Nets coach Byron Scott has led the Nets to the most wins in franchise history. The Nets, led by their superb point guard Jason Kidd, lost a tough 6-game series to the Spurs, who are undoubtedly championship material. But the Nets are in that class, as well. I hope that this team will stay intact and continue on its quest to winning an NBA title.

New Jersey is a haven for great professional sports teams, and on behalf of the whole State of New Jersey, I congratulate the Devils and Nets and wish both teams the best of luck in the future.

Mr. CORZINE. Mr. President, I ask unanimous consent the resolution and preamble be agreed to en bloc, the motion to reconsider be laid upon the table, and any statements relating thereto be printed in the RECORD, without intervening action or debate.

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

The resolution (S. Res. 176) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 176

Whereas the New Jersey Devils defeated the Anaheim Mighty Ducks 3-0 on June 9, 2003 to win the Stanley Cup in 7 games;

Whereas the New Jersey Nets won the National Basketball Association (NBA) Eastern Conference Championship and reached the NBA Finals for the second consecutive year before losing a closely contested series to the San Antonio Spurs in 6 games;

Whereas the Devils won their third Stanley Cup in the last 9 years, as many as any other team in that period;

Whereas the Devils and Nets have won over the State of New Jersey (where the first professional basketball game took place in 1898) with their skillful offenses and stifling defenses;

Whereas the Devils and Nets have come to epitomize the never-say-die spirit of the people of New Jersey and have both become an important part of the State and its identity;

Whereas the fans of both New Jersey teams have shown the same spirit and determination in support of their teams and deserve commendation for their loyalty in this season's playoffs;

Whereas the Devils had a 12 win, 1 loss record at the Continental Airlines Arena, the most home wins in the history of the Stanley Cup playoffs;

Whereas the Nets swept both the Boston Celtics and the Detroit Pistons during a 10-game winning streak in this season's playoffs;

Whereas Pat Burns, head coach of the New Jersey Devils, has enjoyed the kind of success that has eluded so many other great coaches, winning his first Stanley Cup title in his first season as head coach of the Devils;

Whereas Byron Scott, head coach of the New Jersey Nets, has guided the Nets to the most wins in franchise history, and has led them to the NBA Finals in 2 of his 3 seasons as head coach;

Whereas Martin Brodeur, regarded by many as the premier playoff goaltender in hockey history, recorded 3 shutouts in the Finals, giving him 7 shutouts during this season's playoffs and 20 during his illustrious postseason career;

Whereas the outstanding playmaking abilities of Jason Kidd, widely regarded as the best point guard in the NBA, has been key to the success of the Nets during the past 2 seasons;

Whereas the outstanding play of Ken Daneyko, Martin Brodeur, Scott Stevens, Sergei Brylin, and Scott Neidermayer has been a vital part of each of the 3 Stanley Cup Championships enjoyed by the New Jersey Devils organization;

Whereas Jason Kidd has superb teammates in Brandon Armstrong, Jason Collins, Lucious Harris, Richard Jefferson, Anthony Johnson, Kerry Kittles, Donny Marshall, Kenyon Martin, Dikembe Mutombo, Rodney Rogers, Brian Scalabrine, Tamar Slay, and Aaron Williams, allowing the team to win its second consecutive NBA Eastern Conference championship; and

Whereas the name of each Devils player will be inscribed on the Stanley Cup, including Tommy Albelin, Jiri Bicek, Martin Brodeur, Sergei Brylin, Ken Daneyko, Patrik Elias, Jeff Friesen, Brian Gionta, Scott Gomez, Jamie Langenbrunner, John Madden, Grant Marshall, Jim McKenzie, Scott Niedermayer, Joe Nieuwendyk, Jay Pandolfo, Brian Rafalski, Pascal Rheaume, Mike Rupp, Corey Schwab, Richard Schmelik, Scott Stevens, Turner Stevenson, Oleg Tverdovsky, and Colin White: Now, therefore, be it

Resolved, That the Senate congratulates—

(1) the New Jersey Devils for their determination, perseverance, and excellence in winning the National Hockey League's 2003 Stanley Cup; and

(2) the New Jersey Nets for their success during the 2002-2003 NBA season.

HONORING LARRY DOBY

Mr. LAUTENBERG. Mr. President, I rise in sorrow because baseball lost a legend, African Americans lost a pioneer, and I lost a good friend. I went to high school with Larry Doby at Eastside High School in Paterson, NJ, and watched as he amassed records that were beyond comprehension for most people.

He had four All-State letters. He played basketball, baseball, football, and he ran track well enough to earn an All-State letter in a big State like New Jersey, with that population. He was not only an exciting player to watch on the field, he was a good man. His five children and the whole country will miss him greatly.

Few people realize that Larry began his groundbreaking athletic career in 1943 as the first African-American to play in the American Basketball League for the Paterson Panthers. He then moved on to baseball, playing for the Newark Eagles of the Negro National League. After returning from his service in the Navy for two years, Larry hit .414 with 14 home runs in his final season in Newark, NJ.

It was on July 5, 1947, just 11 weeks after Jackie Robinson broke the color barrier in major league baseball, that Larry Doby signed a contract with the Cleveland Indians of the American League. He was the first African-American player in the American League.

Larry had no intention or desire to become an important part of history. When Indians owner Bill Veeck predicted to Larry that he would ''be part of history,'' Larry replied, ''I had no notions about that. I just wanted to play baseball.''

And play baseball he did, and quite well. Larry was an All-Star 7 times in his 13-year career, and he helped the Indians win the World Series in 1948 with a home run in Game 4. He hit at least 20 home runs in 8 straight seasons.

Larry went on to become the second African-American manager of a major league team taking the helm of the Chicago White Sox in 1978. He was also the director of community relations for the New Jersey Nets in the late 1970s, encouraging the development of youth programs in urban New Jersey.

It was not easy for Larry, few things this important are. He was harassed by opposing players and fans. He was forced to eat in separate restaurants, to sleep in separate hotels. Some of his own teammates would not even shake his hand. But he pressed on, and we're a better country for it.

Larry said it best in a speech after his career had ended. He said:

We can see that baseball helped make this a better country. We hope baseball has given (children) some idea of what it is to live together and how you can get along, whether you be black or white.

When historians take note of the great contributions made by citizens of the State of New Jersey, certainly the name of Larry Doby should be included. He is at the top of that long list in my mind.

Mr. CORZINE. Mr. President, let me congratulate my colleague from New Jersey for bringing up this discussion of Larry Doby, who is really a national hero. I commend anyone to read the reports in today's newspapers about his career and the evolution of how African Americans ascended to the role they rightfully should have received in American baseball and American life in general. He was a hero to all of us. I am thankful he was remembered by my senior colleague.

PRESCRIPTION DRUG AND MEDICARE IMPROVEMENT ACT OF 2003—Continued

AMENDMENT NO. 946

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

Mr. DORGAN. I send an amendment to the desk on behalf of myself, Ms. STABENOW, Mr. JEFFORDS, Ms. SNOWE, Mr. JOHNSON, Mr. LEVIN, Mrs. BOXER, Mr. PRYOR, and Mr. FEINGOLD. I ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from North Dakota [Mr. DORGAN], for himself, Ms. STABENOW, Mr. JEFFORDS, Ms. SNOWE, Mr. JOHNSON, Mr. LEVIN, Mrs. BOXER, Mr. PRYOR and Mr. FEINGOLD, proposes an amendment numbered 946.

Mr. DORGAN. I ask unanimous consent the reading of the amendment be dispensed with.

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

(The amendment is printed in Today's RECORD under ''Text of Amendments.'')

AMENDMENT NO. 947 TO AMENDMENT NO. 946

Mr. FRIST. Mr. President, I send a second-degree amendment to the desk and ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report the amendment.

The legislative clerk read as follows:

The Senator from Tennessee [Mr. FRIST], FOR MR. COCHRAN, for himself, Mr. FRIST, Mr. BREAUX and Mr. SANTORUM, proposes an amendment numbered 947 to amendment No. 946.

Mr. FRIST. I ask unanimous consent the reading of the amendment be dispensed with.

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

The amendment is as follows:

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

At the appropriate place, insert the following:

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

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

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

Mr. FRIST. Mr. President, the amendment I send to the desk is sent on behalf of Senators COCHRAN and BREAUX. It addresses an issue that we have addressed on the Senate floor this evening. It has to do with the safety aspects of the underlying Dorgan amendment.

As everyone in the Chamber knows, we have spent the last several days addressing the important issue of adding prescription drugs as a benefit to our Medicare Program today and at the same time strengthening and improving Medicare.

Just a few minutes ago, the Senate passed legislation that will speed access of generics to the market, really making drugs overall, I believe, more affordable and more accessible to all Americans. This merely builds on the rule announced last week by the administration that will enhance the overall process with generic drugs by limiting brand drug manufacturers to only one 30-month stay. But in the midst of the overall bipartisan progress to enhance access to and improve the affordability of prescription drugs, once again this proposal or proposals to look at importation of drugs from Canada have resurfaced.

Very briefly, the Senate has debated this issue several times before. The legislation itself is already on the books. Congress passed, this body passed, indeed President Clinton signed into law the Medicine Equity and Drug Safety Act of 2000, which allows for the importation of pharmaceuticals into the United States. However, the law provided that the Secretary of Health and Human Services had to demonstrate that its implementation, No. 1, would impose no risk to the public's health and safety; No. 2, would result in significant reduction in the cost of covered products to the American consumer.

Since that time, two Health and Human Services Secretaries, one a Democrat and one a Republican, could not demonstrate safety or cost savings from importation.

I reiterate, the law on the books is such that safety concerns have been expressed and, indeed, two HHS Secretaries could not demonstrate safety or cost savings from importation; therefore, the law has not been implemented.

In addition, the FDA, two separate Secretaries of Health and Human Services, the U.S. Customs Service, the Drug Enforcement Administration, and almost every former FDA Commissioner have consistently and repeatedly opposed these proposals and told us they cannot ensure that importing drugs is safe.

I ask unanimous consent to have printed in the RECORD a letter dated June 19 to Senator COCHRAN from Mark B. McClellan, Commissioner of Food and Drugs.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION,
Rockville, MD, June 19, 2003.

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

DEAR SENATOR COCHRAN. This letter is in response to your request for information from the Food and Drug Administration (FDA) on the importation of prescription drugs into the United States from foreign countries. It is currently illegal to import prescription drugs from foreign countries into the United States, but Congress has been debating whether to amend the law to allow such products to flow into the United States and become part of the drug supply. The FDA has serious concerns about proposals that would open America's borders to a stream of imported prescription drugs for which FDA cannot assure safety, effectiveness or quality.

We share with Congress deep concern for senior citizens and other patients who have difficulty paying for their prescription drugs. As I am writing this, the Congress is working towards enactment of landmark legislation to provide a prescription drug benefit that will enable millions of America's seniors to receive coverage for their drugs in Medicare. In addition, under my leadership, FDA has taken a number of significant steps to provide greater access to affordable prescription medications that are safe and effective. These steps include new initiatives to accelerate approval of innovate new medical procedures and drug therapies, changes to our regulations to reduce litigation that has been shown to unnecessarily delay access to more affordable generic drugs and proposals to increase Agency resources for the review and approval of generic drugs—products that are often far less expensive than brand name products.

The overall quality of drug products that consumers purchase from United States pharmacies is very high, and the American consumer can be confident that the drugs they use are safe and effective. However, a growing number of Americans are obtaining their prescription medications from foreign sources and when they do so, consumers are exposing themselves to a number of potential safety risks that must be ignored. In FDA's experience, may drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.—approved prescription drugs are, in fact, of unknown quality. These outlets may dispense expired, subpotent, contaminated or counterfeit, product, the wrong or a contraindicated product, an innocent dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and important information regarding dosage and side effects may not be available. In addition, the drugs may not have been packaged and stored under proper conditions to avoid degradation.

Some have suggested that limiting each drug imports to those from Canada would address these potential safety concerns. But FDA cannot guarantee the safety of Canadian drugs. Additionally, Canadian health officials have made clear in public statements that they can provide no assurance as to the safety and authenticity of drugs products shipped to Canada for resale in other countries. In fact, the Agency has concrete examples of drugs purchased from Canadian pharmacists that violate safety provisions established by FDA and the state pharmacy authorities, and we had been instances of internet sites that offer to sell FDA-approved drugs, but upon further investigations we have determined that the drugs they sell are adulterated, sub-potent, or counterfeit.

The relatively ''closed'' regulatory system that we have in this country has been very successful in preventing unapproved or otherwise unsafe drug products from entering the U.S. stream of commerce. Legislation that would establish other distribution routes for prescription drugs, particularly where those routes traverse a U.S. border, creates a wide inlet four counterfeit drugs and other dangerous products that are potentially injurious to the public health and that pose a threat of our nation's drug apply.

In sum, while we strongly support efforts to make prescription drugs more affordable and have taken several recent steps to accelerate access to more affordable, safe and effective prescription drugs, I remain concerned that provisions to legalize importation of prescription drug products would greatly erode the ability of the FDA to ensure the safety and efficacy of the drug supply. At the time, the Agency simply cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA, or that they are safe and effective.

Sincerely,
MARK M. MCCLELLAN, MD., PH.D.
Commissioner of Food and Drugs.

Mr. FRIST. I will read two sentences from the letter, the entire text of which will be in the RECORD. It says in the first paragraph:

The FDA has serious concerns about proposals that would open America's borders to a stream of imported prescription drugs for which FDA cannot assure safety, effectiveness or quality.

In the last paragraph, one other sentence:

I remain concerned that provisions to legalize importation of prescription drug products would greatly erode the ability of the FDA to ensure the safety and efficacy of the drug supply.

One final point: Canadian health officials just very recently made it clear

that they cannot, and they indeed will not, vouch for the safety of prescription drugs imported from Canada to the United States. Thus, I would argue that there is no need for Congress to pass yet another piece of legislation when a law is already on the books, and doing so only further threatens the safety of the American public, particularly in this time of sensitivity to the dangers of possible biological, chemical, or other terrorist attacks.

Relying on medicines that have been imported from other countries, if that were the case, I believe would lead to seniors and individuals with disabilities opening themselves to unnecessary threats in particular, especially in light of the current bill, where we are giving them access to prescription drugs they simply did not have before. Obtaining drugs from other countries has a certain appeal to seniors who simply have no access to any prescription drugs at all, but the underlying premise of the bill on the Senate floor is that we are going to improve that access to each and every senior, in terms of having better access to those prescription drugs.

I yield the floor.

Mr. COCHRAN. Mr. President, I support the effort to provide prescription drugs to Medicare beneficiaries and to lower the costs of medicines for all Americans. Today's therapies are too valuable, in terms of improving health and quality of life, for Medicare beneficiaries not to have prescription drug coverage.

However, we must not create new opportunities for counterfeit products, or products that have been tampered with, or products of unknown origin to be brought into this country.

The amendment I have offered requires the Secretary of Health and Human Services to certify that the reimportation of drug products will pose no additional risk to the public health and safety and will result in a significant reduction in the cost of covered products to the American consumer.

If reimportation is safe and will reduce costs, this amendment should not pose a problem. However, these are genuine concerns that reimportation may not be safe for Americans.

We have had this issue before the Senate on two previous occasions. Three years ago during consideration of the annual appropriations bill for the Department of Agriculture, Food and Drug Administration and related agencies, a similar amendment was added to the bill. The Senate unanimously approved that amendment.

Then again last July, when we were considering the Greater Access to Pharmaceuticals Act, a similar amendment was offered that limited reimportation to products from Canada. Again, the Senate, by a vote of 99–0 approved this safeguard as part of the legislation that passed the Senate. The House did not act upon this legislation.

In both these cases the Senate has adopted this amendment by a unanimous vote both times for an obvious reason: the safety of the American consumer must be protected.

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

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

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

THE SECRETARY OF
HEALTH AND HUMAN SERVICES,
Washington, DC, December 26, 2000.

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

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

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

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

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

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

Third, the reimportation system has both authorization and funding limitations. The law requires that the system end five years after it goes into effect. This ''sunset'' provision will likely have a chilling effect on private-sector investment in the required testing and distribution systems because of the uncertainty of long-term financial returns. In addition, the public benefits of the new system are diminished since the significant investment of taxpayer funds to establish the new safety monitoring and enforcement functions will not be offset by long-term savings to consumers from lower priced drugs.

Finally, Congress appropriated the $23 million necessary for first year implementation costs of the program but did not without funding core and priority activities in FDA, such as enforcement of standards for internet drug purchase and post-market surveillance activities. In addition, while FDA's responsibilities last five years, its funding authorization is only for one year. Without a stable funding base, FDA will not be able to implement the new program in a way that protects the public health.

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

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

Sincerely,

DONNA E. SHALALA.

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

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

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

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

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

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

DEAR SENATOR JEFFORDS: I am writing to follow up on my earlier response to your letter January 31, 2001, co-signed by fifteen of

your colleagues, regarding the Medicine Equity and Drug Safety Act of 2000 (MEDS Act).

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

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

SAFETY CONCERNS

After a thorough review of the law, FDS has concluded that it would be impossible to ensure that the MEDS Act would result in no loss of protection for the drugs supplied to the American people. As you know, the drug distribution system as it exists today is a closed system. Most retail stores, hospitals, and other outlets obtain drugs either directly from the drug manufacturer or from a small number of large wholesalers. FDA and the states exercise oversight of every step within the chain of commercial distribution, generating a high degree of product potency, purity, and quality. In order to ensure safety and compliance with current law, only the original drug manufacturer is allowed to reimport FDA-approved drugs.

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

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

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

COST SAVINGS

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

CONCLUSION

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

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

Sincerely,

TOMMY G. THOMPSON.

Mr. COCHRAN. Mr. President, just this week, Mark McClellan, Commissioner of the Food and Drug Administration, has written to reiterate this point. I ask unanimous consent that Dr. McClellan's letter of June 19, 2003 be printed in the RECORD.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES, PUBLIC HEALTH SERVICE, FOOD AND DRUG ADMINISTRATION,

Rockville, MD, June 19, 2003.

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

DEAR SENATOR COCHRAN: This letter is in response to your request for information from the Food and Drug Administration (FDA) on the importation of prescription drugs into the United States from foreign countries. It is currently illegal to import prescription drugs from foreign countries into the United States, but Congress has been debating whether to amend the law to allow such products to flow into the United States and become part of the drug supply. The FDA has serious concerns about proposals that would open America's borders to a stream of imported prescription drugs for which FDA cannot assure safety, effectiveness or quality.

We share with Congress deep concern for senior citizens and other patients who have difficulty paying for their prescription drugs. As I am writing this, the Congress is working towards enactment of landmark legislation to provide a prescription drug benefit that will enable millions of America's seniors to receive coverage for their drugs in Medicare. In addition, under my leadership, FDA has taken a number of significant steps to provide greater access to affordable prescription medications that are safe and effective. These steps include new initiatives to accelerate approval of innovate new medical procedures and drug therapies, changes to our regulations to reduce litigation that has been shown to unnecessarily delay access to more affordable generic drugs, and proposals to increase Agency resources for the review and approval of generic drugs—products that are often far less expensive than brand name products.

The overall quality of drug products that consumers purchase from United States pharmacies is very high, and the American consumer can be confident that the drugs they use are safe and effective. However, a growing number of Americans are obtaining their prescription medications from foreign sources and when they do so, consumers are exposing themselves to a number of potential safety risks that must not be ignored. In FDA's experience, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.—approved prescription drugs are, in fact, of unknown quality. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and important information regarding dosage and side effects may not be available. In addition, the drugs may not have been packaged and stored under proper conditions to avoid degradation.

Some have suggested that limiting such drug imports to those from Canada would address these potential safety concerns. But FDA cannot guarantee the safety of Canadian drugs. Additionally, Canadian health officials have made clear in public statements that they can provide no assurance as to the safety and authenticity of drug products shipped to Canada for resale in other countries. In fact, the Agency has concrete examples of drugs purchased from Canadian pharmacists that violate safety provisions established by FDA and by state pharmacy authorities, and we have seen instances of internet sides that offer to sell FDA-approved drugs, but upon further investigation we have determined that the drugs they sell are adulterated, sub-potent, or counterfeit.

The relatively ''closed'' regulatory system that we have in this country has been very successful in preventing unapproved or otherwise unsafe drug products from entering the U.S. stream of commerce. Legislation that would establish other distribution routes for prescription drugs, particularly where those routes traverse a U.S. border, creates a wide inlet for counterfeit drugs and other dangerous products that are potentially injurious to the public health and that pose a threat to the security of our nation's drug supply.

In sum, while we strongly support efforts to make prescription drugs more affordable and have taken several recent steps to accelerate access to more affordable, safe and effective prescription drugs, I remain concerned that provisions to legalize importation of prescription drug products would greatly erode the ability of the FDA to ensure the safety and efficacy of the drug supply. At this time, the Agency simply cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA, or that they are safe and effective.

Sincerely,

MARK B. MCCLELLAN, M.D., Ph.D.,
Commissioner of Food and Drugs.

Mr. COCHRAN. Mr. President, it would seem prudent that the safeguards we have adopted twice, by unanimous votes, should also be applied to

this proposal. That is why I offer this amendment.

We should be certain that any change we make results in no less protection in terms of the safety of the drugs supplied to the American people and will indeed make prescription drugs more affordable. Liberalization of protections that are designed to keep unsafe drugs out of this country, especially considering the terrorist threats we face now, should occur only if the necessary safeguards are in place.

This amendment will ensure that the concerns of the last two administrations regarding the safety and cost-effectiveness are addressed prior to the implementation of this proposal.

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

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

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

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

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

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

More recently, in letter dated November 25, 2002, Asa Hutchinson, then Administrator of the Drug Enforcement Administration at the US Department of Justice, reiterated this position with respect to any type of proposal that might limit the ability of the FDA to inspect and assure the safety and compliance with Federal law of products that would be brought back into the United States.

I ask unanimous consent that Administrator Hutchinson's letter be printed in the RECORD.

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

U.S. DEPARTMENT OF JUSTICE,
DRUG ENFORCEMENT ADMINISTRATION,
Washington, DC, November 25, 2002.

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

DEAR SENATOR COCHRAN: The purpose of this letter is to respond to your inquiry regarding the position of the Drug Enforcement Administration (DEA) with respect to any proposal to limit the authority of the Food and Drug Administration (FDA) to inspect shipments of prescription drugs that are imported into the United States.

In general, DEA opposes any such limitations because they would hinder the ability of federal law enforcement officials to ensure that drugs are imported into the United States in compliance with long-standing federal laws designed to protect the public health and safety. Since its creation in 1906, the FDA has served as the American public's watchdog to ensure safe, medically approved prescription drugs. In undermining the FDA's ability to do its job, we risk undermining the public health and safety.

First, a brief explanation of DEA's role in this issue: DEA's statutory authority is limited to controlled substances (drugs of abuse). DEA is the primary agency responsible for enforcement of the Controlled Substances Act (CSA). Controlled substances can be viewed as a subset of prescription drugs. All legal (pharmaceutical) controlled substances are prescription drugs (e.g., OxyContin, Percocet, Demerol, Valium). However, most prescription drugs are not controlled substances (e.g., Claritin, Prozac, Viagra, erythromycin, insulin). Nonetheless, for the following reasons, limiting FDA's authority to inspect shipments of imported prescription drugs could potentially lead to an increase in the illegal importation of controlled substances into the United States.

DEA is currently facing enforcement challenges on many fronts with respect to controlled substance importation and smuggling. Several foreign countries have been identified as the source of a large amount of controlled substances that have been illegally imported. Additionally, the United States Customs Service (USCS) inspectors on the southern and northern borders must determine whether each traveler entering the United States with a drug is complying with the Federal Food, Drug and Cosmetic Act (FDCA) and the CSA. Information obtained from the USCS indicates that there is an increased volume of prescription drugs being imported through the mail as a result of the Internet. Sometimes the drugs are counterfeit; other times the drugs are real drugs, including controlled substances, sold without the required prescription. Although the CSA clearly prohibits importation of controlled substances in this manner, the FDA and USCS must inspect each package to ascertain the contents. Identifying a drug by its appearance and labeling is not an easy task. From a practical standpoint, inspectors cannot examine drug products and accurately determine the identity of such drugs or the degree of risk they pose. This is particularly true since these drugs are often intentionally mislabeled. Persons who are willing to illegally ship controlled substances to the United States are unlikely to honestly label their packages as containing controlled substances,

Therefore, in order to support DEA's efforts to curtail the illegal importation of controlled substances into the United States, it is crucial that FDA retain its authority to inspect all packages that purport to contain ''prescription drugs.'' If federal law prohibited the FDA from inspecting foreign shipments of prescription drugs, making an exception in the law that would allow the FDA to inspect controlled substance shipments would serve little purpose. The foreign shipper could simply label the package ''prescription drugs—noncontrolled substances'' and the FDA would be powerless to take any investigative steps or to assist the DEA in intercepting these illegal shipments.

I trust that this has been helpful in explaining he DEA's position on this issue. Please let me know if there is anything else I may do to assist you in the future.

Sincerely,

ASA HUTCHINSON,
Administrator.

Mr. COCHRAN. Mr. President, William Hubbard, FDA's Associate Commissioner for Policy and Planning, and the FDA's authority on the topic of reimportation of pharmaceuticals, has testified a number of times before Congress regarding the dangers of reimported products and the inability of the U.S. regulatory system to assure the safety of products brought into this country. Most recently, this month before the House Committee on Government Reform, Dr. Hubbard testified

(T)he overall quality of drug products that consumers purchase from United States pharmacies is very high. The public can be confident that the drugs they use are safe and effective. However, FDA cannot offer the same assurances to the public about the safety of drugs they buy from foreign sources.

There are a number of reasons why these products are not safe. Counterfeiting of drugs is common throughout the world and the transshipment of these counterfeit products through Canada is one of the most serious dangers.

A recent example of the dangers of counterfeiting is the FDA alert issue on May 23 of this year regarding counterfeit version of the cholesterol lowering agent, Lipitor. This product is taken by over 18 million Americans. This investigation is currently ongoing and FDA is still trying to determine the extent of this case.

In March, the FDA discovered counterfeit versions of the drug Procrit which had been contaminated with bacteria or in some cases the product contained no active ingredient.

There are numerous other examples. It is amazing the number of drugs that are now on the shelves in drugstores in America that are counterfeit and no one knows about it. These are difficulties that we now face. The proposal of this amendment by the Senator from North Dakota will further relax our capability to find illegal drugs, and to find those drugs that are dangerous

that are being brought into this country.

It will create a new opportunity for transshipping drugs from all over the world into our country which will be a great danger to the citizens of our country.

The National Association of Boards of Pharmacy, the body that represents the state boards of pharmacy in all 50 United States, as well as eight Canadian Provinces has stated in March of this year

> Of utmost concern is the lack of ability to determine the actual country of origin. An order for what is purported to be a Canadian drug may never be filled by a legitimate Canadian pharmacy with a Canadian drug or even be filled in Canada.

NABP, representing the boards that regulate the practice of pharmacy, has also recently joined the Canadian National Association of Pharmacy Regulatory Authorities in endorsing a statement opposing illegal importation of prescription drugs.

The Canadian government itself has stated publicly that drug products shipped to Canada for resale in other countries do not fall under the Canadian regulatory system, and they can provide no assurance as to the safety or authenticity of such drugs.

The conditions contained in my amendment, which would be added to the legislative proposal before the body, are the same as those previously adopted twice by this Senate. They were adopted both times by unanimous votes of the Senate.

I ask my colleagues to again support this amendment.

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. DORGAN. Mr. President, I was interested in the statement by the majority leader. This, of course, is not the amendment the Senate previously considered. It is not the amendment to which the Senate previously agreed. It is not the provision of law that the Secretary of Health and Human Services has refused to implement in two administrations. It is not that at all.

First, we will sort out the facts.

Let me make a case for the amendment itself. My colleague just won a debate we weren't having. His debate is about a piece of legislation the Senate passed a couple of years ago. I supported that, and I believe the Health and Human Services Secretary and the FDA made a mistake in not implementing it. Nonetheless, that was all a couple of years ago.

Yes, this particular amendment we offered deals with the reimportation of prescription drugs, but it deals only with the reimportation of prescription drugs from the country of Canada—only from the country of Canada.

The Senate previously addressed this issue of reimportation in 2000 by saying reimportation from other countries—as long as it was an FDA-approved drug and brought here under conditions of safety—would be appropriate. We have already said the HHS and FDA did not implement the previous legislation. But now, we will narrow this legislation very dramatically and provide reimportation only from the country of Canada.

I will explain why that is important.

First, miracle drugs offer no miracles to those who cannot afford them. If we don't do something to make drugs more affordable, seniors in the country lose, and others who need prescription drugs and can't afford them lose.

We should and must put some downward pressure on drug prices.

I understand the pharmaceutical manufacturers do not like that. I understand why they resist it. If I were in their position, I would certainly resist it as well.

I don't try to paint with a dark brush all of those who are on the other side of the issue. I think the pharmaceutical industry does many good things. They do a lot of very important research, some of which is original and some of which they take from the National Institutes of Health. They create medicines that are very important for the American people.

I also said the other day that some of the pharmaceutical companies have been providing free and discounted drugs to the lowest income Americans. Five and a half million people have benefitted from free medicines from American drug companies. I commend those companies. I don't have the names of all the companies. Good for them. It is a step in the right direction. They ought to be commended and saluted for their program to help the lowest income Americans.

But the other issue is the larger one of the price of prescription drugs. The fact is, we need to try to do something that puts some downward pressure on prices. Let me describe, if I might, what the problem is. Let me do it with some bottles of medicine.

I ask unanimous consent to be able to show some bottles of medicine on the Senate floor. These are empty bottles.

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

Mr. DORGAN. This is Zocor. A very famous football coach advertises this at halftime at football games. He says he takes Zocor. It is quite a good medicine, I am sure. These are two bottles for Zocor—one from the United States and one from Canada. The same pill is put in the same bottle, manufactured in the same place, by the same company. In both bottles is an FDA-approved drug. The only difference is, when that medicine is sold in the United States to U.S. consumers, it costs $3.03 per tablet. In Canada, the same pill, in the same bottle, made by the same company, cost $1.12 cents per tablet—$3 versus $1. The same pill, same company, different countries. That is Zocor.

This is a drug called Lipitor. It has the same purpose as Zocor—to reduce cholesterol. You can see that it is sold in the United States and in Canada. These are bottles from each country. They are identical bottles, made by the same company, again only the cost is different—$1 per tablet for the Canadians, and $1.86 for the U.S. consumer. The same drug, same pill, manufactured in the same FDA-approved plant, put in the same bottle, but different prices.

This is Vioxx used for arthritis. As you can see, same pill, made by the same company, put in identical bottles. The difference? It costs $2.20 if you buy it in the United States. If you are a Canadian customer, it costs 78 cents for the same tablet—$2.20 versus 78 cents for the same medicine.

Let me use one more example, if I might.

This is Prevacid: Those who are afflicted with ulcers would take this drug. As you can see, once again, the same bottle, identical shape. The difference? It costs $3.58 for the American consumer, and $1.26 for the Canadian consumer—same pill, same bottle, same company, but a different price.

Let me tell you about being in a little one-room drugstore in Emerson, Canada, 5 miles north of the United States. Just 5 miles north of the Canadian border, there is a drugstore. I accompanied a group of seniors to the one-room drugstore in Emerson, Canada, just to make a point.

The point was very simple. The medicines those seniors purchased in Canada—the identical medicines to what they buy in the United States and for which there is no safety concern or issue because the chain of custody is identical in Canada—cost much less.

It begs the question. Why not let the market system resolve these issues? As long as you have the safety of supply and the closed chain of custody which you can be confident in—and you certainly do with Canada because their system is very comparable to ours—allow people to decide where they want to purchase their prescription drugs. If they decided they would purchase their prescription drugs where they are less expensive, it forces repricing of prescription drugs in this country.

Let me use some charts to show what is happening. How much more does the U.S. consumer pay? More than everyone else in the world by far. If we pay $1 for a pharmaceutical product, that same product is 62 cents in Canada. You can see what it is around the globe in different countries—in England, 69 cents, Germany, 65 cents, France, 55 cents, and Italy, 52 cents.

Let me show a chart with specific medications.

I just showed these: U.S. price versus Canadian price for Prevacid, Zocor, Paxil—all heavily used drugs and costing nearly 40 percent more in the United States than in Canada.

Now let me quote, if I might, President George W. Bush during the third Presidential debate in St. Louis, MO.

During the Presidential debates, President Bush was asked about this. Here is what he said:

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

What he was saying there is that the reimportation of prescription drugs makes sense. That is what he said in the third Presidential debate.

I am not making this up. These are the President's words from the debate—prescription drugs coming back into the country would make sense. If I could put words in his mouth, I would believe, of course, that he would say it makes sense, if this is safe.

But, nonetheless, this President, in a debate, said reimportation makes sense.

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

Mr. DORGAN. I would be happy to yield.

Mr. JEFFORDS. I was obviously on this issue with the Senator from North Dakota. We were forced into providing an ''out'' for them so we could get the bill to the floor that said the Secretary would have the authority to be able to set the bill aside and prevent this coming in. I don't think they would be required to make any rationalization. But, obviously, it was something we had to accept at the time in order to get the bill voted on. And then what happened?

Mr. DORGAN. Well, Mr. President, the second-degree amendment that was attached then dealt with safety and so on. What happened was, the Department of Health and Human Services and the FDA indicated they would not implement the law, so it was not implemented. But it is important to point out that this piece of legislation dealt with the importation of prescription drugs from many other countries.

We have narrowed this amendment to the country of Canada, to allow the reimportation of drugs only from Canada. And because Canada has an identical chain of custody to this country, there can be no question as to the safety of allowing licensed distributors and pharmacists to be able to access, from a licensed pharmacy in Canada, FDA-approved prescription drugs. So that is why I do not have a problem accepting the second-degree amendment offered by the Senator from Mississippi.

I cannot think of anybody at HHS or the FDA who can make a credible case that there is a safety issue by allowing a licensed American pharmacist to access prescription drugs from a licensed pharmacy in Canada. There is no safety issue there. It is gone, finished.

So we, I hope, will adopt this. I believe there is no justification for HHS or the Food and Drug Administration to fail to implement this legislation.

Mr. JEFFORDS. I thank the Senator.

Mr. DORGAN. Mr. President, let me conclude quickly and quote what Health Canada's Associate Director General said:

As soon as any drug crosses the border into Canada, it has to meet all the regulations of our laws. . . .

What they are saying in Canada, with that statement, is that they do not have drugs ricocheting around their country that are counterfeit drugs or non-approved drugs. They have a drug safety system very much like ours, in which drugs that go from an inspected plant into this system, all the way through to the local licensed pharmacy, so that you have a safety circumstance that everyone understands.

Let me continue. It was referenced a bit ago that all of the FDA—or virtually all—of the former FDA Commissioners, oppose this. Let me tell you what former FDA Commissioner David Kessler said:

I believe the importation of these products could be done without causing a greater health risk to American consumers than currently exists.

That is David Kessler, former FDA Commissioner.

Let me continue. William Hubbard, FDA Senior Associate Commissioner, September 5, 2001, in a hearing that I chaired before the Senate Commerce Subcommittee on Consumer Affairs said:

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

Simple and easy to understand, I think.

Finally, let me describe the systems in the United States and Canada. Drugs must be proven to be safe and effective. We are talking only about FDA-approved drugs. There are good manufacturing practices required in both countries. There is appropriate labeling required in both countries. There is the inspection of manufacturers, pharmacies, and drug wholesalers in both countries. Pharmacists and wholesalers must be licensed in both countries. And there is a chain of custody required between the pharmacist, the wholesaler, and the drug manufacturers in both countries. There is a regulatory requirement for postmarketing surveillance required in both countries. And a national mechanism for drug recall exists in both countries.

This is a chart that shows the same thing: The regulation in the United States and the regulation in Canada, from the production of the drug to the licensing of the pharmacist, are the same. There isn't any way, in my judgment, that restricting reimportation to medicines from Canada will allow the HHS or FDA folks to say this does not work. Of course, it works. Of course, it will not compromise the safety of the American consumer. The question is, Will we be able to have a circumstance where the American consumer can access lower cost prescription drugs?

It is not my intention—and it has never been my intention—to force U.S. consumers to go outside of this country to access a supply of prescription drugs. It is my intention to find ways to put downward pressure on these prices by injecting competition that will force a re-pricing of drugs in this country.

Now, every year, spending on prescription drugs in this country is increasing 15 percent, 16 percent, 18 percent, every year. Just about every year, there are double-digit increases in the cost of prescription drugs. If we do not do something about this, we will hook a hose up to the Federal tank and suck this tank dry. I guarantee it.

Now, let me end as I began. If I were representing the pharmaceutical industry, I would fight like the dickens to price drugs however I wished to price them. That is in their interest. It is in their stockholders' interest. I understand that. It is in their company's interest. But there is a limit.

This increase every year—15, 16, 18 percent—comes from two main factors: one is increased utilization, the other is price inflation. The fact is, if we do not find some way to moderate these price increases, this system of ours isn't going to work.

I started by saying that I think the prescription drug industry, the pharmaceutical manufacturers in this country, provide a significant service to the American people by doing the research and providing prescription drugs that are, in many cases, breakthrough drugs. I might say at least a fair amount of that which they do comes from National Institutes of Health research which is financed by the U.S. taxpayer. I do not complain about that. Good for them. And I want those companies out there.

I want the NIH and the pharmaceutical manufacturers searching for the cure for diabetes and for cures for cancer and searching for new pharmaceutical products that can help the American people. I want that to happen. I do not want to shut off research.

The argument is made that if somehow the American people do not pay the highest prices in the world, it will shut down research on new drugs. That is not true. The fact is, European drug companies spend more on research on drugs than companies do in the United States. There is more research on drugs that occurs in Europe than in the United States, and prices are lower in Europe than in the United States.

I just do not think it is right. I do not think it is right for the U.S. citizen to pay the highest prices for prescription drugs in the entire world. I just do not believe that is right.

Now, I understand all the arguments that are going to be raised by my colleagues who oppose this and I would just ask them, what happened to your faith in the market system? I hear a lot about this market system: Let the market system work.

As long as you have the safety of the drug supply, and a protected chain of custody—and that exists in Canada; no one can come to this floor and say it does not—why not let the market system work?

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

Mr. DORGAN. Of course. I am happy to yield.

Mr. SANTORUM. Mr. President, if a drug is shipped from outside of Canada to Canada for resale in the United States, does that go through the same handling that the Senator from North Dakota has discussed?

Mr. DORGAN. Yes. As I indicated in one of the charts I presented, the Canadian official said that any drug that crosses into Canada is treated just the same as the drugs that enter the United States. As you know, there are many drugs that are imported into this country. Just as is the case for the importation of drugs into the United States by the drug manufacturers, drugs that are imported into Canada from other sources of production are certified as safe by the Canadians—just as ours are certified by the FDA.

Mr. SANTORUM. If they are for the purposes of being resold in the United States, not in Canada, are they also certified by the Government?

Mr. DORGAN. First of all, the only way they can be reimported into the United States would be if a licensed pharmacist or a licensed distributor in the United States purchases them from a licensed pharmacist or distributor in Canada. So at that point, they have entered the stream of prescription drugs in the Canadian system. At that point, the Canadians say: We assure the safety of the chain of custody of those prescription drugs just as you do in the United States.

I find this debate interesting because I was up on the border of Canada one day. This was before mad cow disease occurred in Canada. My heart goes out to the Canadian ranchers for having discovered one instance of mad cow disease. Do you know what we do with Canada with respect to meat. We say: We have reciprocal inspection procedures for meat. You inspect it and that is good enough for us. What we want you to do is cut one little strip off the meat and lay it in the back of the truck, and we will open the back of the truck and see if it looks decent and smells all right, and then you just run the truck through. Why? Because we have reciprocal inspections. We say: If it is good enough for you, it is good enough for us.

We have identical chains of custody for prescription drugs in Canada and the U.S., but we won't say: If it is good enough for Canada with an identical chain of custody for prescription drugs, it is good enough for us. That doesn't make sense to me.

There is only one reason we won't say that. That is because some are willing to support the notion that the U.S. customer, the U.S. citizen, should pay the highest prices for prescription drugs. I happen to think that is wrong. I believe our citizens ought to pay a good price. Miracle medicines are not cheap. We ought to pay a good price and a fair price. Should we pay the highest price in the world? I don't believe so.

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

Mr. DORGAN. I am happy to yield.

Mr. HARKIN. I thank the Senator for yielding. I compliment him on his amendment. I see seniors from our State sometimes trying to get up to Canada and buy drugs, the same drugs you pointed out, and paying one-third as much as in the United States. The Senator pointed out that one of the arguments we often have here for this higher drug price in the United States is so the drug companies can engage in research. And we want them to do that research. They do a lot of good research, as the Senator just stated. They develop new drugs, and sometimes those drugs don't pan out, and they need to cover the expense of bringing new drugs on the market. We are all for that.

But I ask the Senator from North Dakota, is it not a fact that last year the major drug companies in the United States spent more money on advertising to the public than they did on research, that they actually spent more money advertising prescription drugs which you and I can't even buy unless we get a prescription? Yet we see full-page ads in USA Today, three and four-page spreads in Time and Newsweek magazine, full pages in the New York Times.

I ask the Senator, what sense does it make if, in fact, they are going to charge us high prices for drugs in the United States and they are using it just to advertise for drugs we can't even buy unless we get a prescription? Isn't it a fact they actually spent more money on advertising than they did on research?

Mr. DORGAN. I believe that is the case. I don't have the numbers in front of me. I believe Senator STABENOW referred to that earlier. My understanding is that the expenditures on advertising and promotion exceed the expenditures on research.

Let me make two additional points and then yield the floor. I support research and development, R&D, tax credits for industries, including for the pharmaceutical industry. They benefit greatly from them. I have always supported those tax credits. I think it makes sense to provide credits and incentives for the development of new drugs.

Second, when these drugs are produced and then sold, I don't think we ought to pay the highest prices in the world.

Let me give one more example, if I might. A woman with breast cancer needs Tamoxifen. With a prescription to go buy Tamoxifen, you have one of two choices, if you live near the border. You can pay $10 for a supply of Tamoxifen in the United States, or you can go to Canada and buy exactly the same amount of Tamoxifen for $1—$10 or $1. Why should you have to fight breast cancer and fight these pricing policies at the same time? It is not fair. It doesn't make sense that we should pay the highest prices in the world.

Again, the majority leader started off by saying we have passed this before and it doesn't work. Let me correct it again to say: Legislation limited to Canada has not been enacted before. We passed something else before. You are right, it was not implemented. It was reimportation from other countries in the world, provided it was an FDA-approved drug. That was not implemented.

This will be reimportation from Canada, so the legislation has been dramatically narrowed to a country that has an identical chain of supply for which there can be no safety concerns about unsafe drugs. We are only talking about having licensed pharmacists and licensed distributors accessing those drugs from licensed pharmacists or distributors in Canada.

I am not interested in any way ever compromising the supply of pharmaceutical drugs in America. I wouldn't offer this in a million years if I felt it did that. I know it doesn't. There isn't any way anyone in this Chamber can demonstrate that there is a safety issue with respect to the medicines sold in Canada. You might be able to demonstrate there is a safety issue dealing with Bali or Honduras or Guatemala or Zaire, but you can't do it with Canada. You just can't. And so that is why I have no difficulty accepting the second-degree amendment offered by my colleague from Mississippi.

There is not a safety issue with respect to this narrow amendment. There is only this issue: Shall the American people be able to see a repricing of prescription drugs that results in price fairness with respect to what U.S. and Canadian consumers are charged for identical drugs put in identical bottles produced by the same company?

Mr. HARKIN. Will the Senator yield?

Mr. DORGAN. I am happy to yield.

Mr. HARKIN. The Senator really has made an eloquent case for why we ought to have free trade with Canada in drugs as long as they meet the same requirements. I ask the Senator, do we not in fact have a free trade agreement with Canada?

Mr. DORGAN. Yes, we have free trade with Canada. It actually isn't free trade. We could spend a long time talking about wheat and other issues. We have a free trade agreement with Canada, but it excludes prescription drugs. Why? Because a piece of legislation was passed a decade and a half ago that said the only entity that will be allowed to reimport prescription drugs into the United States is the manufacturer of that prescription drug. That is what perverts the market. If you assume that you have a safe supply of drugs in both countries, why then would consumers simply not decide where to purchase the drug in whatever represents their best interests? Why would they not be able to make their own choice under a free trade agreement? It is perverted by this previous legislation that prohibits the reimportation except by the manufacturer.

What we are saying now is, we would allow the reimportation by the licensed pharmacies. We are not talking about somebody shuffling around in a T-shirt who knows nothing about prescription drugs. We are talking about a licensed pharmacist or a licensed distributor who does this for a living. We are saying they have the ability to go to Canada and access medicines from a licensed pharmacist or a licensed distributor.

I would love to have somebody make a persuasive case that somehow that compromises safety. I don't think the case exists.

Mr. HARKIN. If the Senator will yield for another question, I thank the Senator for yielding again. The Senator continues to make an excellent point here that seems to be lost on the proponents of this bill on the other side.

I continue hearing how this is a bill that is supposed to promote competition. It is supposed to promote free enterprise and the marketplace. Yet here, as the Senator from North Dakota has pointed out, in one place where the marketplace really could save seniors money, by opening up the marketplace for these drugs to come in from Canada as long as they meet all of our FDA requirements, on this the other side says, no, we don't want the marketplace to work in this case.

It kind of gives lie to all of the arguments about how this bill is to promote competition in the marketplace on drugs for the elderly. Quite frankly, it seems to me this bill is to promote higher prices and to ensure the elderly really do not get the best deal they could possibly get in buying prescription drugs which would mean they would not be able to buy them from Canada, which distorts the marketplace.

Again, I thank the Senator for his well-reasoned arguments and his well-reasoned amendment. With this amendment, we ought to strike a blow for the marketplace and let the marketplace work by allowing our seniors to be able to purchase these drugs under this so-called free trade agreement that we have with Canada.

I compliment the Senator from North Dakota for this amendment.

Mr. DORGAN. Mr. President, let me say I will not put this entire report in the record, but we asked the Congressional Research Service, the CRS, to do a comparison of U.S. and Canadian requirements for approving and distributing prescription drugs. This is by the nonpartisan Congressional Research Service. They prepared a memorandum comparing the U.S. and Canadian systems for both approving and distributing prescription drugs. Essentially this report affirms that, in all aspects of the U.S. and Canadian drug systems, drug approval, drug manufacturing, drug labeling, drug distribution, the U.S. and the Canadian systems are similar in all respects.

There just is not a circumstance here where someone can say the U.S. system is terrific and the Canadian system is not. Both countries have chains of custody that I think give people in Canada and the U.S. assurance of safety.

Perhaps before I give up the floor, I should mention this has been something Republicans and Democrats have worked on over a period of time. We have debated these issues before, but not this amendment because this is narrowed to Canada. I would be remiss if I didn't mention our late colleague, Paul Wellstone. If he were in the Chamber, he would be sitting in that back seat, and he either would have offered the amendment, perhaps, or be waiting to be among the first to speak. He, like many others of us—particularly in northern States—felt strongly that the reimportation of prescription drugs was a way for senior citizens, yes, but all Americans, to access the same prescription drugs at a fairer price.

My expectation is that when we finish this debate and have a vote—I believe we will vote on this tomorrow—this amendment will be further amended by the second-degree amendment of Senator COCHRAN, which I indicated I would accept. I don't believe there is a need to vote on that. I believe that amendment will be subject to a recorded vote tomorrow.

I hope my colleagues will do as we have done previously on broader legislation. At least with this narrower bill, let's decide to pass this and see if this can help provide some downward pressure on prescription drug prices.

Ms. STABENOW. Will the Senator yield for a question?

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

Ms. STABENOW. I appreciate that. I wanted first to compliment my friend from North Dakota, who has worked so diligently on this issue. I am very proud to be a cosponsor of the amendment.

The PRESIDING OFFICER (Mr. COLEMAN). The Senator can only yield for a question.

Mr. DORGAN. I was yielding for the purpose of a question.

Ms. STABENOW. I was in the middle of saying I wanted to ask is it not true that even though the report you just indicated made it clear the safety provisions, the oversight, is the same between Canada and the U.S., isn't it true that even in light of that, you have gone the extra mile to put into place basically a 1-year provision for reimportation, and then at the end of that time the program would stay in effect, unless the Secretary submits a certification that in fact there is a problem, that based on experience, based on evidence that the benefits do not outweigh the risks? Isn't that correct that you in fact have gone that extra step, that extra mile to make sure even though we know it is safe, it is the same, that we give a safety valve so that the Secretary in fact could step in and certify if there was a problem?

Mr. DORGAN. Mr. President, Senator STABENOW has done a service by pointing out something in the amendment I did not point out. The other change is that this would be a 1-year pilot program, when approved by the Senate. The certification will still be that this is safe because, clearly, we have identical systems in the U.S. and Canada.

In addition, after a 1-year pilot project, there will be a 6-month period in which the Secretary of Health and Human Services will certify if there is a problem, if in fact there is one. I expect there will not be. At that point, this program will continue. At least it creates a specific 1-year pilot project and an evaluation, so there is a failsafe system if there would be any problem at all. I would not expect a problem—particularly because we have narrowed this—with respect to Canadian drugs.

The PRESIDING OFFICER. The Senator from Pennsylvania is recognized.

Mr. SANTORUM. Mr. President, I rise in opposition to the Dorgan amendment, although as modified by Senator COCHRAN's amendment, I will not oppose it.

Senator COCHRAN's amendment goes to the whole point here, which is that reimportation of drugs is unsafe. I am not the one saying that. I think most Members here are very concerned about the safety aspects of reimportation. We have three Secretaries of Health and Human Services, 10 former FDA commissioners, the U.S. Customs Service, the White House, DEA, CMS, Canadian Pharmacy Regulatory Agency, U.S. Pharmacy Regulatory Agencies, and 44 U.S. pharmacist groups, voicing safety concerns about the reimportation of drugs.

I am satisfied Senator COCHRAN's amendment will sufficiently reflect the concern of Members of this body and of these organizations about the issue before us. So I am going to set that aside. I could argue until the cows come home how this is an unsafe and unwise practice to engage in. But with this amendment, we will leave it up to the Secretary to determine as to what he believes—and he was here a minute ago. We have a statement from him already saying he does not believe it is safe. I am comfortable leaving it in the hands of someone who will study this issue in depth with respect to safety.

I want to dispel a couple of myths that have been created during this debate. One of the myths is that American pharmaceutical companies spend more money on advertising than they do on research. As most people who have followed the pharmaceutical industry and followed this debate know, the pharmaceutical industry is the most research-intensive industry in our country. I have always said I find it remarkable that we are here on the floor of the Senate all the time beating up on the pharmaceutical companies, saying they make too much money or they spend too much money on advertising or they don't spend enough money on research and development, and we need to whack them here and

whack them there until they become like the steel industry, where they become—or other industries—less and less profitable, and then we pass loan guarantee programs to prop them up. That is sort of the way we do things here. If anybody is doing well, whack, we are going to take a shot at them and say they are doing too well for everybody's good.

Let me just suggest the pharmaceutical industry is doing well because they are leading the world in curing disease and treating very serious health problems. They are doing it because of the enormous amount of research they are doing, not because of the money they are spending on advertising. General Motors spends more money on advertising—some $4 billion every year. That dwarfs almost all of the spending by the pharmaceutical industry with respect to advertising. Yet I don't hear the Senators from Missouri or Michigan or any others out here complaining we pay too much for cars. Cars are as much of a necessity for most people as pharmaceuticals. Why don't we hammer General Motors, Ford, and those other folks for wasting this money on advertising.

Companies spend money on advertising because they have an obligation to sell their product. The way you sell your product is by promoting the value that product hopes to bring to an individual's life—the positive attributes of the product. Pharmaceutical companies have the right to do that through advertising to the general public, which may not be informed about new therapies that are available, as well as through direct advertising to physicians who prescribe the medicine. That is a proper role, I believe, in informing the public. We want them to be informed.

I cannot imagine we would want a public that would not want to know what some of the more recent developments and potential improvements to their lives that are available to them. Some have suggested their spending on advertising is more than they are spending on research and development. That is not true. I know that was said in passing. Someone said: I think this is the case. Let me clarify for the record so we do not have this common misstatement that I think this may be the case. Let me tell you what the facts are.

I have a chart. It is just a piece of paper. I do not have it blown up. The black line is the spending on research and development, and the light gray line is the total promotion. Total promotion means, yes, advertising, but it also means the free samples of drugs many receive when they go to the doctor's office. That goes in promotion. That is actually, in a sense, free drugs for the purposes of advertising and promoting the product. All that is included in here.

You can see that research and development while, yes, advertising is going up, research and development is going up even further. In 2001, $30 billion was spent on research and development and a little over $10 billion on advertising—three to one. I daresay General Motors does not spend three to one on research and development versus their advertising. I daresay most companies and most industries do not come close to spending that amount of money. But you know what. They are the bad guys. They are the guys we have to hit upside the head. Why? Why do we have to hit them upside the head? Because they are increasing their prices too much. It is too costly, and we need these products.

Let's look at why they are increasing their prices and why you can go to Canada, Germany, or other places, and receive these drugs for less money. There are a couple of reasons.

No. 1, there was an excellent article in the ''Weekly Standard'' just the other day talking about the incredible cost of getting drugs approved by the FDA.

For a company which starts out with thousands of compounds with which they are experimenting, researching, trying to work themselves through the process to determine what is a viable compound to experiment with and to move forward with, they start out with thousands, tens of thousands. They narrow it down to a few hundred. They do some more intensive research on those. They get to about four or five they do some trials on and some tests on and even further research. They come down to usually one drug where they go through the extensive process of clinical trials and testing.

By the way, the reason Europe, Canada, and other countries around the world get drugs years before we do, in some cases, is because of the incredible costly process the very people who are complaining the drugs cost too much have supported, the extensive approval process that jacks up the price of those drugs in this country.

It costs $1 billion on average for a drug to go from that basic research of compounds all the way through the process of determining whether it is effective, whether it is safe, what conflicts there are. All the issues they have to deal with, it costs about $1 billion in this country.

It does not cost $1 billion in Canada. It does not cost $1 billion in Europe. It does not cost $1 billion in Mexico. It costs $1 billion here because of the extraordinary lengths to which we go to make sure the drugs here are, what? Let's hear that word again. Safe. That those drugs are safe. We put a premium value on, yes, efficacy. They have to be effective. They have to treat what they say they are treating, and do so effectively, but they also have to be safe. So we put a high value on safety, and we require these companies to go through enormous hoops to make sure, in this country, before a drug is sold, we know it is safe.

We are suggesting two points: No. 1, safety is a highly valued commodity when it comes to drug use, and that reimportation is unsafe. No. 2, one of the reasons reimportation is so popular is because the cost of the drugs are cheaper. One of the reasons they are cheaper is because they do not have to go through the safety measures they are put through in this country.

You require them to prove it is safer, and then you say: Gee, why are you charging us more money? Why don't we just get them from this other country, that, by the way, does not require you to go through those hoops. So they do not pass on the costs to these other countries.

There is another reason. The other reason is because in Canada, Mexico, most of the world, they set prices. They set prices. They say: You want to sell drugs in our country? Fine. Pfizer, you want to sell a drug in our country? No problem. Here is what we will pay you.

Pfizer says: Wait a minute, we have all these costs. I want to make a profit.

Fine, if you want to make a profit, here is what we will pay you.

We charge $3 for this drug in the United States. You are only offering to pay us $1.

Well, we have looked at it and your manufacturing costs are 50 cents; $1 is a pretty good price. You will make 50 cents on every pill.

Pfizer says: That is our manufacturing cost. We have hundreds of billions of dollars in research costs. We have litigation costs we have to be concerned about. We have advertising and other related costs that are built into the cost of this drug. You are only giving us the manufacturing cost.

If you don't like the deal, you cannot sell your drug. So if you want to sell your drug and make your 50 cents, sell your drug. If you don't, see ya.

The drug company has to make a decision: Do I agree to sell based on the price the Government wants to give me or am I shut completely out of that market?

A lot of drug companies say: OK, I am not making the money I could in this country because we do not have those kinds of price caps on our drugs yet, and they say: At least I am making some margin. OK, I will agree to sell there. If they say no, they do not have any market share at all.

That is a best case scenario. A worst case scenario in Canada is: I have a breakthrough drug, and there are no other drugs like it in the world. It is a new class. It is, in fact, one of these great discoveries that we hope for every day. They go up to Canada and say: We spent over $1 billion researching, coming up with this great breakthrough drug for a cure or for a treatment for this illness.

Canada says: Great, we would love to sell that drug. There isn't any other drug out there that does this. Yes, you want to charge us $10 a pill, that is nice; we will pay you $5.

The drug company says: Well, that is nice, 10.

Canada says: No, you didn't hear me, 5.

The drug company says: I am just not going to sell the drug.

A lot of drug companies will sell it anyway. Why? Because they feel a social responsibility to have that drug available, as we see with the AIDS drugs in Africa that are being sold at well below the costs in any other country in the world. They may feel a social responsibility to sell it, and, in many cases, they do.

Let's assume for some reason this company says: No, I do not feel any social responsibility here; I am going to play hard ball. What does the Canadian Government do? What do they by law have the right to do? They have the right to steal that patent, make the drug in Canada, and sell it for whatever price they want.

That is a pretty strong bargaining position. It is wonderful to stand out here on the floor of the Senate and beat up on these companies for selling drugs for less money in Canada, for less money in Mexico, for less money in Germany. Why?

No. 1, it is a one-sided bargaining situation. You either take the price we give you or you are out of the market. If we want your drug anyway, we will steal your patent. Not a lot of bargaining power. Plus, by the way, the United States costs so much more because of the FDA process, not to mention the litigation costs on top of the research and development costs.

The litigation costs in this country, because of runaway malpractice suits and liability suits, product liability suits, class action suits, the costs associated with drugs are higher here on top of that.

So what do we do? We blame the pharmaceutical company. We blame them because Canada sets prices. We blame them because we have an extensive and very costly FDA process. We blame them because we cannot put our tort liability system in place. It is their fault because they want to advertise their product. God forbid that someone knows what my product is. This is the bad work that is being done.

Now what are we going to do? We are going to say that, yes, well, maybe you are right, Senator, maybe it does cost more to bring a market here. I think everybody would admit that, yes, our litigation system is more costly; yes, Canada sets prices and blackmails them if they do not go along. We agree with all of that, but you know what, it is still not fair, because our seniors—and not just seniors but anybody—our people in America deserve the same price they get in Canada.

Okay. Let's make a decision. Let's make a decision that, in a sense, we are going to set prices in this country, that we are going to adopt the Canadian formula. Now, obviously not every drug is sold in Canada. So there are a lot of drugs that will not be affected by this reimportation because Canada does not pay for every drug. There are certain drugs that just are not sold up there. Why? Because the drug company decided they were not going to play ball and sell at a price that is well below what they believe is a profitable price for them to sell. So we are only talking about a certain group of drugs. We understand that.

We saw an amendment earlier today that is going to make sure these research-oriented drug companies, the ones that are creating the new therapies for the future, now that their patents expire on time, they have no patent extensions, even though some may be worthy or not; we are going to tighten down on that so generics can get into the business. Generics, by the way, make no breakthrough drugs, do no research on new therapies to treat diseases that are heretofore untreated or not sufficiently treated, but we are going to squeeze down these drug companies that are making these research investments and doing these kinds of innovative therapies. We adopted that earlier. Now we are going to whack them again and we are going to basically take the Canadian prices that were set in Canada and have them apply in the United States, so there will be free trade.

I heard people say free trade, free trade with a country that sets prices. Now, I would suspect the Senator from North Dakota would not be for free trade if they set the price of wheat in Canada at 50 percent below the price of wheat in the United States. I do not think the Senator from North Dakota would call that free trade—I could be wrong—or if we set the price of timber at half, by law, in Canada, of what the product was here. I do not think the Senator from Iowa would consider that free trade if they set the price of corn or the price of milk in Canada, by law, at half the price of the product in this country. I do not think we would be up here extolling the virtues of Canadian free trade. I know for a fact the Senator from North Dakota would not because he is on the floor with great frequency extolling the evils of free trade in Canada, particularly when it comes to wheat. They do not set the price of wheat in Canada, but he is for free trade on a product that is artificially priced below the market to come into this country. Interesting economic theory but certainly not consistent economic theory.

So what happens? We now have this product coming into this country at below what arguably it could cost to get that product approved and researched, with the liability costs, all the other costs associated. Now what would be the result? If it is that pervasive, we may force the drug companies to lower their prices. It could happen. In either event, we are going to take a significant piece of the market share away from the pharmaceutical companies selling drugs in this country.

What is the effect of that? Well, the effect of that is obviously lower profits for pharmaceutical companies. There are a lot of folks, I guess, who do not want people to be profitable, not at the expense of our consumers who want to buy pharmaceuticals. In the end, the result is this: We have to make a decision as to whether we want an industry that is going to spend 30-plus-billion dollars a year in finding the next cure, in doing the next level of research for that disease someone in our family may have or some neighbor may have, or whether we are more concerned with having cheap drugs today.

Let's understand, with eyes wide open, what we are balancing. We subsidize the world's research. Admit it. I accept that. People say we pay more for drugs here than everybody else in the world. All we are doing is subsidizing the drug companies in this country and the rest of the world is riding along on the money we give drug companies by paying higher prices for drugs. They piggyback on us, and that is not fair. Okay. You are right. What do you want to do about it?

Well, one thing we could do is talk to our trade officers and get them to pound away at these other countries so they do not set formularies and artificially low prices. We could do that. Do we tell Canada they cannot blackmail our companies by threatening to make the drug and steal the patent? We could do that. Short of that, which is not happening right now and this debate is happening right now, we have to make this decision, and the decision is this: Do we want to eliminate the research and development of new drugs and new therapies to solve new problems or problems that exist, diseases that exist, and, yes, subsidize the world in the research and development or in exchange for that next generation of drugs coming on line next year, are we willing to trade cheaper drugs today for no cure tomorrow or cheaper drugs today instead of the cure tomorrow, 3, 4, or 5 years from now?

That is a legitimate debate. I say to the Senator from North Dakota if he wants to enter into that debate—and the Senator from Michigan who is going to speak next, if she wants to enter into that debate—I will accept that debate. I will truly accept the integrity of people who say it is worth it to have cheaper drugs today to get more drugs to people today who need them than to develop the next generation of drugs down the road for people who will need them then. That is a legitimate argument to make.

I assume many Americans would agree with that argument, particularly if they are the people who do not have the money to afford the drugs they need today. There are probably a great number of Americans who would say that is a good tradeoff.

I come down on the other side. I do not believe it is a good tradeoff. The reason I do not believe it is a good tradeoff is I think there is a better way to solve what seems to be an intractable problem: either research, innovation, new disease treatment, or cheaper drugs.

Interestingly enough, the solution is what we are talking about in this Chamber this week and next week, and that is drug coverage. The solution is, let's provide drug coverage to lower the cost out of pocket to the consumer, particularly catastrophic drug coverage.

In my mind, the most important thing we are doing, not some of what I consider very broad coverage that we have in this bill, but most important is including the catastrophic coverage. If we have a high drug user or the low-income subsidies in this bill for low-income individuals, those are the people I am most concerned about. They are the ones who, I argue, are the most compelling cases for saying we need cheaper drugs now as opposed to cures later.

If we can solve those compelling cases of the low-income individual and the high user of pharmaceuticals, if we can solve those two problems, then we take a lot of pressure off this issue of cures tomorrow versus drugs now.

This amendment does not belong. It is an anachronism. We get to the heart of the problem that this amendment attempts to solve. I believe it solves it in the wrong way.

I also believe reimportation is unsafe. It is unfair to an industry in this country which is much maligned—until, of course, you get that diagnosis. Once you get that diagnosis and you find out within the last few years a little white pill that keeps you alive, that keeps you walking, keeps you breathing, keeps you eating, once you find out there is an industry out there that you never had a good word for up until that moment, who you thought were bad people because they were raking these people over the coals with all this money they were making, until you found out because of the research and development that went on, your life will continue and you will be able to see your children grow up or you will be able to see and play with your grandchildren, all of a sudden these companies are not so bad after all.

I know this is not a popular view for Members of the Senate to hold. I have been told on numerous occasions defending drug companies is not a term extender for Senators. I understand that. This is not a populist issue. I accept it. But I have the gift in my State of having thousands of employees who go to work every day with the focus on creating the next little pill, the next little serum that will save somebody's life. They are proud of the work they do. They have a right to make money and do it. They have an absolute right to make money and do it. I will stand by their right to do that. It is an industry that not just makes money, but we are saving people's lives. We are changing people's lives. We are giving that grandson the opportunity to know his grandma. We should be willing to pay for it.

We should not be blackmailed by other countries that want to use us for their research ground. We have some work to do. In my opinion, we have work to do in the international trade arena to go after these countries that do use us as the funding of their laboratories. But the mistake is not to adopt their policies. It is to get them to change their policies. What this does is adopt a flawed, fatal system for far too many people.

I yield the floor.

The PRESIDING OFFICER. The Senator from Michigan.

Ms. STABENOW. Mr. President, it is hard to know where to begin. I would like to talk about some of the facts and realities for folks who are struggling to pay for those medications that are being developed or being advertised on television.

I hope we will remember in these debates we are not talking about automobiles or tennis shoes or peanut butter or any other optional product. We are talking about lifesaving medicine.

I celebrate the fact we have lifesaving medicine and that we have those who have dedicated their lives to that research. We have a lot of such individuals in Michigan. I am very proud of them and the work they do.

At the end of the line, if you cannot afford the medicine, it does not matter. So price does matter. Affordability does matter. Competition to bring prices down does matter.

I am very pleased a little earlier this evening we voted together in a bipartisan way to close loopholes the brand-name companies have been using to game the system, to keep competition off the market, and generic drugs. We passed a very important amendment to this bill. I commend, again, all who have worked very hard on that. The system has been out of whack. I suggest it is out of whack in a number of other ways.

First, it is absolutely true that the most profitable, successful industry in this country is the pharmaceutical industry. No question about it. It is great they are doing well. Any other business in this country would love to have their situation. They are, arguably, the most highly subsidized industry by taxpayers in this country. They have a set of rules that up to this point have been highly in their favor to allow them to keep the competition off the market. It is a great deal if you can get it.

I know we have hundreds if not thousands of folks working here, lobbyists, making sure we keep that good deal for them. I appreciate that. Unfortunately, that good deal for them, that great deal for them, has been at the expense of every other business trying to provide health care for their employees, every other employee trying to keep their health care and not lose their job because of rising health care costs, every senior, every family in this country. The debate about pricing is about not only making sure we have a healthy pharmaceutical industry but we have other healthy businesses and consumers who help pay the tab for that research and can afford to buy the product at the end of the line.

What do I mean by that? I have said this before. We start with a lot of the basic research in this country being paid for by American taxpayers through the National Institutes of Health. I am proud we have greatly increased the amount of money going into basic research. We have done that on a bipartisan basis. It makes a difference. We are very close on many different illnesses from Parkinson's to Alzheimer's to diabetes, critical research. We need to be doing more. But that is done by American taxpayers, investing our money. Because we benefit, we understand how critical this is.

That information, that research, is then given to the pharmaceutical companies who then develop it. We give them a writeoff for their research, tax deductions, tax credits for new research, all of which I support, as well as deductions for their advertising, their marketing, their administration, their other business expenses. Tax deductions, tax credits, are subsidies from American taxpayers. So we have a real stake in this operation. We are already helping pay for it.

Once the drug has been developed, because it is very expensive for new breakthrough drugs, because it is very expensive, we have a policy of creating a patent for up to 20 years to limit the competition so that company can, in fact, be covered at cost, because with new lifesaving drugs it is very expensive.

We have a stake in this. We have a stake in it. We helped pay for it. We helped create rules that are favorable to the companies, so that, in fact, they can succeed. The deal, though, I believe, is that at the end of that process the American consumer, the American senior should be able to afford to buy that product that they helped pay to develop, to research, to make happen. That should be the deal.

That is the point. In too many cases right now that is just not happening. We get to the end of the line, and there are many ways in which the companies sue currently to keep generics off the market or keep the border closed so we can't buy them from Canada or do a variety of other things to make it difficult for the competition to come in and to keep the prices low. They make sure Medicare doesn't negotiate on behalf of all the seniors of the country to be able to force a group discount. There are a wide variety of methods to make sure the rules stay the way they are and we are all paying a big price for that, I believe.

We certainly want this industry to be successful. I think it is clear by the rules, the subsidies, the support that has been there and will continue to be there. But this is not a pair of tennis shoes. It is not an automobile, as much as coming from Michigan I want everybody to buy a new automobile every single year, an American-made automobile. But if you don't, you will not

lose your life. But if you don't get your cancer medicine, you might. This is very different.

Let me speak to the issue of advertising. Since 1996, the FDA has taken the cap off of direct consumer advertising, as we know, radio and television, other direct consumer advertising. We know, we have seen advertising skyrocket. We do not have to debate that. All you have to do is turn on your television set. If not every commercial, it is every other commercial—they are very nice commercials—but they are commercials for prescription drugs. We do not have to argue about whether advertising has gone up. Every single person in this country knows that advertising has gone up.

You do not have to tell a doctor that marketing has gone up. My doctor talks to me about the line of drug reps at the door to come in and promote particular medicines.

We know from studies that have been done, and FCC filings, that about 2.5 times more is claimed under the line item for ''advertising, marketing, and administration'' than is claimed under research.

What I find very interesting is that I keep hearing that more is spent on research than on advertising and marketing. Last year, I offered legislation to say OK, if that is true, then let's just cap the amount you can write off for advertising and marketing to the same level you can write off for research on your income tax form. It should not matter to anybody because they spend more on research. You would have thought I had proposed the worst thing you could possibly propose. It was adamantly and is still adamantly opposed by industry. It should not matter if they are spending more on research than on advertising and marketing.

I would like to speak to the business at hand here, the question of allowing Americans to buy American-made drugs, subsidized by Americans, the research funded in part by Americans, at the price they are sold in every other part of the world—half the price we pay here.

This particular amendment is a very conservative, cautious amendment. It focuses only on Canada. We know, in fact, there is importation already back and forth from Canada. Drugs are already frequently imported into this country but predominantly by manufacturers. They are already bringing them back across the border. In fact, according to the International Trade Commission, $14.7 billion in drugs were imported into the United States in the year 2000, and $2.2 billion in drugs sold in Canada were originally made in the United States.

It is ironic that the drugmakers are saying drugs cannot safely move between the border between the two countries. What they are saying is they don't want individuals to be able to do it or pharmacists to be able to do it or wholesalers to be able to do it, but they do it every day.

Also, we hear there is a difference in terms of oversight and inspections. According to the CRS, our Food and Drug Administration already inspects pharmaceutical production lines in Canada for 341 prescription drugs run by about 30 drugmakers. So they are already doing it for the pharmaceutical industry. We pay to send FDA inspectors to Canada to inspect already.

Another report dated September 2001, a report by our Congressional Research Service—again, the nonpartisan Congressional Research Service—confirms that:

> The U.S. and Canadian systems for drug approvals, manufacturing, labeling and distribution are similarly strong in all respects. Both countries have similar requirements and processes for reviewing and approving pharmaceuticals, including ensuring compliance with good manufacturing practices. Both countries also maintain closed drug distribution systems [which is very important] under which wholesalers and pharmacists are licensed and inspected by Federal and/or local governments. All prescription drugs shipped in Canada must, by law, include the name and address of each company involved along the chain of distribution.

So that is the reason this amendment is narrowly focused on Canada because we are talking about a system that is very similar, almost exactly the same in terms of the safety and the rigorous oversight. We are also talking about a process that is already going on, it is just going on by the manufacturers and not by licensed pharmacists or by individuals or by wholesalers.

I think this amendment is very conservative because the amendment not only has Senator COCHRAN's provisions in terms of certification, but this is an amendment that would affect 1 year. We are going to affect things for a year, to open the border to Canada. After that 1-year period, the program would stay in effect unless the Secretary submits a certification to Congress that, based on substantial evidence and the experience of the 1 year, the benefits of reimportation do not outweigh the risks. So there are multiple protections in this amendment, and strict FDA oversight is in this amendment.

I think this is particularly important to do in the context of the prescription drug legislation that we are working on and that will be passed by this body because the bill in front of us to provide a Medicare prescription drug benefit does not take effect until 2006. So other than a discount card, which is not new to seniors, those who have been listening to the debate we have been having all week and anticipating help right away are going to be sorely disappointed because there will not be a prescription drug benefit until 2006. In the meantime, we can help not only seniors but families and businesses and everyone who is involved in paying for prescription drugs right away, immediately. It doesn't cost anything to open the border to Canada for prescription drugs for pharmacists and for individuals. We can do it now. If there is an evaluation that there is a problem, it can stop. But we know, based on information about the inspection systems, based on what is already occurring, that it is highly unlikely that there would be a problem.

I think it is critically important that we give major help now. We can cut prices in half; in some cases much more. I have had the opportunity to go with a number of different seniors to Canada where they have met with a Canadian physician and received a prescription and gone to a Canadian pharmacy. We have been shocked at the difference in prices for literally the very same drug. It is particularly significant in Michigan where we can look right across the river which you can swim across, and go from Detroit to Windsor and see that kind of a price difference. We have many seniors now looking to Canada for opportunities to see Canadian doctors because they are so desperate to get help.

Let me mention just a couple of things. Again, we are not talking about some optional product where people are advertising and making good profits. We wish them well. That is the American way. That is the capital system. Good for them. But we are talking about a health care system where we are not seeing doctors being reimbursed, nor hospitals, nor nursing homes, nor home health agencies. The only part of the system that is exploding in cost and which is driving up the cost of the health care system is in the area of pharmaceutical drugs. This is not optional. It is medical. It should be viewed as part of the health care system. That is what we are debating today.

Let me mention Tamoxifen. Tamoxifen is a very important drug in battling breast cancer. I had an opportunity to visit with Barbara Morgan from Michigan when she went to Canada and visited a Canadian doctor and going through the process there where she was able to get her monthly Tamoxifen for $15 instead of $136. That is a huge difference for her. She and her husband are retired on average means. She did not expect to get breast cancer after retirement. They had, like many others, been saving up to do things in their retirement. They now find themselves spending money on her treatment and on her prescription drugs. These are not theoretical discussions about people. This is not a theoretical debate about allowing Americans to get American-made, American-subsidized prescription drugs from Canada. This is very real. It can literally make the difference between life and death for people when they are struggling for critical lifesaving medicines.

That is why I feel so strongly about this amendment. That is why I am hopeful the Secretary will look at the evidence, will look at the narrow construct of this amendment and be willing to work with us, be willing to allow the borders to be opened for 1 year. We

are asking for 1 year with all of the safety precautions that are in this amendment—just 1 year to allow our seniors and others to be able to see a dramatic cut in the prices they have to pay for their medicines; 1 year to try this and to evaluate the issues that have been raised by those who are opposed.

I appreciate the time. This is, I believe, a very serious part of this debate. If we want to make the difference right now for people, right now doesn't involve money in the budget resolution. It doesn't involve waiting until 2006. If we want to help folks right now, the way to do that is to give them the opportunity to get their prescription drugs at the lowest possible price. That is what this amendment will do.

The PRESIDING OFFICER. The Senator from Montana.

Mr. BAUCUS. Mr. President, I don't see any more speakers who wish to speak on the second-degree amendment. Am I correct in suggesting that the regular order is now to vote on the second-degree amendment?

The PRESIDING OFFICER. The second-degree amendment is the pending question.

Mr. BAUCUS. Mr. President, I think we are ready to vote.

AMENDMENT NO. 947

The PRESIDING OFFICER. If there is no further debate, the question is on agreeing to the amendment.

The amendment (No. 947) was agreed to.

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

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. ALEXANDER. 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. VOINOVICH. Mr. President, the Finance Committee has laid before the Senate a bipartisan bill that will finally provide every senior access to affordable prescription drugs. Passing this long-awaited legislation is one of the best things we can do right away to help solve the health care crisis in this country.

I applaud the efforts of the committee and specifically commend the leadership of the chairman and ranking member, Senator GRASSLEY and Senator BAUCUS, in developing this critical legislation.

The bill reported out of the Finance Committee, S. 1, is the culmination of years of hard work in the Senate to bridge the gap between the Medicare of 1965 and the Medicare for today and the future.

Currently, seniors are paying too much for their needed prescription drugs out-of-pocket. The cost of these life-saving drugs is increasingly becoming a large burden for seniors, with some even traveling to Canada to find cheaper drugs. Seniors should not have to go to a foreign country to receive the drugs that their doctors prescribe. We need to provide an environment where America's seniors don't have to go to Canada.

The bill reported out of the Finance Committee accomplishes that.

This bill not only provides every senior access to affordable prescription drugs, but it will also provide seniors access to benefits that a modern health plan should have, such as preventive care and disease management—options that Medicare does not currently provide. Moreover, these additional benefits are provided by giving seniors a choice and control over their prescription drug plans and health care providers.

These changes will only improve and strengthen Medicare. As my colleagues know, when Medicare was enacted in 1965, Congress made a commitment to our Nation's seniors and disabled to provide for their health security. Unfortunately, that security is on shaky ground because Medicare has not kept up with the evolving nature of health care.

The delivery of health care has vaulted ahead so dramatically 38 years after the inception of Medicare, that this system which was once sufficient is now antiquated and ineffective.

For example, conditions that used to require surgery or in-patient care can now be treated on an out-patient basis with prescription drugs. But more than the progress that has evolved from the utilization of prescription drugs, medicine has too evolved to the extent that preventive care can now eliminate the need for extensive reliance on the health care system. It is time for Medicare to reflect the realities of today's health care delivery system.

My colleagues from the Finance Committee have found a solution that is a good compromise and is a result that can be agreed to by both Democrats and Republicans. Is this bill a panacea for seniors' health? No. But it is a quantum leap forward from a system that has been stuck in a time when the Ed Sullivan Show and the Dick Van Dyke Show were seen as original programming in America's living rooms.

While the Senate has finally begun its debate on Medicare I would be remiss if I did not take a step back and point out the roadmap that has lead us to this point.

The President deserves great credit in providing in his budget substantial funding to add a prescription drug benefit to Medicare. The amount the President allocated, $400 billion, illustrates his commitment to our nation's seniors. Time and again, the President has called for strengthening and improving Medicare.

Additionally, this year we are operating under a budget resolution. Last year, the Senate operated without one because we never voted on the fiscal year 2003 budget resolution—the first time the Senate has not done so since 1974.

The Senate got the job done this year. Through the leadership of Chairman NICKLES of the Budget Committee, the Senate laid out a blueprint for future spending that has brought us to where we are today.

The Senate is standing at the brink of providing seniors access to affordable prescription drugs. This is long overdue, and we cannot delay any further.

Over the past year, I have traveled throughout Ohio holding health care roundtables to hear what the citizens in my State are saying. These roundtables have included seniors that inevitably tell me it is past time that Congress added a prescription drug benefit to Medicare.

I believe this is the year Congress will deliver on its longstanding promises.

I am ready to go to my constituents in Ohio and say we were finally able to move past partisanship and provide real security for their health.

While it is vital that we pass a prescription drug benefit this year, it is also vital that we pass one that is fiscally responsible. Ideally, seniors would receive the assistance they need to have access to every medicine prescribed by their doctor. Unfortunately, we live in the real world and are subject to limited resources.

I would like to take a few moments to shed some light on our Government's current fiscal condition. As recently as fiscal year 2000, the Federal Government had a combined surplus of more than $100 billion. Every penny of payroll tax was retained in the Social Security trust fund and the General fund was generating enough revenue to fully fund its contribution to Medicare and still pay down the National Debt.

As my colleagues know, this rosy budgetary picture is long gone.

According to the Congressional Budget Office's latest monthly budget estimate, May 2003, the unified deficit for fiscal year 2003 will exceed $400 billion even after borrowing every penny of this year's Social Security trust fund surplus.

With this in mind, it is imperative that we act not only to provide Medicare benefits for today's beneficiaries, but also for the baby boomers that will arrive in 2011.

The Finance Committee bill strikes a balance between providing seniors and the disabled access to needed prescription drugs today and doing so in a fiscally sensible way that would allow benefits to extend to future generations.

Senator GRASSLEY and the Finance Committee have put before the Senate a bill that will cost $400 billion as scored by CGO.

The natural question that I think the American people would like to know is what does $400 billion buy? In my opinion, $400 billion provides a real prescription drug benefit that is affordable to both the beneficiaries and the Federal Government.

First of all, seniors would get assistance immediately through the prescription drug card. And our neediest seniors would receive an additional $600 on top of the discounts Medicare will provide through this card.

When the prescription drug program begins in 2006, under the Finance Committee bill, premiums would average $35 a month.

After a $275 deductible, the government would cover half of all prescription drug costs up to $4,500.

Now, critics of this approach will claim that the so-called ''doughnut hole'' after $4,500 will be the financial ruin of every senior. The truth is that the vast majority of seniors—80 percent—would never even hit the hole.

As a matter of fact, for 2003, the Kaiser Family Foundation estimates that the average Medicare beneficiary will consume approximately $2,300 in pharmaceuticals. And should seniors consume over $5,800 in prescription drugs, the Federal Government would pick up 90 percent of drug costs.

While this benefit will greatly help seniors throughout the Nation, there are still some seniors for whom the $35 per month premium and additional cost-sharing is too high. For those individuals, the bipartisan Finance Committee bill provides protections that will allow access to prescription drugs.

For those seniors under 135 percent of poverty, $12,123 for an individual and $16,362 or a couple, the Finance Committee bill would provide a full subsidy for monthly premiums. In addition, the government would cover 95 percent of their prescription drug costs to the initial benefit limit and 97.5 percent above the stop-loss limit.

And for those seniors between 135 and 160 percent of the poverty level, S. 1 would provide assistance with their monthly premiums on a sliding scale. In addition, these individuals would pay no more than 50 percent of their drug costs once the $250 deductible has been reached.

When we talk about dollars being spent, we should also point out to seniors that they will receive more bang for their buck under the Finance Committee bill through Medicare Advantage.

Under Medicare Advantage, seniors will not just receive direct assistance from the government to cover their prescription drug bills. Rather, private health plans will have to compete for beneficiaries and will attempt to attract seniors by providing the best health care plan—including prescription drugs and possibly preventive care, disease management, vision and dental services.

To the advantage of both Medicare beneficiaries and the Federal Government, this competition will decrease the price of prescription drugs and permit all parties to stretch their dollars further.

This body has been playing this political posturing game with senior's health care for too long.

I am tired of explaining partisanship as the excuse for the Senate's failure to pass a prescription drug benefit, which has forced the least of our brothers and sisters to choose between food and prescription drugs.

I am pleased that the Senate will have the opportunity to show the American people, especially our nation's seniors and disabled that we are serious about enacting legislation to provide a prescription drug benefit this year.

The bill before us seems to have broad support from both sides of the aisle. The President is ready and willing to sign a bill into law this year. It is time to get the job done.

ORDER OF PROCEDURE

Mr. ALEXANDER. Mr. President, I ask unanimous consent that today after the consideration of S. 1, the Senate proceed to the consideration of Calendar No. 140, S. 504, and that it be considered under the following limitation: no amendments be in order, and there be 45 minutes equally divided for debate between Senator ALEXANDER and the ranking member or his designee; provided further that at the expiration of that time, the bill be read a third time, and the bill be set aside; provided that the Senate resume consideration of the bill upon convening on Friday, June 20, and that the time until 9:15 be equally divided for debate; further, that at 9:15 a.m. the Senate proceed to a vote on passage of the bill, with no intervening action or debate.

I also ask unanimous consent that following that vote, the Senate resume consideration of S. 1 and Dorgan amendment No. 946, and there then be 4 minutes of debate equally divided prior to the vote in relation to the amendment, with no further amendments in order to the amendment prior to the vote.

Finally, I ask unanimous consent that following the Harkin amendment, the next sequence of Democratic first-degree amendments be the following: Conrad, 2-year fallback; Pryor, reimportation; Kerry, grant program; Clinton, study; and Graham, premium.

The PRESIDING OFFICER. Is there objection?

The Democratic whip.

Mr. REID. Mr. President, I would ask the Senator to modify the request in this manner: First, I would control the time, rather than the ranking member, on the minority side on this bill.

The PRESIDING OFFICER. Is there objection to the modification?

Mr. ALEXANDER. Mr. President, I have no objection to the modification.

Mr. REID. Secondly, Mr. President, we have checked with the majority, and they have no problem with the fact that Senator PRYOR would offer his amendment on Monday rather than tomorrow. Even though he is in order following Senator CONRAD, I ask that he be allowed to offer his amendment on Monday.

The PRESIDING OFFICER. Is there objection to the modified request?

Mr. REID. No objection.

Mr. ALEXANDER. No objection.

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

AMERICAN HISTORY AND CIVICS EDUCATION ACT OF 2003

Mr. ALEXANDER. Mr. President, I ask that the Senate proceed to S. 504, as under the order.

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

The assistant legislative clerk read as follows:

A bill (S. 504) to establish academies for teachers and students of American history and civics and a national alliance of teachers of American history and civics, and for other purposes.

The PRESIDING OFFICER. Who yields time?

The Senator from Tennessee.

Mr. ALEXANDER. Mr. President, I yield myself such time as I may consume.

Mr. President, this week there was a great celebration of National History Day. There were high school students from all over the country in our offices and at the University of Maryland.

Last Friday, when I was sitting where the distinguished Senator from Minnesota now sits, presiding over the Senate, I had the privilege of hearing Senator BYRD deliver an address about Flag Day.

Since 9/11, President Bush has spoken more regularly about the American character. Suddenly, in our country there is a lot of interest in what it means to be an American.

In the mid-1990s, I read a book by Samuel Huntington, a professor at Harvard, called ''Clash of Civilizations.'' A lot of people read that book in terms of understanding in what conflicts the United States, the West, might find in future years. But I read it for a different reason. It made me think that if the new world order was to be a group of civilizations whose differences began with their cultures, their religions, and a variety of other things that made them unique—it made me think if we were moving into that kind of an era, then maybe we ought to have a better understanding of just what made our culture unique. What did it mean to be an American?

I was invited to hold a professorship at Harvard University and taught in the John F. Kennedy School of Government there. And the course I taught was on the American character and on American Government. In that course, the graduate students applied the great principles which unite us as a country to the great controversies which we in the Senate debate—about race-based scholarships, about military tribunals, about faith-based institutions—and the conflicts of those principles. The students were fascinated by that.

And then suddenly I found myself, last year, in a Senate race that I did