U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Wednesday, Feb. 9, 2005

Grassley: It Should be Legal to Buy Cheaper Prescription Drugs from Other Countries

Senator Sponsors Bill to Ensure Safety of and Timely Access to Lower-priced Pharmaceuticals

WASHINGTON — Sen. Chuck Grassley, chairman of the Committee on Finance, today introduced a bill that would make it legal for U.S. consumers to buy safe prescription drugs from other countries. Grassley joined forces with other key senatorial advocates of safe importation to introduce the bipartisan legislation.

"I've always considered making it legal for Americans to import their prescription drugs a free-trade issue," Grassley said. "Imports create competition and keep domestic industry more responsive to consumers. In the United States, we import everything consumers want. So why not pharmaceuticals? Today, consumers in the United States pay 60 to 112 percent more for brand-name prescription drugs than consumers in other countries.

"If Americans could legally access prescription drugs outside the United States, then drug companies would be forced to re-evaluate their pricing strategy. The pharmaceutical industry would no longer be able to gouge American consumers by making them pay more than their fair share of the high cost of research and development. With this new legislation, we're moving ahead together to get the job done."

Grassley introduced his own legislation in the last Congress – the *Reliable Entry for Medicines at Everyday Discounts through Importation with Effective Safeguards Act of 2004*, or the REMEDIES Act. This time, he combined forces with importation legislation sponsors Sen. Byron Dorgan, Democrat of North Dakota, and Sen. Olympia Snowe, Republican of Maine, and others including Sen. Ted Kennedy, Democrat of Massachusetts, to introduce the *Pharmaceutical Market Access and Drug Safety Act*. House members are introducing a companion bill.

Grassley said the new, combined bill builds upon and improves last year's bills:

- It tears down the trade barriers that Congress put up in 1991.
- It provides legalized access to lower-priced drugs through importation.
- It addresses safety concerns by providing the Food and Drug Administration with the necessary resources and authority to implement a safe and effective program.
- To make sure that drug makers don't interfere with legalized importation, the legislation includes non-discrimination provisions to be enforced by the Federal Trade Commission.

"We're working to make sure Americans have more affordable access to wonder drugs by opening the doors to competition in the global pharmaceutical industry," Grassley said. "Working together, we're committed to getting the job done."

Grassley has been a consistent supporter of importing prescription drugs from Canada. The first reimportation vote in the U.S. Senate occurred in July 2000, on an amendment offered by Sen. Jim Jeffords of Vermont. Grassley supported the Jeffords amendment. Grassley voted a second time for reimportation of prescription drugs from Canada in July 2002, on an amendment offered by Sen. Byron Dorgan of North Dakota. Grassley voted for another Dorgan amendment when it was offered in June 2003. This legislation became part of the Senate bill to add a prescription drug benefit to Medicare, but it was eliminated in the final conference report on the bill.

The text of two documents follows here, including 1) FAQs about the *Pharmaceutical Market Access and Drug Safety Act*, 2) a summary of key elements of the legislation.

FREQUENTLY ASKED QUESTIONS
PHARMACEUTICAL MARKET ACCESS AND DRUG SAFETY ACT

How is this bill different from the REMEDIES Act?

· The Grassley bill included a carrot-and-stick, in the form of tax credits and deductions, to induce drug companies not to interfere with drug importation.

· This bill takes a different approach – it subjects drug companies to civil damages if they interfere with drug importation.

· The bottom line is the still the same — to ensure that drug companies do not interfere with legalized drug importation.

Does this bill create any trade issues for the United States?

· No, the bill is narrowly drafted so as not to create any litigation risk for the United States, either in the WTO or under our bilateral trade agreements.

Who will be eligible to import prescription drugs under this legislation?

· Licensed U.S. pharmacies and drug wholesalers that register with the Food and Drug Administration will be able to import prescription drugs for commercial re-sale.

· Individuals will be allowed to purchase medicines directly from Canadian pharmacies.

How will American consumers be able to purchase medicines under this legislation?

· Individual consumers will be able to purchase prescription medicines from registered Canadian pharmacies for their personal use or the personal use of a family member via mail-order or the Internet.

· Drugs imported by American consumers would have to be in a 90-day supply or less, accompanied by a valid prescription.

· Consumers traveling to other countries such as Canada and Mexico and returning with a 90-day supply of medicine for their personal use, as allowed today by the FDA's current "personal use" enforcement policy.

What prescription drugs can be imported under this legislation?

· Only prescription drugs approved by the FDA and made in an FDA-inspected plant can be imported.

· Drugs that require special handling or storage or that pose special safety concerns are not to be exported, such as controlled substances, infused or injected drugs, biologics, or drugs inhaled during surgery.

From what countries can medicines be imported?

· U.S. pharmacies and drug wholesalers can import medicines from Canada and two dozen or more other major industrialized nations beginning in a year: the European Union, Australia, New Zealand, Japan, and Switzerland. FDA is given the authority to add other countries with equivalent drug approval and distribution systems.

· Individuals can purchase medicines from Canada via mail-order or the Internet from Canadian pharmacies registered with the FDA.

What are the safety features of this bill?

· FDA has the ability to verify the drug pedigree back to the manufacturer, to require FDA to inspect frequently, and to require fees to give FDA the resources to do this.

· For imports by individuals from Canada, exporters in Canada are required to register with FDA and to post a bond that they will lose if they send unsafe drugs. Frequent inspections by FDA are required to ensure compliance.

· For commercial imports, U.S. wholesalers and pharmacists must register with FDA and are subject to criminal penalties if they import unsafe drugs. Again, frequent inspections by FDA are required to ensure compliance.

· Manufacturers are required to inform FDA whether foreign drugs meet FDA standards, and if they don't, the manufacturers have to give FDA the information necessary to evaluate the safety of the drug.

When will this legislation take effect?

· Importation by individuals from Canada via mail-order or the Internet would be legalized 90 days from enactment.

· Commercial importation from Canada and from other major industrialized countries in Europe, Switzerland, Australia, New Zealand, and Japan will begin after one year.

· The legislation will not be subject to a certification by the Secretary that importation poses no risk or that it will save money. Certification is a poison pill that will prevent importation.

How is this bill similar to the Gutknecht-Vitter drug importation legislation, the Pharmaceutical Market Access Act (H.R. 328/S. 109)? How is it different?

· In broad outline, the bills are similar.

· Wholesalers, pharmacies, and individuals can import drugs under either bill.

· Drugs can come from multiple major industrialized countries in addition to Canada under both bills.

· Wholesalers and pharmacies must register with FDA to be able to import under both bills.

· The drugs imported are supposed to meet FDA standards under both bills, and certain drugs, like

controlled substances, are excluded from both bills.

· Both bills allow for drug importation to begin without first requiring certification by the Health and Human Services Secretary.

· The Gutknecht-Vitter bills also prevent manufacturers from deterring importation by discriminating against suppliers that sell to Americans or suing them for patent violations.

· *Differences*: Dorgan-Snowe-Grassley bill provides additional assurances that the imported drugs will be safe. We require frequent FDA inspections of importers and exporters, verification of the chain of custody of each drug imported, and provide the resources FDA needs to do the job.

How is this bill different from the bill Senator Gregg introduced, the Safe Importation of Medical Products and other RX Therapies Act (S. 184)?

· The Gregg bill does not include any non-discrimination provisions to prevent manufacturers from thwarting drug importation, such as by shutting off the supplies of their drugs to pharmacies that sell to Americans, as they are currently doing in Canada.

· The Gregg bill limits drug importation to Canada only for at least the first three years.

· After 3 years, the FDA could allow imports from Europe, but only if FDA first *certifies* that imports from Europe "would not present an increased risk to the public health." Since FDA has been unwilling to make a similar certification with respect to Canada, it seems highly unlikely that FDA would allow drug imports from Europe.

· There is no mechanism in the Gregg bill for the FDA or an importer to know whether a drug distributed in another country meets FDA approval requirements or not.

· The Gregg bill does not require FDA inspection of Internet pharmacies, while the Dorgan-Snowe bill requires frequent, random FDA inspection of Canadian pharmacies, including those marketing their drugs via the Internet.

· The Gregg bill does not require inspections of commercial drug shipments, does not authorize inspection of other entities in the chain of custody, and only permits inspection of records if FDA has "reason to believe" that an imported drug "presents a risk to public health." The Dorgan-Snowe bill requires frequent FDA inspection of importers and provides FDA with the authority to inspect records and other entities in the chain of custody.

How much does the bipartisan bill cost and how would it be paid for?

· CBO has not yet scored this bill.

· The costs associated with establishing the drug importation safety system created under this bill would be fully financed by user fees on registered importers and Canadian exporters. These fees would be capped at 1 percent of the total value of drugs imported annually to the United States in order to ensure that this fee does not become unduly burdensome or cost prohibitive for registered importers and Canadian exporters.

· There are currently about 40 Canadian pharmacies supplying most of the $1 billion in drugs now being imported from Canada; the 1 percent user fee works out to $250,000 per Canadian pharmacy, which should be more than adequate to pay for FDA inspection.

How do you respond to those who say that drug importation won't generate much savings?

· The House-passed Pharmaceutical Market Access Act was scored by the Congressional Budget Office as reducing total drug spending by ***$40 billion over 10 years.***

· In its cost estimate, CBO assumed that drug companies and foreign governments would take actions

to limit the volume of medicines that could be imported to the U.S., thus limiting the savings.

· Although the savings generated by the House-passed bill are nothing to sneeze at, we would expect the bipartisan Senate bill to generate even larger savings for American consumers and other drug purchasers. That's because the bipartisan Senate bill includes strong provisions to prevent drug companies from cutting off drug supplies in foreign countries, thereby removing the incentive for foreign governments to prevent importation due to fear of drug shortages in their own country.

Pharmaceutical Market Access and Drug Safety Act

I. Importable Drugs:

· FDA approved drugs from an FDA-inspected plant.

· Oral prescription drugs and not a controlled substances, an infused or injected drugs, or biologics, or a drug inhaled during surgery.

II. Commercial importation by pharmacies and drug wholesalers:

· Allows importation by licensed pharmacies and drug wholesalers from Canada, the European Union, Australia, New Zealand, Japan, and Switzerland beginning one year from enactment.

· Requires registration of wholesalers and pharmacies with FDA, and levies capped fees to support the costs of the program.

· Drugs must be re-labeled in English to comply with FDA requirements. The FDA will provide approved labeling information to importers.

· FDA may ban the importation of a product that has been determined to be counterfeit, contaminated, or is otherwise adulterated so as not to meet the requirements of this legislation. FDA may require use of approved anti-counterfeiting technologies to verify the chain-of-custody of a drug.

· This bill specifically protects pharmacies, wholesalers, and individuals from patent damages arising from the importation of drugs.

III. Personal importation by individuals:

· Beginning 90 days from enactment, individuals may be shipped prescription drugs purchased via mail-order or websites from Canadian pharmacies registered with the FDA.

· The bill also would not change the current practice of American consumers traveling to foreign countries such as Canada and Mexico and returning with 90-day supplies of medicines for their personal use.

IV Gaming the system:

· Prevents manufacturers from taking discriminatory actions that would thwart drug importation. Such actions against a pharmacist, wholesaler, or consumer to hinder their importation of prescription drugs will be an unfair and discriminatory practice, and treble economic damages may be awarded. The bill makes it clear that a drug manufacturer is not compelled to sell its product in a country.

· Prevents manufacturers from blocking importation of drugs, such as by changing the color, dosage form, or place of manufacture of the drug so that it is no longer FDA-approved. Drug manufacturers that make these kinds of changes would be required to notify the FDA, and the FDA would be given the authority to take the steps needed to approve the drug.

V. Limiting unsafe drug imports:

· Customs could seize and destroy small quantities of drugs imported by individuals from foreign exporters that are not registered with the FDA.

· The FDA would provide the individual whose drugs were seized with a simple notice explaining how the individual can import drugs from registered Canadian exporters safely and legally.

VI. Funding for implementation:

· Funding for the FDA to administer the drug importation system created fully financed by user fees on registered importers (U.S. licensed pharmacies or drug wholesalers) and Canadian exporters (registered Canadian pharmacies).

VII. Domestic Internet pharmacy consumer protections:

· Sets new disclosure standards for domestic Internet pharmacies.

· Bars domestic Internet sites from selling or dispensing prescription drugs to consumers who are provided a prescription solely on the basis of an on-line questionnaire.

· Would allow state Attorneys General to go to federal court to shut down rogue domestic Internet pharmacy sites.