lab testing to ensure purity, potency, and safety of medications. It is all clear.

I have a letter from the National Community Pharmacists which is in favor of this exact concept of our pharmacists and wholesalers being able to reimport these drugs so our consumers can afford it.

The only protection we don't have in this amendment is protection for the pharmaceutical industry to continue to make excessive profits. I quote from Fortune magazine:

> Whether you gauge profitability by median return on revenues, assets, or equity, pharmaceuticals had a Viagra kind of year.

We are talking about an industry making enormous profits, profits as a percentage of revenue up around 18.6 percent. We have all the protection for consumers. We just don't want to protect the pharmaceutical company from being able to gouge consumers. People in Minnesota and in Alabama and in Vermont and in North Dakota are saying: Why can't we have the trade? Why can't we have the competition? Why can't our pharmacists and wholesalers reimport these drugs back to us so we can get the drugs we need for ourselves and our families at a price we can afford?

This is a real simple amendment. You are on the side of consumers, you are on the side of real competition, or you are on the side of the pharmaceutical industry. On this one, Senators have to be on the side of consumers.

I am glad we finally have the chance to bring up legislation that corrects the injustice that finds American consumers the least likely of any in the industrialized world to be able to afford drugs manufactured by the American pharmaceutical industry because of the unconscionable prices the industry charges only here in the United States.

When I return to Minnesota which I do frequently, I meet with many constituents, but none with more compelling stories than senior citizens struggling to make ends meet because of the high cost of prescription drugs—life-saving drugs that are not covered under the Medicare program. Ten or twenty years ago these same senior citizens were going to work everyday—in the stores, and factories, and mines in Minnesota—earning an honest paycheck, and paying their taxes without protest. Now they wonder, how can this government—their government—stand by, when the medicines they need are out of reach.

But it is not just that medicare does not cover these drugs. The unfairness which Minnesotans feel is exacerbated of course by the high cost of prescription drugs here in the United States—the same drugs that can be purchased for frequently half the price in Canada or Mexico or Europe. These are the

exact same drugs, manufactured in the exact same facilities with the exact same safety precautions. A year ago, most Americans did not know that the exact same drugs are for sale at half the price in Canada. Today, you can bet the pharmaceutical industry wishes no one knew it. But the cat is out of the bag—and it is time for Congress to right these inequities.

All the legislators speaking today have heard the first-hand stories from our constituents—in Minnesota, Vermont, North Dakota, South Dakota, Washington state—constituents who are justifiably frustrated and discouraged when they can't afford to buy prescription drugs that are made in the United States—unless they go across the border to Canada where those same drugs, manufactured in the same facilities are available for about half the price.

Senior citizens have lost their patience in waiting for answers—and so have I.

Driving to Canada every few months to buy prescription drugs at affordable prices isn't the solution; it is a symptom of how broken parts of our health care system are. Americans regardless of party have a fundamental belief in fairness—and know a rip-off when they see one. It is time to end that rip-off. While we can be proud of both American scientific research that produces new miracle cures and the high standards of safety and efficacy that we expect to be followed at the FDA, it is shameful that America's most vulnerable citizens—the chronically ill and the elderly—are being asked to pay the highest prices in the world here in the U.S. for the exact same medications manufactured here but sold more cheaply overseas.

That is why I introduced with Senator DORGAN the International Prescription Drug Parity Act, and with Senator JEFFORDS the Medicine Equity and Drug Safety Act, two bills which will amend the Food, Drug, and Cosmetic Act to allow American pharmacists and distributors to import prescription drugs into the United States as long as the drugs meet FDA's strict safety standards. Pharmacists and distributors will be able to purchase these drugs—often manufactured right here in the U.S.—at lower prices overseas and then pass the huge savings along to American consumers.

What these bills do is to address the absurd situation by which American consumers are paying substantially higher prices for their prescription drugs than are the citizens of Canada, and the rest of the industrialized world. These bills do not create any new federal programs. Instead they use principles frequently cited in both Houses of the Congress—principles of free trade and competition—to help make it possible for American consumers to purchase the prescription drugs they need. Now we have the chance to adopt an amendment that includes the best of both those bills.

And the need is clear. A recent informal survey by the Minnesota Senior Federation on the price of six commonly used prescription medications showed that Minnesota consumers pay, on average, nearly double (196%) that paid by their Canadian counterparts. These excessive prices apply to drugs manufactured by U.S. pharmaceutical firms, the same drugs that are sold for just a fraction of the U.S. price in Canada and Europe.

Pharmacists could sell prescription drugs for less here in the United States, if they could buy and import these same drugs from Canada or Europe at lower prices than the pharmaceutical companies charge here at home.

Now, however, Federal law allows only the manufacturer of a drug to import it into the U.S. Thus American pharmacists and wholesalers must pay the exorbitant prices charged by the pharmaceutical industry in the U.S. market and pass along those high prices to consumers. It is time to stop protecting the pharmaceutical industry's outrageous profits—and they are outrageous.

Where the average Fortune 500 industry returned 3.8 percent profits as a percentage of their assets, the pharmaceutical industry returned 16.5 percent.

Where the average Fortune 500 industry returned 15 percent profits as a percentage of shareholders equity, the pharmaceutical industry returned 36 percent.

Those record profits are no surprise to America's senior citizens because they know where those profits come from—they come from their own pocketbooks. It is time to end the price gouging.

We need legislation that can assure our Senior Citizens and all Americans that safe and affordable prescription medications at last will be as available in the United States of America as they are in all the other countries of the industrialized world. This amendment which I am introducing along with Senators JEFFORDS and DORGAN accomplishes that end.

And contrary to the campaign of false information being promoted by the pharmaceutical industry, the Amendment includes all the safety precautions needed to protect the American public. This amendment includes the specific protections—which were not included in the House-passed amendments—to make sure we are not sacrificing safety for price.

The only things that are not protected in this amendment are the excessive profits of the pharmaceutical industry. My job as a United States Senator is not to protect those profits but to protect the people. Colleagues, please join in and support this thoughtful and necessary amendment that will help make prescription drugs affordable to the American people.

Mr. JEFFORDS. Mr. President, I yield 4 minutes to the Senator from Michigan.

The PRESIDING OFFICER. The Senator from Michigan.

Mr. LEVIN. Mr. President, I commend Senator JEFFORDS and Senator DORGAN for this amendment. There is no reason why American consumers should not have access to lower-priced medicines, while assuring the safety of those medicines that are imported.

I quote from an editorial from the Detroit News. This is an editorial department which is very outspokenly conservative, avowedly conservative in its editorial policy. It says:

> . . . Congress should remove the prohibition because the federal government ought not to restrict the purchasing options of Americans.

It goes on to say:

> . . . using government coercion to prevent Americans from purchasing drugs from abroad is not the way to go.

That is what this issue is all about. This is whether or not we are going to use the free market. This has nothing to do with setting prices. This has to do with using a free market to allow the reimportation of something manufactured in the United States after it has been certified by the FDA that it is safe to do so.

It is incredibly galling as well as incredibly expensive for my constituents in Michigan to go across the border to Canada in order to buy drugs at about half the price of what they are charged for those same drugs in Michigan. Again, these are drugs manufactured in the United States and exported to Canada. All this amendment says is that it ought to be possible for our wholesalers and our pharmacists to import something back into the United States manufactured in the United States and having been approved by a process of the FDA to make sure that it is safe.

We have done a survey in my home State. We have compared the prices of these drugs. They are quite extraordinary. We have many people who cannot afford these drugs. These are often lifesaving drugs, life-extending drugs. These are drugs which reduce pain, which make it possible for people to be more mobile than they otherwise would be.

We looked at seven of these most popular drugs because there were three on which we could not make a comparison because they were over-the-counter drugs in Canada or otherwise unavailable to get prices, but seven of the most popular drugs. Premarin is an estrogen tablet taken by menopausal women. It costs $23 in Michigan, $10 in Ontario. Synthroid—this replaces a hormone which is normally produced by the thyroid gland—costs over $13 in Michigan, under $8 in Ontario. We could go through the next five drugs on this list, and I have done this already in the RECORD in previous remarks I made on the Senate floor.

We cannot afford to be subsidizing the consumers in other countries. We ought to use the free market that we are all so proud of to allow the import of something which is, by the way,

manufactured in the United States and, by the way, in some cases had previously received financial support from the taxpayers of the United States through either the Tax Code on research and development or, in some cases, direct grants from the National Institutes of Health to the scientists who developed these drugs.

It is really an intolerable situation when we have people in our States who can't afford these critically important drugs and are simply prohibited from having a wholesaler or a pharmacist import that drug from another country. Since the amendment provides for safety through a process which has to be approved by the FDA, it seems to me this is a sensible thing to do.

I thank the Chair.

The PRESIDING OFFICER. Who yields time?

Mr. JEFFORDS. Mr. President, I yield 5 minutes to the Senator from North Dakota.

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

Mr. DORGAN. Mr. President, there is nothing worse than losing an argument you are not having. We had four or five opponents talk about this legislation, and they were making arguments about a bill that doesn't exist. So they win. What is the argument? Listen carefully and you will hear the scare tactics, suggesting that somehow in an old garage with a dirt floor on a dusty street somewhere in Haiti, someone is going to produce a counterfeit drug and ship it to the U.S. We should not do that, they say. Well, I agree. But that has nothing to do with this legislation. They are winning an argument we are not having.

This legislation establishes very strict controls and pertains only to prescription drugs that are produced in manufacturing plants approved by the FDA, with strict FDA oversight and proof of FDA approval on all imported medicines. Only licensed pharmacists and wholesalers can import the medicine for resale, and there is lab testing to screen out counterfeits. That is what this is about. Risk? This isn't about risk.

One of our colleagues said what we need is more insurance coverage for prescription drugs. Well, I agree that we need to add a prescription drug benefit to Medicare to help our senior citizens pay for their medications.

But we also need lower prices for prescription drugs. There is a famous football coach who is on television just about every night in an advertisement for a drug called Zocor. He is one of America's better professional football coaches and, I gather, a wonderful man. He says that Zocor reduces his cholesterol. I am sure it does; it is a wonderful drug. Zocor is advertised widely on television. If you buy it in the United States it is $3.82 per tablet. If you buy it in Canada—the same pill by the same company—it is $1.82 per tablet.

I ask anybody who spoke today in opposition to this amendment, how does one justify that? Do you support it? Do you think it is right? Do you want to tell the American consumer we have a global economy for everyone except for them? The compounds and chemicals used in this pill can be accessed globally by the companies that produce it, and that is fine. But the global economy isn't for you, American consumers. The drug companies can price their products any way they want here in the United States, and the American consumer has no business accessing them at a lower price anywhere outside the United States.

I ask all those who oppose this, do you support this pricing strategy—$1.82 for the person in Winnipeg, Canada, and $3.82 for the U.S. consumer?

The Senator from Vermont offers a very simple piece of legislation. The amendment allows for the importation only of products approved for sale in the United States by the FDA and manufactured in FDA-approved plants.

At a hearing before the HELP committee earlier this year, Dr. Christopher Rhodes, a professor of applied pharmaceutical sciences at the University of Rhode Island, who has 30 years of experience on the development and evaluation of drug products, said this:

> It is my considered professional opinion that the process of using re-imported prescription drugs in the United States need not place the American public at any increased risk of ineffective or dangerous products.

I understand what is at work here. The pharmaceutical industry wants to protect what they have. They have a pretty good deal. They can price their products at whatever price they want. But this is about fair prices for American consumers. I heard a colleague say: If we don't price products like this in the U.S., there won't be research and development for new drugs.

Oh, really? Every European country receives lower prices for the same drugs. Yet a larger percentage of research and development on prescription drugs takes place in Europe than in the United States. Explain that.

This is a good piece of legislation. I hope my colleagues will see it for what it is. It doesn't pose any risk. It says to the American consumers that they have rights as well.

Mr. COCHRAN. Mr. President, I yield the remainder of the time on our side to the distinguished Senator from North Carolina, Mr. HELMS.

Mr. HELMS. Mr. President, I ask unanimous consent that I may deliver my remarks while seated at my desk.

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

Mr. HELMS. Mr. President, I don't question the sincerity of those who advocate this amendment which is intended to repeal the law that prohibits the wholesale reimportation of potentially unsafe drugs from Canada or Mexico. While they may scoff at the opposition, I predict that one day, somewhere down the line, they will regret sincerely their support of this proposal which is fatally flawed.

Most Americans never doubt the safety of the drugs in our pharmacies and hospitals. That is because they understand that no drug can be sold in America without manufacturers first making enormous investments in research and development, the compound passing rigorous testing and review by the FDA, and then being distributed through a supply system that ensures that drugs must pass through a reliable and verifiable chain of custody.

No country in the world does as much to ensure the safety and efficacy of drugs used by its citizens.

FDA Commissioner, Dr. Jane Henney, recently warned that the United States demand for Canadian drugs could cause Canada to ''be used as a front for counterfeit or contaminated products becoming available.''

Some Senators have said: Forget that; it is not going to happen. Well, I predict that it is going to happen. Commissioner Henney went on to emphasize: ''One has to be concerned about a safety issue here.''

Echoing Commissioner Henney's concerns, the former FDA Commissioner and current Dean of the Yale Medical School, Dr. David Kessler, warned last year: ''with the rise of Internet pharmacies, the opportunities for illicit distribution of adulterated and counterfeit products have grown . . . Repealing the prohibition on reimportation of drugs would remove one of the principal statutory tools for dealing with this growing issue.''

Mr. President, current law has protected American consumers from the importation of substandard, impotent, adulterated, contaminated, and counterfeit pharmaceuticals—problems that have plagued many other countries. There is simply no good reason to undermine the integrity of our pharmaceutical supply system and to expose American consumers to corrupt middlemen and counterfeiters.

Foregoing the benefits of free markets and innovation for the false promise of cheaper, price-controlled drugs will lead not to improved health care but rather to a proliferation of unsafe and counterfeit drugs, a reduction in incentives and investment to develop new life-saving and life-improving medications; and ultimately, if this proposal passes, disastrous and fatal consequences for countless Americans.

Mr. President, I yield the floor.

Mr. JOHNSON. Mr. President, I rise to join Senators DORGAN and JEFFORDS in support of the prescription drug amendment being offered to the Agriculture Appropriations bill currently pending before this body. I commend my colleagues for their steadfast commitment to addressing this critically important issue. Like all of my colleagues, I deplore conditions that lead to Americans choosing between buying food for their family or medicine for their illnesses which is a choice that millions of consumers in this country are forced to make every day. This is a travesty and one that I am committed to put an end to.

The discussion of prescription drug pricing, accessibility, affordability, and safety has been elevated to new heights in the last year as we in Congress work to develop a practical and cost-effective approach to providing relief to combat escalating prescription drug prices for consumers throughout the United States.

Numerous studies have been conducted that highlight the price differentials existing between the United States, our neighbors to the North and South, and countries in the European Union. Several reports confirm that pharmaceutical prices are substantially higher in the United States than other countries.

Consider how drug prices charged to Americans differ from the drug prices paid by people living in other areas of the world as reported from a study done by the PRIME Institute at the University of Minnesota.

The study found that if Americans pay an average of $1.00 for a pharmaceutical product, that exact same product with the exact same dosage would have a much lower average cost in other industrialized nations. On average, that $1.00 product in the United States would cost .64 cents in Canada, .68 cents in Sweden, .65 cents in England, .71 cents in Germany, .57 cents in France, and .51 cents in Italy.

This amounts to price-gouging of Americans. It's wrong, and it has to stop.

So you ask, why don't Americans just buy it over the border and bring it back to the U.S.? Well, some individuals are being forced to take such drastic measures. South Dakota, though it does not share a border with another country, has an increasing number of individuals willing to make the drive to either Mexico or Canada, knowing full well that the savings are great enough to more than offset any expenses occurred in the process.

Presently, anecdotal evidence suggests that thousands of Americans cross the border to see a doctor and get their prescriptions filled for 25–50% less in cost for many popular prescription drugs. Here are a couple stories that have been shared with me over the last year:

A 72 year-old woman in Arlington, SD who spends $243 a month on prescription drugs wrote to me and said, ''The meds are so high in South Dakota. I try to get as much of them in Mexico as I can. I don't understand why there has to be such a difference in price.''

A 41-year-old man suffering from a disease that requires daily medication at a cost of more than $400 per month wrote to me and said, ''I want you to know that while I recognize that seniors are particularly hurt by unfair prescription pricing due to their fixed incomes, other Americans also feel the pinch. The same medication that I take is available in Mexico at less than half the price that it costs me in the U.S. Unfortunately, I can not afford to travel to Mexico periodically to obtain my prescription.''

Under current federal law, however, pharmaceutical companies are the only ones allowed to import drugs approved by the U.S. Food and Drug Administration into this country. Yet, if an American pharmacist or distributor wants to purchase these FDA-approved drugs at the lower prices available in other countries and pass the savings along to their customers, they are prohibited by law from doing so.

On July 10, the House of Representatives overwhelmingly passed two amendments to the Agriculture Appropriations bill that would allow widespread importation of prescription drugs without any FDA oversight. The overwhelming bipartisan support for these amendments clearly shows that Congress no longer wants to deny American consumers access to FDA approved medications that are available in other countries at much lower prices. I support that position and, in fact, have sponsored legislation introduced by my colleagues Senators DORGAN and JEFFORDS regarding international pricing disparities.

While I agree with the intent of the House action, I have concerns that the House provisions do not include the safety mechanisms necessary to ensure that only safe and effective FDA approved medications cross our borders. Perhaps the number one concern mentioned in regard to the reimportation of prescription drugs is the safety of the consumer. As with any product that passes through multiple distribution channels, it is important that a baseline be established to ensure proper handling and storage. This is particularly crucial in maintaining the therapeutic equivalence of prescription drugs.

The amendment we are offering today, which would amend federal law to allow pharmacists, distributors and licensed wholesalers to legally import U.S. FDA approved prescription drugs, addresses this concern by implementing assurances that any prescription drug reimported under this proposal be manufactured, packaged, and labelled according to FDA standards. It includes the essential safety provisions that will allow American consumers to benefit from international price competition for prescription drugs in the safest manner possible.

Many pro-consumer groups such as Families USA, Public Citizen and the National Community Pharmacists Association endorse this amendment saying it is a positive step towards leveling the playing field for prescription drug prices and would save U.S. consumers billions of dollars by allowing the safe reimportation of American-made, FDA-approved prescription drugs.

Of course, the pharmaceutical industry presents many economic and proprietary rationales for price disparities. From price controls to R&D to currency exchange rates, arguments are made that the prices garnered by some pharmaceutical companies are justified in a world where price is a measure of willingness to pay and price elasticity, not compassion or empathy.

Industry representatives have stated it would be profoundly fatal to allow for the reimportation of pharmaceutical drugs from other countries who purchase them at a much lower cost than our nation's senior population as this will create instability in the world's pharmaceutical markets. Personally, I can think of nothing more tragic than charging Americans prices for prescription medications that cost far more than the majority of Americans are able to pay without sacrificing one or more basic needs in their lives.

In my home state of South Dakota, I am conducting prescription drug meetings where constituents are able to communicate their concerns regarding prescription drug prices and express their ability, or perhaps inability, to pay for therapeutic regiments prescribed by their physician. Many of them ask, ''Why are citizens of other countries able to purchase their prescriptions at such lower prices?'' After all the arguments I have heard from the industry on why this is the case, I have yet to hear an acceptable response that I could give.

Perhaps the most disturbing argument that I have heard in the past year came from an industry representative during an Alliance for Health Reform briefing last year. Our colleague, Senator ROCKEFELLER, read a question from the crowd that asked why this individual's brother-in-law got the same medication from the same U.S. manufacturer for a considerable amount less. What I heard in response was shocking. The following quote is taken verbatim from the transcript of that briefing:

> Price discrimination is an economic concept that merely means different people in different markets are charged different things. In this particular case, price discrimination exists between the Canadian market and American market, for lots of reasons: differences in medical practice, how much of the product is sold, difference in exchange rates, different kinds of patent protections, the length and cost in time of distributing drugs and the marketing of drugs, and differences in living standards.
>
> [You] could have used Mexico as your example and would have found that it is less than a third of the price potentially and that's in large part because the standard of living is substantially lower and they can afford so much less. Beyond that, and the other income differences, there is the difference in willingness to pay.

The idea that Americans are charged what they are because they are willing to pay for it, is perhaps the most insensitive of all arguments. Can you imagine measuring the value of someone's life by whether or not they are willing to fill their prescription to control their cholesterol level or pay their rent? As well, the standard of living that exists for most elderly in the United States is precisely the reason

why we are having this hearing today. The simple fact is many seniors are not able to meet all of their basic needs and adhere to their prescription regiment. The number of South Dakotans who, due to their standard of living, can not afford their prescription drugs suggests that the pricing of pharmaceutical goes far beyond reasons based on standard of living and willingness to pay otherwise South Dakotans would have no problem affording their prescription drugs.

Mr. President, I am reminded of a popular fast food chain motto some years back that proclaimed, ''Make a run for the border.'' Who would have ever thought that we would be applying this same motto to the citizens of our country with regard to their prescription drug needs.

The amendment before us is an appropriate response to the discriminatory pricing practices engaged in by much of the pharmaceutical industry. The pharmaceutical industry, year after year, sits at the top of the Fortune Magazine list of most profitable industries in the country. The latest report covering 1999 showed the industry maintained top rankings from previous years: No. 1 in return on revenues, No. 1 in return on assets, No. 1 in return on equity. And the prices they charge to the uninsured in America remain the highest in the world.

For years, Americans have paid the price in more ways than just at the pharmacy counter for the cost of their prescription drugs. Improper prescription drug usage results in thousands of deaths a year though the exact number of seniors included in this number may never be known. How many seniors skip a day's pill or cut them in half in order to stretch their prescription just one more day? I would argue that even one is too many.

We are all working to address the concerns of not only our constituents in our respective home states but for citizens across this nation that rely on prescription drugs for their health care needs. I believe that every Senator here today is deeply concerned about the rising out-of-pocket costs for prescription drugs and hopefully we can address many of these concerns here today with passage of this amendment.

I am pleased to join Senators DORGAN and JEFFORDS in cosponsoring this crucial amendment and urge all of my colleagues to support its immediate passage.

Mrs. MURRAY. Mr. President, I applaud the efforts of the sponsors of this amendment.

As a Senator from a border State, I recognize the frustrations that have brought us to this point.

American consumers must have access to safe, affordable prescription drugs.

Mr. President, I intend to vote for this amendment because I believe we must move this debate forward.

I know that many Americans are facing serious problems because of the cost of prescription drugs.

I hope this amendment will have some impact on the market forces and that we will see some savings as a result.

But, Mr. President, while I will support this amendment, I do have two serious concerns.

First, we must be careful that we don't weaken the high safety standards for drugs in this country.

And second, we should not think for a moment that passing this amendment will mean we have helped senior citizens get access to the drugs they need.

We still must pass a Medicare prescription drug benefit.

I'm concerned that this amendment could draw attention away from the much larger issue of providing a prescription drug benefit through Medicare.

Mr. President, I've spent a lot of time working on this issue.

In fact, back in 1997—as a member of the Senate Health, Education, Labor and Pensions Committee—I examined the drug approval process so that we could enact a responsible and balanced FDA reform bill.

The one lesson I took away from that process is that, while some of the rules for drug approval in this country can be lengthy, they have been successful in ensuring that America's prescription drugs are safe and effective.

We've worked hard to ensure we have safe pharmaceuticals in this country, and I don't know any American who would accept anything less than the safety we have today.

Unfortunately, this amendment does not guarantee that those standards will remain as strong as they must be. That's because other countries have lower standards.

In fact, a recent hearing in the House Commerce Committee clearly illustrated a number of lapses in safety inspection at facilities outside the United States.

I'm concerned that even with ''importation restrictions'' we can't be as confident as we should be of the manufacturing standards used abroad.

This amendment gives us no assurance about the conditions under which the products were packaged, stored, handled, or shipped.

Consumers have no way to determine the potency of the individual units.

We know there are these types of problems with imported drugs today, and I'm concerned that unless this amendment is implemented very carefully, we could magnify those problems.

While I am pleased that the sponsors have made significant improvements from the House-passed amendment on drug reimportation, I'm still concerned that implementation could undermine our faith in the safety of all prescription drugs.

Mr. President, I'm also concerned that there is no guarantee that consumers would reap the benefits that are being suggested.

There is no requirement that the wholesaler or distributor pass the savings on to consumers.

Today, each consumer today often pays a different price for a prescription drug depending upon whether or not they have insurance coverage.

This amendment could simply enrich drug wholesalers at the expense of consumers.

In fact, back in 1999 David Kessler, the former FDA Commissioner, made this point regarding the effect on the consumer when he said:

> . . . prices to ultimate consumers are generally not lowered. . . . Rather, the profits go to the various middlemen, here and abroad, while consumers bear the risk.

Mr. President, the bottom line is that drug re-importation does not guarantee any savings for the consumer.

Mr. President, I have heard many of my colleagues talk about the need for a prescription drug benefit for seniors to ensure affordable access to prescription drugs.

If any of my colleagues think this amendment will meet this objective, they will be disappointed.

This amendment will simply not provide affordable, continuous, comprehensive access to prescription drugs for Medicare beneficiaries.

A prescription drug benefit is not just something to be ''tacked-on'' to Medicare. It has to be a fundamental change in how we provide health care to seniors and the disabled.

Today, prescription drugs are the doctor's office visits of 20 years ago and that must be considered as we work on adding a prescription drug benefit.

Mr. President, I do plan on supporting this amendment with the reservations I've mentioned.

I am hopeful that the regulatory process can address some of these risks, and I believe this amendment will—at the least—address some of the issues of fairness that have been raised.

I just hope that America's seniors are not fooled by this amendment.

No one should claim that—with this amendment—we have addressed the issue of prescription drug costs for seniors.

It is still a job we must undertake, and I hope that this amendment strengthens—rather than weakens—the resolve of the Senate to provide a prescription drug benefit through Medicare.

Mr. JEFFORDS. Mr. President, how much time do I have remaining?

The PRESIDING OFFICER. The Senator has 5 minutes.

Mr. JEFFORDS. Mr. President, we have heard long arguments today about the bill. I think there is general agreement, however, that if it is safe and possible, we should allow our people in this country to be able to take advantage of international competition to bring the cost of pharmaceuticals down to a reasonable rate and to that which other people in this world are able to receive.

Keep in mind, that is what the goal is. Right now, the bill requires the FDA to ''contain such additional safeguards as the Secretary may specify in order to ensure the protection of the public health of patients in the United States.''

I would like to pose a question to the chairman on his amendment. The amendment requires that the section may not operate unless it poses ''no risk.'' Am I correct in assuming that the author's intent is that there be ''no risk'' above that which prevails today?

Mr. COCHRAN. Mr. President, to respond to the question of the distinguished Senator, I answer in the affirmative. Yes.

Mr. JEFFORDS. Mr. President, I accept the amendment.

Mr. COCHRAN. Mr. President, time has been used on this side.

Does the Senator yield back his time?

Mr. JEFFORDS. I yield the remainder of my time.

Mr. COCHRAN. Mr. President, I ask for the yeas and nays on the Cochran amendment.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The question is on agreeing to amendment No. 3927. The clerk will call the roll.

The legislative clerk called the roll.

Mr. REID. I announce that the Senator from Delaware (Mr. BIDEN) and the Senator from New Jersey (Mr. TORRICELLI) are necessarily absent.

I also announce that the Senator from South Carolina (Mr. HOLLINGS) is absent due to a death in the family.

The PRESIDING OFFICER (Mr. VOINOVICH). Are there any other Senators in the Chamber who desire to vote?

The result was announced—yeas 96, nays 0, as follows:

[Rollcall Vote No. 216 Leg.]

YEAS—96

Abraham	Feingold	Lugar
Akaka	Feinstein	Mack
Allard	Fitzgerald	McCain
Ashcroft	Frist	McConnell
Baucus	Gorton	Mikulski
Bayh	Graham	Moynihan
Bennett	Gramm	Murkowski
Bingaman	Grams	Murray
Bond	Grassley	Nickles
Boxer	Gregg	Reed
Breaux	Hagel	Reid
Brownback	Harkin	Robb
Bryan	Hatch	Roberts
Bunning	Helms	Rockefeller
Burns	Hutchinson	Roth
Byrd	Hutchison	Santorum
Campbell	Inhofe	Sarbanes
Chafee, L.	Inouye	Schumer
Cleland	Jeffords	Sessions
Cochran	Johnson	Shelby
Collins	Kennedy	Smith (NH)
Conrad	Kerrey	Smith (OR)
Craig	Kerry	Snowe
Crapo	Kohl	Specter
Daschle	Kyl	Stevens
DeWine	Landrieu	Thomas
Dodd	Lautenberg	Thompson
Domenici	Leahy	Thurmond
Dorgan	Levin	Voinovich
Durbin	Lieberman	Warner
Edwards	Lincoln	Wellstone
Enzi	Lott	Wyden

NOT VOTING—3

Biden	Hollings	Torricelli

The amendment (No. 3927) was agreed to.

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

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

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. The question is on the first-degree amendment.

Mr. JEFFORDS. Mr. President, have the yeas and nays been ordered?

The PRESIDING OFFICER. They have not.

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

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

Mr. JEFFORDS. Mr. President, I ask unanimous consent I have 20 seconds to explain the amendment.

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

Mr. JEFFORDS. The Jeffords amendment, as modified by the COCHRAN amendment——

Mr. WELLSTONE. Mr. President, may we have order in the Chamber.

Mr. BYRD. Mr. President, may we have order in the Chamber.

The PRESIDING OFFICER. There will be order in the Chamber.

The Senator from Vermont.

Mr. BYRD. Mr. President, may we have order in the Chamber.

The PRESIDING OFFICER. The Senate will suspend until there is order in the Chamber.

The Senator from Vermont.

Mr. JEFFORDS. The Jeffords amendment, as modified by the Cochran amendment, now states the bill requires the Food and Drug Administration——

Mr. BYRD. Mr. President, we still do not have order. May the Senate be in order. May we have order.

The PRESIDING OFFICER. The Senate will be order.

The Senator from Vermont.

Mr. BYRD. Mr. President, I insist that there be order in the Senate before the Senator from Vermont proceeds.

I hope Senators will listen to the Chair. The Chair is entitled to that respect, and so is the Senator from Vermont.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, on the critical provision, the bill now requires that the Food and Drug Administration's regulation contain such additional safeguards as the Secretary may specify in order to ensure the protection of the public health of patients in the United States so that it creates no risk above that which prevails today.

I ask for a yes vote and I urge the question.

Mr. BREAUX. Mr. President, is there any time in opposition to the amendment?

The PRESIDING OFFICER. There is none.

Mr. NICKLES. Mr. President, I ask unanimous consent the Senator from Louisiana be recognized.

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

Mr. BREAUX. Thank you very much.

I just make the point, we have a Food and Drug Administration and Health and Human Services Department that already is overburdened. The amendment as is currently pending is going to require them to set up a program in 150 countries around the world to ensure that every warehouse, every manufacturer, every person who handles every drug in their country that is coming to this country be certified as healthy. They cannot do that. That is an impossible burden.

This should not be passed. I think we should vote no.

The PRESIDING OFFICER. The question is on agreeing to amendment No. 3925, as amended. The yeas and nays have been ordered. The clerk will call the roll.

The bill clerk called the roll.

Mr. NICKLES. I announce that the Senator from Mississippi (Mr. LOTT) is necessarily absent.

Mr. REID. I announce that the Senator from Delaware (Mr. BIDEN) and the Senator from New Jersey (Mr. TORRICELLI) are necessarily absent.

I also announce that the Senator from South Carolina (Mr. HOLLINGS) is absent due to death in family.

The PRESIDING OFFICER. Are there any other Senators in the Chamber who desire to vote?—

The result was announced—yeas 74, nays 21, as follows:

[Rollcall Vote No. 217 Leg.]

YEAS—74

Abraham	Feingold	Mikulski
Akaka	Feinstein	Moynihan
Allard	Fitzgerald	Murkowski
Ashcroft	Gorton	Murray
Baucus	Graham	Reed
Bingaman	Grams	Reid
Boxer	Grassley	Robb
Brownback	Gregg	Roberts
Bryan	Harkin	Rockefeller
Burns	Inouye	Roth
Byrd	Jeffords	Sarbanes
Campbell	Johnson	Schumer
Chafee, L.	Kennedy	Sessions
Cleland	Kerrey	Shelby
Collins	Kerry	Smith (NH)
Conrad	Kohl	Smith (OR)
Craig	Kyl	Snowe
Crapo	Landrieu	Specter
Daschle	Lautenberg	Stevens
DeWine	Leahy	Thomas
Dodd	Levin	Thurmond
Domenici	Lieberman	Warner
Dorgan	Lincoln	Wellstone
Durbin	Lugar	Wyden
Edwards	McCain	

NAYS—21

Bayh	Frist	Inhofe
Bennett	Gramm	Mack
Bond	Hagel	McConnell
Breaux	Hatch	Nickles
Bunning	Helms	Santorum
Cochran	Hutchinson	Thompson
Enzi	Hutchison	Voinovich

NOT VOTING—4

Biden	Lott
Hollings	Torricelli

The amendment (No. 3925), as amended, was agreed to.

Mr. JEFFORDS. I move to reconsider the vote.

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

The motion to lay on the table was agreed to.

NOTICE OF INTENT TO MOVE TO SUSPEND PARAGRAPH 4 OF RULE XVI

Mr. ASHCROFT. Mr. President, in accordance with Rule V of the Standing Rules of the Senate, I hereby give notice in writing that it is my intention to move to suspend paragraph 4 of rule XVI for the purpose of considering title IV of H.R. 4461, making appropriations for Agriculture, Rural Development, Food and Drug Administration and Related Agencies programs for the fiscal year ending September 30, 2001, and for other purposes, as amended on July 18, 2000, by unanimous consent. (The UC is as follows: That all after the enacting clause of H.R. 4461 be stricken and the text of S. 2536 with a modified division B be inserted in lieu thereof, and that the new text be treated as original text for the purpose of further amendment, and that no point of order be waived.)

At the request of the Senator from Nevada (Mr. REID) the following statement was ordered to be printed in the RECORD.

● Mr. BIDEN. Mr. President, because of the sudden death of the former mayor of Wilmington, Delaware, who was a close friend of mine, I had to return to Delaware today directly after the funeral for Senator Pastore. Consequently, I was necessarily absent for the roll-call votes on Senate amendments No. 3925 and No. 3927 to the Agriculture Appropriations bill. Had I been present, I would have voted yes on both amendments.

The high cost of pharmaceuticals in this country relative to the cost of the same drugs in nearby countries, such as Canada and Mexico, is a major irritant to many seniors struggling to make ends meet in the face of fixed incomes and high expenses for medications. Reimportation of drugs from foreign countries, although it may lower prescription drug costs for Americans, should not be permitted if it will jeopardize the health of this country's citizens. The potential effect of these provisions to reduce pharmaceutical research and development in the U.S. is an unknown but important factor. The controversy over these provisions serves to emphasize once again the need to expand Medicare to provide prescription drug insurance coverage for seniors and the disabled.●

The PRESIDING OFFICER. The Senator from Alabama.

Mr. SHELBY. Mr. President, I ask unanimous consent to speak as in morning business for 5 minutes.

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

REMEMBERING SENATOR PAUL COVERDELL

Mr. SHELBY. Mr. President, I rise today to join some of my fellow Senators in remembering the extraordinary life and service of our friend and colleague, PAUL COVERDELL.

It is a somber day in the Senate Chamber, as we deal with this loss. PAUL COVERDELL served the people of Georgia with distinction for over 30 years. His passing leaves a significant mark on the many lives he has touched over his lifetime. On behalf of myself and my wife Annette, I offer my condolences to PAUL'S wife Nancy and his family.

Anyone who dealt with PAUL COVERDELL over the years came to respect him. He was honest, loyal, and dedicated to public service. It was these characteristics that PAUL brought to the table every day in his life. PAUL'S vision as a legislator and commitment to the principles and values for which he truly believed were demonstrated time after time in this Chamber. His commitment to improving education in the U.S. sets a high standard for all public officials. His hard work in the Republican leadership and his vision of a prosperous future for all Americans deserves tremendous praise.

Personally, it was truly my privilege to know and work with PAUL over the years. We sat next to each other recently in the Senate, as can be seen.

He will be remembered as a dedicated American who gave much of his life in service to his Nation. I offer my thoughts and prayers to those close to PAUL in this difficult time, especially to his family.

Mr. COCHRAN. Mr. 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. FITZGERALD. 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. FITZGERALD. Mr. President, I ask unanimous consent to speak for 5 minutes as in morning business.

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

Mr. FITZGERALD. Mr. President, I rise today to deliver some remarks upon the death of our beloved colleague, PAUL COVERDELL.

It is no exaggeration to say that the whole Senate is in a state of shock that we no longer have PAUL with us. Just last week, Senator COVERDELL was among us on the Senate floor debating legislation, visiting with us in the Cloakroom, speaking up in our weekly Republican conference. And now, only a short period later, he is no longer with us. To my knowledge, PAUL never seemed to have had any health problems. He certainly seemed fine last week.

My last remembrance of him is just how happy he was when we adjourned on Friday afternoon after we passed that landmark legislation repealing the death tax. I guess the fact that PAUL is no longer with us reminds us all that we need to keep life in perspective.

I first met Senator COVERDELL when I was first campaigning for the Senate 2 or 3 years ago. From that first time I met him, I came away with a very powerful impression that he was a most sincere and decent and friendly person. In all my dealings with him in my year and a half in the Senate, that impression never changed. PAUL was always in a good, cheerful mood. He was always positive and upbeat. I never once saw him raise his voice or get angry at anybody. He was unfailingly polite and courteous at all times and to everyone. He was the quintessential southern gentleman and a delight to know.

In the Senate, we debate issues of great moment to our country: war and peace, the economy, education policy. I guess it is sometimes the little, personal, seemingly inconsequential gestures of friendship that one remembers. I used to sit next to Senator COVERDELL every week in our Wednesday Republican luncheons. I got to know PAUL that way, not only as a colleague but as a person. Every week PAUL would gently rib me for eating my main course before I ate my salad. Week after week he would comment on that. I think finally he just concluded that that was a peculiar habit of midwesterners.

I will always remember the smile and the twinkle in PAUL COVERDELL's eyes, and I won't easily forget him or my friendship with him.

PAUL, I am proud to have served with you. I am going to miss you. We are all going to miss you. You enriched this Senate, the State of Georgia, and the whole country by your service. Our thoughts and prayers are with you and your wonderful wife Nancy and your family. May God bless you and keep you.

The PRESIDING OFFICER. The Senator from Illinois.

Mr. DURBIN. Mr. President, I ask unanimous consent to speak for up to 5 minutes as in morning business.

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

Mr. DURBIN. Mr. President, I join my colleague from Illinois in paying tribute to our fallen colleague, Senator PAUL COVERDELL.

I have been in the Senate for 4 years and have worked with many colleagues on both sides of the aisle. I agree completely with Senator FITZGERALD: Senator COVERDELL brought to this floor a certain dignity and demeanor to which we all aspire. He was a person of good humor. I think it may be difficult for many people who follow the debates in the Senate to believe that a Democrat who believes very strongly in his party and a Republican who believes very strongly can be engaged in a hot debate on the floor of the Senate and then, as soon as the debate is over, meet each other in the corridor or the well or at another time and be friends. That was the case with PAUL COVERDELL.