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**Testimony**

Mr. Chairman, members of the committee, my name is David Kessler. I was Commissioner of the Food and Drug Administration from 1990 until 1997. Currently, I am vice chancellor of medical affairs and dean of the School of Medicine at the University of California, San Francisco. I am pleased to be here today to address the important issue of the safety of our drug supply. During my more than 25 years as a physician and particularly in my role at FDA, protecting the public health and assuring the safety of prescription drugs has been one of my greatest concerns. I am here today to ask you to take important steps to protect American consumers from our current system of unregulated drug importation that presents uncontrolled risks to the American public. In the past couple of years, there has been an exponential increase in the number of prescriptions brought into the United States from Canada and other countries. The Department of Health and Human Services has estimated that the number of shipments has grown from 2 million packages in 2001 to 10 million in 2004. With this explosion in shipments, FDA has seen a growing number of counterfeit and questionable drugs. Currently, FDA is unable to adequately assure that the imported drugs reaching American consumers are safe and effective because the agency lacks both the resources and an effective statutory framework to regulate or stop the shipments. The continued increase in prescription drug prices, the ease of setting up what looks like a legitimate pharmacy on the Internet, and the absence of regulation all contribute to this worrisome trend. I am sure that most American consumers making these purchases truly believe they are getting the drugs that their doctors prescribed to keep them healthy. And the low prices offered on web sites and by email may be hard to resist. But the current system amounts to uncontrolled risk. Consumers have no way to verify whether the drugs they receive measure up to U.S. standards for efficacy and safety. Even worse, the FDA lacks the regulatory structure to efficiently police the marketplace.

The current system is out of control. There is no reliable way to know whether an Internet pharmacy outside the United States is legitimate and sells authentic, safe and effective drugs, although some cities and States have identified legitimate Canadian pharmacies from which consumers can order Canadian drugs.

The existing framework in section 801(a) of the Federal Food, Drug and Cosmetic Act effectively ties the FDA's hands so that it cannot halt packages containing questionable drugs on their way to U.S. consumers. Currently, if an FDA inspector identifies a questionable drug shipment, the agency must conduct a detailed inspection and send a specific notice to the addressee detailing the violations before it can take final action. FDA currently lacks the jurisdiction and resources to verify that legitimate pharmacies in Canada or elsewhere are delivering safe and effective drugs to people here in the United States. The FDA does not have the authority or the resources to inspect pharmacies, wholesalers or manufacturers in Canada or anywhere else outside the United States. The agency's current ability to inspect manufacturing plants producing drugs for the U.S. market does not extend to facilities manufacturing drugs for Canada or anywhere else.

Mr. Chairman, the choice before you is not the choice of imports or no imports. We already have a system of importation of drugs that jeopardizes public health. Congress has the responsibility to fix this serious problem. The risk to consumers in the current scenario is not just theoretical. FDA investigators ordered prescriptions from one web site purporting to be selling approved drugs. Although the site advertised what it said were Canadian generic versions of Viagra, Ambien and Lipitor, none of the drugs that were delivered measured up to the minimum U.S. standards. All three of the drugs had the wrong amount of active ingredients; the Lipitor and Viagra pills also were contaminated and failed dissolution tests. Simply put, these prescriptions were not safe and not effective. While that web site may no longer operate, there are literally hundreds of other web sites that exist today without any regulatory oversight whatsoever. As I understand it, the Pharmaceutical Market Access and Drug Safety Act of 2005 includes provisions that would address these problems. This legislation goes farther than previous attempts at addressing this issue. This bill would allow FDA to implement safeguards to effectively and efficiently stop dangerous imports that currently reach American consumers. American citizens who choose to buy their drugs from another country or via the Internet will have confidence they are getting drugs that are indeed safe and effective, if they work within the confines of the safety system created by this legislation. The health benefits of modern pharmaceuticals are possible only if patients get the right doses of the right medication. S. 334 would enable FDA to determine where a drug comes from and whether it truly is the drug that the seller claims. By requiring FDA inspection and approval of both the manufacturing source of the drug and the chain of custody of the drug, the act allows consumers and commercial entities to buy prescription drugs from Canada and certain other countries with reasonable assurance that the drugs are safe and effective. S.334 gives the FDA the authority to assess the manufacturing source of drugs according to the same standards used for domestic drugs and to ban the importation of any drug it finds inadequate. Furthermore the bill gives the FDA the authority to inspect and verify the "chain of custody" of the drugs all the way back to the source of manufacture.

It also bars imports from countries known to be major sources of counterfeit pharmaceuticals. In addition to assuring the safety and efficacy of the supply of imported drugs, S.334 would increase the safety of drugs purchased via domestic Internet sites. Legitimate pharmacies require a doctor's prescription. This bill makes that rule apply to online pharmacies, and it authorizes state Attorneys General to go to federal court to shut down rogue pharmacies. The provisions of S.334 make it possible for consumers to safely import drugs for their own use and enables American pharmacies to obtain safe and effective drugs from other countries for the benefit of consumers here. It also anticipates and accommodates anti-counterfeiting technology that is now or may become practical.

Mr. Chairman, as Congress debates this legislation, there are some important points I would ask you to keep in mind. First, the proposed regulatory system that would permit importation of safe and effective prescription drugs should be implemented in a carefully phased manner. S.334, in effect, creates a safe system for drug importation. I commend the bill for its provisions that limit the number of authorized pharmacies, wholesalers and drugs in the first two years. Let me suggest that Congress consider whether similar limits

should be included in the legislation for subsequent years, in order to keep the program manageable and of the highest quality.
Second, creating a safe environment for drug importation also means giving the FDA clear jurisdiction and sufficient resources to do its job effectively. S. 334 gives FDA the authority to take strong regulatory action against questionable imported prescription drugs, while at the same time, creating a program for safe and effective imports.

Implementing this program will require significant resources. The bill provides funding through user fees, but these should be periodically evaluated to make sure this funding is sufficient to assure the safety of the drug supply. Mr. Chairman, I believe that the American public will be safer with a regulated system than with the system of uncontrolled risk that we allow today.