ONE HUNDRED NINTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOE BARTON, TEXAS
CHAIRMAN

July 20, 2005

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

For the past fifteen years, the Committee on Energy and Commerce has been actively investigating a range of issues related to the sale and distribution of prescription drugs entering the United States from foreign sources. As part of this effort, we have directed minority staff to visit various border crossings, international mail-branch facilities, and major consignment carriers to examine the types and amounts of unapproved prescription drugs entering the United States. The Committee has had numerous hearings documenting the dubious nature of these drugs. In particular, these hearings have extensively examined the problem of rogue Internet pharmacies and how the drugs sold on these Web sites enter the U.S. through the U.S. international mail facilities and express consignment carriers, such as FedEx, UPS, and DHL.

Through these hearings and repeated correspondence, we have provided extensive input into how and why current policies adopted by the key agencies responsible for combating this problem -- namely, the Drug Enforcement Administration (DEA), the Bureau of Customs and Border Protection (Customs), and the Food and Drug Administration (FDA) -- are ineffective. We have suggested possible solutions, both legislative and regulatory in nature. It remains clear to us that the unabated flow of unregulated drugs entering the U.S. poses a growing threat to the Nation's public health. The nature of online pharmacies and the inability of key agencies to provide even rudimentary controls over rogue Internet pharmacies is producing measurable harm. For example, it is likely that at least some of the unregulated drug flow that we have documented entering the U.S. from foreign sources is finding its way into the wholesale chain, and even onto pharmacy shelves.

We have also pointed out repeatedly that significant amounts of controlled substances are now entering the U.S. from foreign sources. Recently, a report by the National Center on Addiction and Substance Abuse at Columbia University noted that Americans are now abusing

prescription drugs more than cocaine, hallucinogens, inhalants, and heroin combined. That report also found that the abuse rate of prescription drugs by teenagers has increased substantially in just the past decade (*see* "Under the Counter: The Diversion and Abuse of Prescription Drugs in the U.S.," National Center on Addiction and Substance Abuse at Columbia University, July 2005). One reason cited for the recent increase in abuse rates is the easy access of prescription drugs purchased through the Internet. Our investigation has repeatedly demonstrated the ease at which foreign-purchased prescription drugs can enter the U.S. with the click of a mouse, and anybody who has visited an international U.S. mail facility would understand that the Internet is the source of many of these drugs. We believe that the failure to deal with the inflow of non-controlled prescription drugs is also causing an inflow of controlled substances and that the two problems are closely linked: Web sites that sell non-scheduled prescription drugs often offer controlled substances as well.

It is no surprise that prescription drug abuse is rapidly increasing and that some of this increase is linked to online pharmacies. In June of 2003, majority and minority staff issued an investigative memorandum regarding a series of visits to just one international mail entry point, the international U.S. mail facility in Miami. That memo showed that thousands of shipments of controlled substances (and other forms of unregulated prescription drugs) were arriving weekly at that facility. The memo also reported that the volume of such entries were overwhelming all efforts to adequately process or deny entry to the bulk of these drugs. While Customs and the FDA were making some attempts to stop a portion of these drugs (mostly the controlled substances), after the purposeful release of hundreds of packages of counterfeit Sildenafil, it became evident through visits to other mail facilities that the entire screening system had collapsed. In short, the system used by Customs and FDA was no longer capable of addressing this problem. The memo also pointed out that both senior FDA and Customs management had been aware of the deteriorating situation at this and other facilities for nearly half a decade. Nonetheless, at this time no meaningful proposals have been enacted to effectively address this problem.

Some attempts were made by FDA officials to make some constructive changes to this problem. At a June 7, 2001, hearing before the Subcommittee on Oversight and Investigations of this Committee, for example, FDA's Senior Associate Commissioner for Policy and Planning, Mr. Bill Hubbard, testified that the agency was recommending a straightforward denial of entry policy for the massive amounts of unregulated and suspect drug products that were entering the mail facilities each day. He offered the following potential fix:

> ". . . we have been examining [the issue of foreign drugs entering the mail facilities], Mr. Chairman. We have been surveying the drugs that come in. We have been consulting with our sister agencies, and we have been carefully considering what to do about this. The inescapable conclusion for us is that these drugs are virtually all unapproved in the United States. They are provided without proper manufacturing controls. They often lack instructions for safe use, and they

> may be counterfeit, or worse. These factors, combined with the rapid increase in the Internet that's caused the explosion of these things, leads us to believe that they pose a risk to our citizens that must be reduced. So, accordingly, we have recommended to Health and Human Services Secretary Thompson that he approve our recommendation to request that the Customs Service deny entry of all of these drugs, and to return them to their sender . . ."

Secretary Thompson later testified before the Subcommittee on Health on March 13, 2002, that the Department "should have at least the authority to reject these [drugs], and be able to send them back to the manufacturer, instead of sending them on" (*see* Printed Hearing No. 107-100, p. 43). But no legislative proposals on this matter have been forthcoming from the Administration. Since those hearings, in fact, we believe that the problem of unregulated prescription drugs (including controlled substances) has only grown and continues to overwhelm U.S. mail facilities. We believe that much of this is caused by rogue Internet sites.

We are pleased that you already appear to understand the potential dangers online pharmacies present, as underscored in your recent comments that appeared in an interview with Morton Kondrocke, Executive Editor of Roll Call Newspaper. You responded to a question on reimportation with the following comment:

> ". . . You could go onto your internet service provider, go to your search engine and put in 'Canadian drugs,' it would pull up a number of different sites. You will see one, I saw one the other day called the Canadian Generics. And it offered name brand drugs and generic drugs. FDA tracked it down to look at it; they found out that the Internet service provider was in China. They found that the Web site was managed out of Belize. They found that the check we sent them to buy drugs was cashed in St. Croix. And the postmark was in Dallas. We got the drugs, and the first box I looked at was impeccably counterfeited. It looked exactly like one that would come from a manufacturer. But when you tested the fluid that was in the syringe that it packaged, it was tap water. When you tested the chemical compound that made up the medications, it had the right ingredients, but they were just in the wrong proportion. Some of them were as high as 200 percent of what was supposed to be there. Some of them were as little as 50 percent. . . . I think drug safety is going to become a much bigger problem." (*See* Roll Call, "The Health of Our Nation," July 11, 2005.)

Nonetheless, each day thousands of potentially dangerous packages -- perhaps like the very one you describe above -- enter the U.S. via the mail facilities and the express consignment carriers without any FDA scrutiny or review. This is largely taking place because of failed FDA policies and the inability of the Administration to pursue effective policies that provide affordable drugs to those that are otherwise forced to take such risks. Americans are using these drugs daily, and at ever-increasing rates. They are risking their health in doing so. And while

this Committee has repeatedly pointed out to your Department that there are almost no controls surrounding those drugs that are entering the U.S. through these channels, no effective actions have been pursued to address this dangerous situation. Therefore, we are now asking whether you believe FDA's earlier recommendation, as cited above -- or some form of that recommendation -- should be enacted. At a minium, we request that you respond to the following questions:

1. What is the status of the recommendation made by FDA to HHS (as cited above from the hearing held before our Committee more than four years ago)? Please explain how HHS has examined that recommendation.

2. What is HHS's current position on this matter? Does it differ since you assumed your position and if so, how? Does HHS still believe that new legislation is needed to allow FDA to expeditiously return these unregulated drugs to the original sender, or even to rapidly destroy such products? If so, please describe your plan. If additional tools are not required by FDA, please describe what evidence you have that FDA and Customs officials are no longer inundated by unregulated drugs at these facilities.

3. Does the Department intend to offer any legislation to provide controls over the present situation at the express consignment carriers and the mail-branch facilities that handle most of the Nation's inbound U.S. mail and parcels? If so, please explain those proposals.

4. If HHS does not intend to propose any legislation, does HHS support any existing legislation or proposals currently under consideration? If so, which ones?

5. Does HHS have any plan to oversee the credit card companies, express consignment shippers, and search engines that are essentially the "infrastructure" for these Internet Web sites? If so, please describe that plan.

We look forward to working with you on this major public health challenge. We would appreciate answers to these questions by no later than Monday, August 22, 2005. If you have any questions about this request, please do not hesitate to contact us, or have your staff contact Christopher Knauer of the Committee Democratic staff at (202) 226-3400.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON ENERGY AND COMMERCE

BART STUPAK
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable Ed Whitfield, Chairman
Subcommittee on Oversight and Investigations