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United States Senate

COMMITTEE ON
GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

October 23, 2003

The Honorable David M. Walker
Comptroller General of the United States
U.S. General Accounting Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Walker:

Over the last few years several factors, including the advent of Internet pharmacies and the globalization of the pharmaceutical market, have led to a dramatic surge in drug imports, especially personal imports, which overwhelmed the FDA. It is estimated that 20 million packages containing pharmaceutical products are imported into the U.S. every year. This is an increase of over 1,000 percent in only 2 years.

According to the FDA, drugs procured outside the United States regulatory system can be dangerous for numerous reasons. FDA acknowledges that it cannot monitor nor guarantee the safety and effectiveness of drugs purchased outside the closed U.S. distribution system. FDA has warned the public that drugs purchased from foreign countries could be counterfeit, cheap foreign imitations of FDA approved drugs that could be sub-potent or super-potent, expired drugs, contaminated drugs or drugs stored under unsafe conditions.

Pursuant to these concerns and as part of an on-going Subcommittee investigation, I request that you authorize the Office of Special Investigations (OSI) of the General Accounting Office (GAO) to purchase Scheduled, prescription pharmaceuticals over the Internet. These pharmaceuticals should be purchased from Internet sites that purport to be operating in the United States, as well as those sites that are located in foreign countries. In addition, the pharmaceuticals should include both controlled and non-controlled pharmaceuticals and should be purchased without a prescription and without providing verification of medical need or the age of the consumer. Lastly, the pharmaceuticals purchased by OSI should be shipped by a variety of means, including the U.S. Postal Service, United Parcel Service, and Federal Express.

The results from these purchases by OSI will enable the Subcommittee to determine the actual origin of the pharmaceuticals, and whether the pharmaceuticals could be counterfeit, cheap foreign imitations of FDA approved drugs that could be sub-potent or super-potent, expired drugs, contaminated drugs or drugs stored under unsafe conditions. These OSI purchases will also enable the Subcommittee to assess the procedures utilized by the Drug Enforcement Agency, the Food and Drug Administration, and the Bureau of Customs and Border Protection to prevent the illegal importation of foreign pharmaceuticals.

Thank you in advance for your prompt attention to this request. Please contact Raymond V. Shepherd III, Staff Director of the Subcommittee, at 224-3721, if you have any questions concerning this request.

Sincerely,

A handwritten signature in black ink, appearing to read 'Norm Coleman', with a long horizontal flourish extending to the right.

Norm Coleman
Chairman
Permanent Subcommittee on
Investigations