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