Statement of

The Honorable Chuck Grassley

United States Senator
Iowa
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Chairman Hatch, Ranking Member Leahy and Members of the Senate Judiciary Committee, thank you for holding this important hearing today regarding the importation of prescription drugs. More and more we are hearing about unsafe drugs imported into the United States through rogue Internet pharmacies and personal importation. There have been several hearings on Capitol Hill regarding the illegal importation of prescription drugs, as well as newspaper articles detailing the pharmaceutical black market that has developed through foreign pharmacies, criminal profiteers and unscrupulous wholesalers. What once was boasted as the safest, most closely regulated pharmaceutical system in the world has turned into a broken system that allows illegal and counterfeit drugs into the United States.

On June 24, 2003, Elizabeth Durant, Director of Trade Programs for the Bureau of Customs and Border Protection (BCBP) testified before the House Committee on Energy and Commerce. In her testimony, Ms. Durant stated that, out of the millions of packages that come through international mail and express courier facilities every year, thousands of these packages are found to contain illegal and unapproved pharmaceuticals. Additionally, the BCBP estimates that about 10 million individuals cross the land border annually carrying the same unapproved products.

The Permanent Subcommittee on Investigations for the Senate Government Affairs Committee also conducted an investigation into current drug importation. They found that about 40,000 parcels containing prescription drugs come through the mail facility at JFK airport every single day of the year. In addition, the committee estimated that 30,000 packages of drugs are shipped into the U.S. through Miami and 20,000 packages are shipped through Chicago each day of the year. About 28 percent of these drugs are controlled substances.

Although the Federal Food, Drug and Cosmetic Act prohibits the importation of unapproved, misbranded, or adulterated drugs into the U.S., the fact is that thousands of counterfeit and unregulated drugs are seeping through our borders. John Taylor, Associate Commissioner of Regulatory Affairs for the Food and Drug Administration (FDA), in his testimony before the House Committee on Energy and Commerce in June 2003 stated that, "the growing volume of unapproved imported drugs, which often are generated from sales via the Internet, presents a formidable enforcement challenge."

Despite the hard work of both the FDA and BCBP to control our borders, the importation of illegal drugs has become an unenforceable problem. Increased funding by the Federal government to combat the influx of these drugs alone will not solve this problem. Rogue Internet pharmacies located outside and inside the United States can open and close at a moment's notice.

Successfully identifying these rogue Internet pharmacies presents a daunting task for law enforcement and medical leaders alike.

Congress must act now on legislation that will not only shut down rogue Internet pharmacies selling unsafe drugs to consumers, but will also lower the cost of prescription drugs. Legalizing the importation of prescription drugs through a highly regulated system overseen by FDA will stem the tide of unregulated pharmaceuticals coming into the U.S. and create a safe and effective system for obtaining low-cost prescription drugs.

On April 8th, I introduced the Reliable Entry for Medicines at Everyday Discounts through Importation with Effective Safeguards (REMEDIES) Act of 2004. My legislation would provide legalized access to lower drug prices through importation. At the same time, my bill addresses the safety concerns associated with the importation of prescription drugs into the United States and would provide the FDA with the necessary resources and authority to implement a safe and effective program. I would like to take this opportunity to tell you about the specifics of my legislation.

If enacted, the REMEDIES Act would halt unsafe importation by allowing individuals to immediately obtain legal drugs from Canadian pharmacies during the 90 day interim period that the FDA would have to get the new drug importation system up and running. Under this new system, individuals, pharmacies, and drug wholesalers could purchase qualified drugs for import into the U.S. from foreign exporters that register with the FDA. To obtain registration, a foreign exporter would have to demonstrate compliance with safety measures, submit to jurisdiction of U.S. courts, and take other steps to assure safety of imported drugs. A user fee charged to registered exporters would provide the financing needed for FDA to register and oversee foreign drug exporters and ensure the safety of imported drugs.

Filling a prescription overseas would employ the same process as mail order pharmacies in the U.S. use today. Consumers that want to have their prescriptions filled at an overseas prescription drug exporter would be able to go to the FDA website and find a list of companies that have passed FDA's requirements to become a registered exporter. The patient would have to have a valid prescription written by a health care professional licensed in a state in the U.S. to prescribe drugs. The patient would then compare drug prices at the different registered exporters to find the best price available. To get the prescription filled, the patient would have to contact that exporter and either mail or fax the prescription to them. Alternatively, the registered exporter could call the patient's prescriber and get the prescription over the phone.

The prescription could only be filled according to the prescriber's instructions and with brand-name drugs approved by the FDA and manufactured by the same company as approved by the FDA for sale in the U.S. Individuals could also have a prescription filled that is technically not an FDA-approved drug, so long as the drug contains the same active ingredients, dosage form, strength, and route of administration as the FDA-approved drug, and is made by the same manufacturer as the FDA-approved drug.

It would be the responsibility of the registered exporter to verify that the drug can be traced back to the original manufacturer and that the drug has been stored and handled properly. The FDA, through onsite inspectors, would also verify that the prescription drugs dispensed to patients

meet FDA's criteria. Exporters would have to permit FDA inspectors to be present onsite on a continuous basis and the FDA would be required to have inspectors assigned to each exporter.

My legislation also includes methods to ensure that only qualified drugs are entering the United States. Once a prescription is filled, the registered exporter would place a counterfeit-resistant label or other marking on the package to identify the shipment as being in compliance with FDA's safety requirements. This marking would be designed by FDA and could include track-and-trace technologies. When the package enters the U.S., that marking would signify to Customs officials that the product was dispensed from a registered exporter and can therefore be permitted to enter the country. Packages with drugs that lack this marking would be automatically seized by Customs, which will ensure that products without FDA approval do not slip into the country through the mail.
For the first two years, my legislation would only allow importation of prescription drugs from Canada. In the second year of the importation program, the Department of Health and Human Services (HHS) would be required to submit a report to Congress on the safety of the program and its impact on trade and drug pricing. The program would then be expanded in its third year to include importation from the European Union, the European Free Trade Association, Japan, Australia and New Zealand. Other countries that meet specific statutory criteria may also be added to the list.

Finally, my legislation would offer both an incentive for drug makers to import prescription drugs and a penalty should they attempt to impede the importation of prescription drugs. Drug manufacturers may not want to see their lower priced products from other countries coming into the U.S.

Under my bill, drug makers that take steps to prevent importation of their products from FDA-approved drug exporters would lose their tax deduction for advertising costs. There are some drug makers who argue that lowering prices would take money from research and development. To combat these assertions, my bill also creates an incentive for companies that do not prevent importation by offering them a 20 percent increase in their R&D tax credit.

Now is the time for Congress to legalize the importation of prescription drugs from Canada and other developed countries. We cannot, however, assume that importing drugs from Canada and other developed nations is safe without further steps. We need legislation that includes specific safety standards to protect American consumers, such as my REMEDIES Act.

I believe that by utilizing available technology and with proper oversight of registered exporters, we can shut down rogue Internet pharmacies and achieve a safe and effective system for legalizing the importation of prescription drugs.