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CRS Report for Congress

Prescription Drug Importation: How S. 242 / H.R. 380 Would Change Current Law

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Summary

Current law prohibits the importation of a prescription drug by anyone other than its manufacturer. S. 242/H.R. 380 would amend the Federal Food, Drug, and Cosmetic Act to allow commercial and personal-use importation. The legislation would create a detailed set of procedures to address concerns relating to the safety and effectiveness of imported drugs, cost savings to U.S. consumers, and administration of the program. Senator Dorgan offered S. 242 as an amendment to S. 1082, the Food and Drug Revitalization Act, during Senate Floor consideration. The amendment was agreed to, but only after Senators voted to approve a second-degree amendment offered by Senator Cochran, which effectively nullified the language in S. 242. Drug importation is likely to be taken up by the House when it considers legislation to reauthorize Food and Drug Administration (FDA) user fees.

Context

As public concern over rising spending on prescription drugs continues, many in Congress have co-sponsored legislation to amend the Federal Food, Drug, and Cosmetic Act (FFDCA) and permit the importation of FDA-approved drugs from lower-priced foreign sources.[1] Lawmakers have also sought to use the appropriations process to counter administrative blocks to drug importation.[2]

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[1] House-passed H.R. 2427, and S. 1 and H.R. 1, as amended, in the 108th Congress; S. 109/H.R. 328, S. 184/H.R. 753, and S. 334/H.R. 700 in the 109th; and S. 242/H.R. 380, and S. 251 in the 110th.

[2] Members have offered amendments to appropriations bills that would prohibit the use of funds to enforce importation prohibitions (e.g., the House-passed agriculture appropriations bills for FY2006 and FY2007; and P.L. 109-295, the Department of Homeland Security FY2007 appropriations bill).

On May 1, 2007, Senator Dorgan offered his drug importation bill, S. 242, the Pharmaceutical Market Access and Drug Safety Act of 2007, as an amendment during Floor consideration of S. 1082, the FDA Revitalization Act. S. 242 would change FFDCA Section 804 to allow personal and commercial importation of prescription drugs under a detailed set of procedures to address concerns of safety and cost. Before accepting the amendment on a voice vote, the Senate first voted 49-40 to approve a second-degree amendment offered by Senator Cochran that would effectively prevent the importation provisions from taking effect. The Cochran amendment to the Dorgan language would require the government to certify the safety of imported drugs, something it has indicated it is not able to do. The House companion bill to S. 242, H.R. 380, was introduced by Representatives Emanuel and Emerson. The congressional debate on prescription drug importation will likely continue — the House is expected to take up FDA legislation soon.

This report provides a brief look at the issues surrounding the debate over S. 242 and compares its provisions to current law. The report concludes by listing other CRS reports on drug importation.

Background

Current law and the bills introduced over the past several years all seek to balance the availability of imported prescription drugs with the assurance that these imports would be safe and effective. Sponsors of drug importation legislation want to reduce or restrain the financial burden prescription drugs place on U.S. consumers — Senator Dorgan's website description of his legislative proposal uses the title "Reducing the Cost of Prescription Drugs."

Under current law, it is illegal for anyone to import a prescription drug other than its manufacturer. The law includes provisions for pharmacists and wholesalers to import, but provides that they not become effective until the Secretary of Health and Human Services (HHS) certifies that the importation program would be safe and offer cost savings to U.S. consumers. Secretaries in both the Clinton and Bush Administrations have declined to provide that certification, referring to safety and cost concerns. The requirement was first established by the Medicine Equity and Drug Safety (MEDS) Act of 2000, which added FFDCA Section 804. Despite much debate to change that approach, Congress included importation provisions in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA, P.L. 108-173) that retained the certification requirement.

Current law addresses importation for personal use differently. Until a Secretary provides the certification, the law does not permit individuals to import prescription drugs for their own use. If a Secretary were to certify and allow the importation program, Section 804 still would not directly allow individual importation. It would authorize the Secretary to waive, under specific conditions, the provisions that prohibit importation by individuals. FDA has chosen to leniently enforce that ban, and has allowed individuals to bring into the United States a small amount (i.e., a 90-day supply) of non-FDA-approved drugs for personal use. This FDA enforcement policy requires that those individuals affirm in writing that the drugs are for their own use, and provide the name and address of their treating physician. When FDA's personal use import policy began, it was not envisioned as a way for consumers to bring lower-priced prescription drugs into the United States. According to its policy statement on importing drugs for

personal use, FDA intended this "enforcement discretion" to allow individuals to get treatments not otherwise available in the United States.[3]

S. 242/H.R. 380, the Pharmaceutical Market Access and Drug Safety Act of 2007, would rewrite Section 804. It would eliminate the Secretary's certification requirement and allow pharmacists, wholesalers, and individuals to import prescription drugs under a program that would address potential safeguards regarding drug safety and effectiveness.

In S. 242/H.R. 380, Senator Dorgan (and co-sponsors led by Senator Snowe) and Representative Emanuel (and co-sponsors led by Representative Emerson) continued the approach they had taken in the 109th Congress. S. 242/H.R. 380 differs in a few aspects from its predecessor, in part by including some provisions from the other 109th Congress bills. Those provisions related primarily to aspects of packaging that address identification and protections against tampering and counterfeiting, and requirements to impede unlawful drug importation requests by prohibiting certain payment system transactions involving unregistered foreign pharmacies.

S. 242/H.R. 380 differs from current law in its approach to ensuring that imported drugs are safe and effective. The bill also includes provisions to influence industry behavior so that drugs are available for import by U.S. consumers at cost savings to current domestic prices. Finally, it includes administrative arrangements, including financing.

Safe and Effective Drugs

Relationship to FDA Approval. Current law explicitly requires that an imported drug be approved for U.S. sale by the FDA. S. 242/H.R. 380 would require that a manufacturer notify the HHS Secretary when a drug that could be imported differs from the version FDA has approved for sale in the United States (the "U.S. label drug"). The bill would require extensive information about whether the difference, if it were to be made to a U.S. label drug, would require a supplemental application to FDA, and whether FDA would require that the application be processed before the drug could be marketed.

Permitted Countries. Current law would allow the importation of prescription drugs from Canada, if the HHS Secretary were to certify that the program of importation would be safe and cost-effective to U.S. consumers. S. 242/H.R. 380 would permit prescription drug importation from Australia, Canada, Japan, New Zealand, Switzerland, and members of the European Union, except for the 10 countries admitted to membership in May 2004. The legislation includes criteria by which the Secretary could add other countries to this list.

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[3] FDA, "Information on Importation of Drugs," prepared by Marvin A. Blumberg, Division of Import Operations and Policy, Office of Regulatory Affairs, FDA, HFC-170, April 3, 1998, at [http://www.fda.gov/ora/import/pipinfo.htm]; and FDA, "Coverage of Personal Importations," *Regulatory Procedures Manual*, Office of Regulatory Affairs, FDA, January 11, 2003, at [http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html].

Ensuring Drug Identity. To address the possibility that adulterated or counterfeit drugs could enter the U.S. market, S. 242/H.R. 380 calls for a variety of procedures regarding registration; monitoring, inspecting, and testing; packaging and labeling; and Internet pharmacies.

Registration. Current law requires that a Canadian establishment involved in the distribution of a prescription drug that is imported or offered for importation into the United States register with the Secretary its name and place of business and the name of its U.S. agent. S. 242/H.R. 380 would require all exporters from permitted countries and all commercial importers to register.

Monitoring, Inspecting, and Testing. While current law relies on laboratory testing of samples of every shipment of imported drugs to verify their content, potency, and labeling, S. 242/H.R. 380 would instead require documentation of a monitored, uninterrupted chain of custody from manufacturing facility to importer. The requirements related to registration involve ongoing and onsite physical monitoring of the facilities of a drug's manufacturer, exporter, and importer. If the Secretary determines it necessary, these would include the inspection of any facility (and its records) that handles the product along the chain of custody.

Packaging and Labeling. To ensure that a drug dispensed to individual consumers is the same product that was tested, monitored, or inspected at a specific manufacturing, shipping, or storage facility, S. 242/H.R. 380 would require that the packaging of all prescription drugs (not just those being imported) incorporate overt, optically variable, counterfeit-resistant technologies that provide visible identification of the product, and be similar to those used to secure U.S. currency. In addition, manufacturers must incorporate the technologies into elements of the packaging (including blister packs, shrink wrap, package labels, package seals, bottles, and boxes). The bill would require that the exporter and importer agree to mark each shipping container to identify its compliance with all registration conditions. The markings must include anti-counterfeiting or track-and-trace technology, taking into account their economic and technical feasibility, and must be designed to prevent unauthorized affixation.

Internet Pharmacies. Current law does not address use of the Internet to sell or purchase imported prescription drugs. S. 242/H.R. 380 would require that detailed information be accessible on an Internet pharmacy's website, covering pharmacist credentials, address and telephone contacts, and the name and professional licensure information of the person, if any, who provides for medical consultations through the site for purposes of providing prescriptions. The bill includes many restrictions, such as: no one could dispense or sell a drug if the purchaser or patient who communicated through the Internet did not have a valid U.S. prescription; and the dispenser of the prescription drug must have a "qualifying medical relationship with the patient."

Cost Savings to U.S. Consumers

Even if a Secretary were to issue the certification necessary to begin the drug importation section in the FFDCA, many analysts and Members of Congress anticipate manufacturer resistance to a practice that might limit the industry's revenue. S. 242/H.R. 380 contains specific provisions designed to influence industry behavior.

Discrimination and Unfair Acts. S. 242/H.R. 380 would make it "unlawful for a manufacturer, directly or indirectly (including being a party to a licensing or other agreement)," to discriminate or act unfairly against an exporter, importer, or person who distributes, sells, or uses an imported prescription drug by charging a higher price; denying, restricting, or delaying supplies; or refusing to do business.

Drug Differences. S. 242/H.R. 380 would make it unlawful for a manufacturer to make a drug for distribution in a permitted country so that it differs from the drug made for U.S. distribution "for the purpose of restricting importation of the drug...." Enforcement provisions include the involvement of the Federal Trade Commission and the state attorneys general.

Patent Law. A recent federal court case has raised the prospect that a drug manufacturer could, under certain circumstances, sue a drug importer for patent infringement and block U.S. imports of drugs the company sells abroad. The court ruled that a U.S. patent is not exhausted by foreign sales, and, thus, a drug manufacturer could exercise its patent rights and block imports of its patented drug products into the United States. S. 242/H.R. 380 would insert a new subsection in the Patent and Trademark Act to reverse this judicial precedent. Under the provision, goods that were the subject of authorized foreign sales by a U.S. patent holder may be imported into the United States without regard to the U.S. patent.

Administration of Importation Provisions

S. 242/H.R. 380 would set up a fee mechanism to fund the administrative and regulatory tasks of the importation program. It also would set specific implementation dates.

Funding. Current law includes no explicit funding mechanism other than authorizing appropriations of such sums as necessary to implement the prescription drug importation provisions. S. 242/H.R. 380 provides for both exporter and commercial importer fees designed to cover all costs of the program. It links the aggregate total of all fees to the estimated costs of the importation program, setting a limit of 2.5% of the total price of drugs imported. The Secretary would collect from each exporter and importer both a flat registration fee and a proportional registration fee. Each individual importer or exporter would pay the latter fee based on the extent of its own activity and calculated to estimate its proportion of the aggregate amount. S. 242/H.R. 380 would require that these fees be used only for the administration of the importation provisions that the bill would add.

Effective Dates. Current law does not specify when importation could begin, other than by linking it to required safety and cost certification by the Secretary. It directs the Secretary to exercise discretion to permit importation by an individual for personal use, if it does not appear to present an unreasonable risk to the individual.

S. 242/H.R. 380 would require that the Secretary promulgate a final rule for implementing the importation provisions not later than one year after promulgating an interim rule. It also states that the importation provisions shall "permit the importation of qualifying drugs … without regard to the status of the issuance of implementing regulations" from registered exporters (to individuals in the United States) 90 days after enactment, and from permitted countries by registered importers (commercial) one year after enactment.

Severability. S. 242/H.R. 380 states that if any provision of the Pharmaceutical Market Access and Drug Safety Act of 2007 were to be held unconstitutional, the remainder of the act would not be affected.

CRS Reports On Prescription Drug Importation

Three CRS reports cover in greater depth the current policy and legal issues surrounding the importation of prescription drugs:

- CRS Report RL32511, *Importing Prescription Drugs: Objectives, Options, and Outlook*, by Susan Thaul.
- CRS Report RS21711, *Legal Issues Related to Prescription Drug Sales on the Internet*, by Vanessa K. Burrows.
- CRS Report RL32191, *Prescription Drug Importation and Internet Sales: A Legal Overview*, by Vanessa K. Burrows.

Several archived CRS products provide additional historical detail.[4]

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[4] See CRS Report RL33175, *Importation of Prescription Drugs: A Side-by-Side Comparison of Current Law, S. 109/H.R. 328, S. 184/H.R. 753, and S. 334/H.R. 700*; CRS Report RL32568, *Senate Prescription Drug Legislation: A Side-by-Side Comparison of Current Law, S. 2307, S. 2328, and S. 2493*; and CRS Report RL32271, *Importation of Prescription Drugs Provisions in P.L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, all by Susan Thaul, and Donna U. Vogt. Also see the following products, which are out of print but available on request: CRS Report RL32107, *Importing Prescription Drugs: Comparison of the Drug Import Provisions in the Medicare Reform Bills, H.R. 2427 and Current Law*; CRS Report RL31503, *Importing Prescription Drugs*; CRS Report RS20996, *Prescription Drugs: Importation for Personal Use*; CRS Report RS20961, *Prescription Drug Imports: Proposed Amendments to the FY2002 Agriculture Appropriations Act*; CRS Report RS20750, *The Prescription Drug Import Provisions of the FY2001 Agriculture Appropriations Act, P.L. 106-387*; and CRS LTR00-217, *Summary of H.R. 1885, the International Prescription Drug Parity Act*.