The PRESIDING OFFICER. The Senator from Mississippi.

Mr. COCHRAN. Mr. President, I support the effort to make prescription drugs more affordable for all Americans. However, I am concerned that creating new opportunities to bring counterfeit or dangerous drugs into the United States from foreign countries is not the way to do it.

The amendment I have sent to the desk on behalf of myself and the Senator from Louisiana, Mr. BREAUX, will provide an opportunity for the Secretary of Health and Human Services to make a certification that the reimportation of drugs from Canada will not jeopardize human safety, the consuming public who buys these drugs, and it will, in fact, lower the cost of prescription drugs for Americans.

I have also been asked to state that other Senators who want to be added as cosponsors to this bill are Senator ROBERTS of Kansas and Senator SANTORUM of Pennsylvania. I make that request.

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

Mr. COCHRAN. Mr. President, the amendment of the Senator from North Dakota could very well make it easier to avoid U.S. standards and inspections at a time when we are increasing border surveillance and trying to prevent acts of terrorism.

Two years ago, a similar amendment was added to the Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Act for Fiscal Year 2001. However, the Senate-approved language that I offered at that time required the Secretary of Health and Human Services to certify that implementation of the amendment would pose no additional risk to the public's health and safety and would result in a significant reduction in prescription drug costs for U.S. consumers.

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 letter was ordered to be printed in the RECORD, as follows:

THE SECRETARY OF HEALTH
AND HUMAN SERVICES,
Washington, DC, December 6, 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 reimportation legislation. Unfortunately, our most significant concerns about this proposal were not addressed. These 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 approved 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 so 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 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. More recently, 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 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 at this point.

There being no objection, the letter 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 of 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 asked 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, FDA 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 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