U.S. SENATE COMMITTEE ON
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Testimony of Senator Chuck Grassley
Chairman, Committee on Finance
Submitted for the Record to the Senate Committee on Health, Education, Labor and Pensions
Hearing on the Importation of Prescription Drugs
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Thank you for the opportunity to submit testimony today regarding the importation of prescription drugs from Canada. I commend Chairman Gregg and Senator Kennedy for bringing this important issue before the Committee, and I look forward to working with them to ensure the safe importation of prescription drugs from Canada and other industrialized nations.

Today U.S. citizens are paying from 30 percent to 300 percent more than their counterparts in Canada and Europe for life-saving drugs such as Xeloda, which is an oral cancer drug for breast and colon cancer. In Canada, the price of Xeloda is $730. In the United States, the same drug with the same ingredients used by Canadian citizens is costing American cancer patients $1,500. This is highway robbery of our most vulnerable citizens and it must be stopped.

Drug manufacturers are using American consumers to subsidize lower prescription drugs prices in countries such as Canada. They are forced to sell their products at lower prices in other countries and try to re-coup their research and development costs by making Americans pay higher prices for the same products. If importation is legalized in the U.S. and lower cost pharmaceuticals are made available to Americans, drug companies will be forced to re-think their pricing strategy.

Legislation to legalize importation would not only help to lower the cost of prescription drugs for all Americans, but also should shut down rogue Internet pharmacies selling unsafe drugs. We see news accounts on a regular basis describing Americans who log on to the Internet to purchase drugs from Canada and elsewhere.

The Permanent Subcommittee on Investigations for the Senate Government Affairs Committee conducted an investigation into current drug importation. They found that about 40,000 parcels containing prescription drugs come through the JFK mail facility every single day of the year.

The JFK airport houses the largest International Mail Branch in the U.S. Each day of the year 30,000 packages of drugs enter the U.S. through Miami, and 20,000 enter through Chicago. About 28 percent of the drugs coming in are controlled substances. These are addictive drugs that require close physician supervision. While most people are ordering their prescriptions from Canada, I was surprised to hear that drugs were also ordered from Brazil, India, Pakistan, the Netherlands, Spain, Portugal, Mexico and Romania.

Over the past few years there have been several amendments that I have supported legalizing the importation of prescription drugs from Canada. In 2000, I voted for Senator Jeffords' amendment to H.R. 4461 that would have allowed pharmacists or wholesalers to import into the U.S. prescription drugs manufactured in Food and Drug Administration (FDA) approved facilities. Most recently during the Medicare debate, I voted for Senator Dorgan's amendment which also would have legalized importation. Unfortunately, each of my votes on these amendments has been rendered meaningless by second degree amendments mandating certification by the Secretary of Health and Human Services.

I believe that any legislation allowing the importation of prescription drugs from Canada and other developed nations should have three objectives. First, it should act without delay to assure U.S. citizens access to lower drug prices from Canada and other industrialized countries. Second, it should put an end to the unregulated and unsafe situation with drug imports that exist today – mainly through unregulated rogue internet pharmacy operations. Third, it should provide the FDA with the resources and authority to ensure the safety of imported drugs.

On April 8, 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 from 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, but the drug would have to have the same active ingredients, dosage form, strength, and route of administration as the FDA-approved drug and be made by the same manufacturer as the FDA-approved drug. These drugs would be manufactured by the same brand-name manufacturer and are made for sale in the market of the approved country.

It would be the responsibility of the registered exporter to verify that the drug can be traced back to the original manufacturer and the drug must have been stored and handled properly. The FDA, through onsite inspectors, would also be verifying that the prescription drugs being dispensed to patients meet FDA's criteria. Exporters would have to permit FDA inspectors to be present onsite on a continuous day-to-day 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 was filled, the registered exporter would place a counterfeit-resistant label or other markings on the package for shipping that identify the shipment as being in compliance with FDA's safety requirements and all registration conditions. These markings 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 that have not been subjected to FDA scrutiny 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, 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 year three 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 reprimand for them if they 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.

So under my bill, drug makers that take steps to prevent importation of their products from these registered drug importers would lose their tax deduction for their advertising costs. I am fully in favor of free speech, but if some drug companies are not going to allow U.S. consumers to have access to lower priced drugs from other countries, then they will lose the tax deduction for the cost of those advertisements.

On the other hand, drug makers complain that these lower prices take money from research and development. So, my bill also creates an incentive for the drug companies to allow importation. Companies that do not prevent importation from the registered exporters will get 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. American consumers are sick and tired of paying up to 300 percent more for life saving drugs than their counterparts around the world. Free-trade principles argue in favor of permitting importation of prescription drugs as long as we can implement a system for safe importation.

We cannot, however, assume that importing drugs from Canada and other developed nations is safe. We need legislation that includes specific safety standards to protect American consumers, and I applaud the efforts by both Chairman Gregg and by Senator Kennedy to place an emphasis on safety. I believe that with today's sophisticated technology and proper oversight of registered exporters, we can achieve a safe and effective system for legalizing the importation of prescription drugs. Let's not allow the partisan politics of an election year interrupt our goal of providing low cost drugs to American consumers.

Thank you again for the chance to submit testimony. I look forward to working with Chairman Gregg and the entire Health, Education, Labor and Pensions Committee to get an importation bill passed in Congress and signed into law by President Bush.