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