

CRS Report for Congress

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Prescription Drugs: Importation for Personal Use

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Summary

The 107th Congress, concerned about the high costs of pharmaceuticals in the United States, is considering legislation that would give U.S. citizens the legal right to import less costly prescription drugs from foreign countries. The House, in the FY2002 appropriations for the Department of Agriculture (H.R. 2330), adopted an amendment, sponsored by Representative Gutknecht that would let persons, who are not commercial drug importers import prescription drugs for personal use. Under the amendment, drugs must be Food and Drug Administration (FDA) approved, non-narcotic, and manufactured in an FDA-registered facility. In the Senate, a different proposal to allow drug imports (S.1229) was introduced by Senator Wellstone. It would allow patients to import prescription drugs if they are FDA-approved, non-narcotic, made in FDA-registered facilities, originate from specified countries, and are accompanied by a special import form. FDA would have to keep records of the drugs imported. These proposals would change FDA's current "personal use import policy," which lets patients with life-threatening conditions (i.e., AIDs or cancer, etc.) bring small quantities of unapproved drugs into this country for personal use, to one that lets patients import approved prescription drugs for personal use. The proposals were introduced when the past and present Secretaries of Health and Human Services (HHS) declined to implement last year's Medicine Equity and Drug Safety Act (MEDS), legislation which would have let pharmacists and drug wholesalers import drugs originally made in the United States. According to the Secretaries, the MEDS Act would have raised health risks and not lowered the cost of prescription drugs. Also, they were worried that the program might make it easier for counterfeit drugs to enter the country.

Introduction

In recent years, the cost of prescription drugs has become a major issue for Congress. At present, U.S. consumers, particularly the elderly and uninsured, oftentimes pay more for prescription drugs than citizens in other countries. This price disparity has prompted some Americans to purchase cheaper prescription drugs through the Internet, by mail-order, or by traveling outside the United States, often to nearby Canada or Mexico.

To address these concerns, the 106th Congress passed the Medicine Equity and Drug Safety Act (MEDS). The MEDS Act would have let pharmacists and drug wholesalers re-import FDA-approved prescription drugs previously manufactured in the United States. However, Congress said that the new law could not be implemented unless the Secretary of Health and Human Services (HHS) could show that the Act would result in a cost savings for imported prescription drugs and not pose additional risks to public health. (See Text Box) Saying they were unable to meet these conditions, both the past and present Secretaries of HHS, declined to implement the law stating that prescription drug safety could not be adequately guaranteed if drug re-importation were allowed under the MEDS Act.¹ Secretary Tommy G. Thompson, further explained that the costs associated with documenting, sampling and testing of imported drugs, as the Act requires, would make it difficult for consumers to get any significant price savings.

**Summary of Drug Import Provisions
in the Agriculture Appropriations Act for FY2001**

Medicine Equity and Drug Safety Act (MEDS). The 106th Congress passed the MEDS Act in October 2001, as part of the FY2001 agriculture appropriations law (P.L. 106-387). An amendment to the Federal Food, Drug, and Cosmetic Act (FFDCA), the law established a 5-year import program to allow pharmacists and drug wholesalers to import less costly prescription drugs into the United States. The following summarizes two of the legislation's major clauses as enacted:

Regulations and Limitations. Under the MEDS Act, the Secretary of HHS was to have promulgated regulations that would have guaranteed that all drugs imported under the program would be FDA-approved, tested for authenticity, and be properly labeled before distribution.

Conditions. Before the Act could be implemented, the Secretary had to demonstrate to Congress that its implementation would pose no additional risk to public health and safety, and would result in a significant reduction in the cost of drugs for U.S. consumers.

Prescription Drug Import Fairness Act of 2000. This Act, also passed as part of the FY2001 agriculture appropriations law, prevents FDA from sending warning letters to persons who import drugs for personal treatment unless the agency specifies how the import violates the law.

The MEDS Act was never implemented by either Secretary of HHS. The Prescription Drug Import Fairness Act, however, is currently in effect.

Subsequently, some Members of the 107th Congress have looked for other legislative ways to deal with the drug pricing issue. On July 12, 2001, the House agreed to an amendment by Representative Gutknecht to the FY2002 appropriations bill for the Department of Agriculture (H.R. 2330), that would let U.S. citizens who are not in the drug importation business import FDA-approved, non-narcotic prescription drugs for personal use. On July 24, 2001, Senator Wellstone introduced the Personal Prescription Drug Import Fairness Act (S. 1229), that would also let individuals import prescription drugs, if they meet the requirements in the bill. While these measures are similar (i.e., both would allow patients to import FDA-approved, non-narcotic prescription drugs), they also

¹ "Secretary Thompson Determines That Safety Problems Make Drug Reimportation Unfeasible," *HHS News*, Press Release July 10, 2001. [<http://www.hhs.gov/news>]

have their differences. The House-passed amendment would let persons import prescription drugs for personal use from any country. The Wellstone bill, however, would only let persons import drugs from specified countries,² and only if accompanied by an import form. The Senate bill would also require FDA to keep records of all drugs imported.

Background

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), all drugs have to be proven safe and effective before they can be marketed in the United States. To gain FDA approval, foreign or domestic drug manufacturers must first submit New Drug Applications (NDAs) which include reports of clinical studies documenting safety and efficacy. As the NDA is being evaluated, the agency inspects the plant and the production line where the new drug will be manufactured to ensure that it will be made to specification and in accordance with good manufacturing practices (GMPs). Also, it approves the companies that supply the raw ingredients that go into making the final product. As these inspections are carried out, other FDA officials check the drug's labeling to make sure that it is both accurate and comprehensive. Pharmaceuticals imported into the United States, whether they were originally made here or abroad, must be FDA-approved and properly labeled. Imported drugs have to be accompanied by information telling where they were made, the name and address of the importer, and evidence that the drugs were made in an FDA-inspected facility following proper GMPs. Imported pharmaceuticals that do not meet U.S. standards are considered "unapproved" drugs and cannot be imported legally. To reduce the chance that adulterated or subpotent drugs could enter a U.S. retail pharmacy, Congress passed the 1987 Prescription Drug Marketing Act (P.L. 100-293). The law made it illegal for anyone other than the original manufacturer to import a drug back into the United States.

Today, both U.S. Customs and FDA officials have broad authority to deny entry to imported drug products that "appear" to violate U.S. regulatory requirements. For enforcement purposes, the FDA separates imported prescription drugs into three categories: (1) drugs for commercial distribution; (2) prescription drugs that arrive by mail or common carrier; or (3) prescription drugs that are brought into the country by persons passing through customs.

FDA's Current Mail and Personal Use Import Policy. Although it is illegal to import unapproved drugs into the United States, the FDA, for years, has maintained a policy that lets patients bring a small amount (i.e., a 90-day supply) of non-FDA approved drugs into this country for compassionate use. The so-called "personal use import policy" makes it easier for patients with life-threatening diseases (such as AIDS) to bring therapies into this country to be treated by their personal physician.³ Under the policy, drugs cannot be imported commercially, and patients must affirm in writing that the drug is for personal use and provide the name and address of their physician. Enforcing the personal use policy often requires a lot of discretion on the part of FDA and Customs inspectors. When drugs

² Australia, Canada, European Economic Area (including the European Union, Norway, Iceland, and Liechtenstein), Israel, Japan, New Zealand, South Africa, or Switzerland.

³ U.S. Food and Drug Administration. [<http://www.fda.gov/ora/import/pipinfo.htm>].

are brought into this country for personal use today, they are either carried in by persons, or arrive via the mail, after being purchased from pharmacies operating over the Internet.

When the personal use import policy was established, it was never intended to be a way for patients to bring lower priced drugs into this country; nor was it a means for patients to buy drugs that are already available in the United States. While the policy has not changed, where it once let patients import drugs for compassionate use, today it is being used to import drugs to treat all kinds of medical conditions, by patients seeking lower price prescription drugs from other countries.⁴ Over time, FDA's import policy, and its discretionary enforcement, have led to a dramatic increase in drug imports. Today, this increase has become a major concern of both FDA and the Customs Service.

Earlier this year, in order to determine the amount and types of drugs being imported through the mail, the FDA and Customs conducted a 5-week survey of drugs entering the United States by mail in Carson City, California. According to the agencies, many of the drugs detained during the survey were for treating health conditions that normally require a doctor's diagnosis.⁵ This finding raised the concern that patients who obtain prescription drugs without a doctor's prescription may be exposing themselves to serious risks. During a June 7, 2001 congressional hearing on drug import policy, the FDA said that it was on the verge of recommending that the Secretary of HHS end the practice of allowing drugs imported via the mail, as long as there was an exception for drugs intended for compassionate use.⁶ The large number of drugs entering the country by mail has become an enforcement problem, and FDA's concern is that government inspectors cannot, with any assurance, determine whether the products being shipped are safe.

The Gutknecht Amendment

When the House considered the FY2002 appropriations bill for the Department of Agriculture, it agreed to an amendment sponsored by Representative Gutknecht, that would allow individuals to bring FDA-approved drugs into the United States for personal use. The text of the amendment says:

None of the amounts made available in this Act for the Food and Drug Administration may be used under section 801 of the Federal Food, Drug and Cosmetic Act to prevent an individual who is not in the business of importing prescription drugs within the meaning of section 801(g) of such Act from importing a prescription drug that (1) appears to be FDA-approved, (2) does not appear to be a narcotic drug; and (3) appears to be manufactured, prepared, propagated, compounded, or processed in an establishment registered pursuant to section 510 of such Act.⁷

⁴ U.S. citizens who want to have their prescriptions filled by Canadian pharmacies must have the prescription confirmed by a Canadian physician before the pharmacy will fill it.

⁵ Hubbard, William K., Senior Associate Commissioner for Policy Planning and Legislation, Food and Drug Administration. Statement before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, June 7, 2001.

⁶ Ibid.

⁷ Section 801(g) was enacted by the Prescription Drug Import Fairness Act of 2000 to keep the (continued...)

The amendment would likely make it easier for U.S. citizens to bring less costly prescription drugs into this country for personal use. It prohibits the commercial importation of prescription drugs, as well as the importation of narcotic products. The amendment would allow all drugs that appear to be FDA-approved to be imported. FDA believes that it would still have the authority to stop drug imports from entering this country, but only if it proved that the imported drug violated the law.

The Personal Prescription Drug Import Fairness Act (S. 1229)

On July 24, 2001, Senator Wellstone introduced a bill entitled the Personal Prescription Drug Import Fairness Act. In essence, the bill would create a legal framework for FDA's current policy that allows patients to import small amounts of drugs for compassionate use and extend it for treatments of other health conditions. It would amend the FDCA to require the Secretary of HHS, in consultation with the U.S. Trade Representative and the Commissioner of Customs, to promulgate regulations to let individuals, either in person or by mail, bring a 90-day supply of prescription drugs into the country for personal use. All drugs imported under the measure, would have to be FDA-approved, be made in FDA-registered facilities, come from designated countries, be in a finished form, and could not be resold in this country.

Prescription drugs, either brought in by individuals or mailed into this country, would have to be accompanied by a new "import form." The form must include the name, address and telephone number of the patient, the pharmacy that dispensed the drug, and the place where it was manufactured. It must also include the name of the patient's doctor in the United States responsible for treatment with the prescription drug, or evidence that the drug is for the continuation of treatment that began outside of the United States.

Under the bill, the Secretary would be required to maintain records of each prescription drug imported. Additionally, the Secretary would have to make publically available a list of FDA-approved drugs that could be imported for personal use that: 1) are manufactured outside of the United States; or 2) are U.S. made but intended for export.

Legislative Issues

Prescription Drug Costs. Supporters of the proposals contend that, as long as drug price disparities continue between countries, consumers will benefit from being able to purchase lower cost pharmaceuticals from other countries. Given that many foreign governments impose strict controls on drug prices, it would be difficult to determine a set of circumstances that might eliminate the price differences that are currently driving demand for foreign prescription drugs.

Product Integrity and Inspection Issues. Some believe that FDA's current compassionate use policy favors the import of unapproved drugs over approved drugs. To

⁷ (...continued)

FDA from sending to individuals who import drugs for personal use warning letters about the illegality and potential health risks of imported drugs, unless the agency specifies how the import violates the law. Section 510 requires the registration of drug manufacturing facilities, whether or not they are in the United States or abroad.

address this, the House amendment would change the policy so that a greater number of prescription drugs could be imported. In addition, it would not impose any special requirements on prescriptions obtained from foreign pharmacies. If these changes become law, FDA claims that it would be unable to guarantee the integrity of these drugs since its inspectors would have a hard time examining every parcel and determining the quality of its contents. Under such circumstances, FDA has stated that it would be “buyer beware” for consumers who decide to import prescription drugs. The Senate bill provides for a more formal system for checking the safety of imported drugs, but also does not guarantee the integrity of the drugs by FDA standards. All imported drugs would need an import form disclosing the name of the patient, the address of the dispensing pharmacy, the name of the health care provider or evidence that the drug was for treating a health condition that began overseas, and where the drug was made. However, the success of such a system would, in all likelihood, depend on consumers being able to make purchases and obtain approved drugs without undue administrative hardships.

Lack of Physician Involvement. FDA is concerned that under the House-passed bill many patients who order prescription drugs via Internet pharmacies do not necessarily do so with a doctor’s prescription. In some instances, there may be no doctor-patient relationship whatsoever. At times, prescription drugs can produce side effects known only to professional health care providers. Without professional oversight, some drugs can pose serious health risks. The Senate bill would require the name of the patient’s doctor, or evidence showing that the drug is for treatment that began outside of the United States.

FDA Enforcement Issues. The United States has the most rigorous system for ensuring drug safety in the world. Before drugs can be marketed, they have to be FDA-approved, labeled properly, manufactured in FDA inspected facilities, and sold through licensed distributors and pharmacists. Currently, the FDA has broad authority to stop the importation of a drug if the agency suspects it is unapproved or does not appear to meet U.S. standards. The House-passed amendment states that a drug can be imported if it “appears to be FDA-approved.” If the amendment becomes law, FDA is concerned that it would first have to allow drugs to enter the country that appear to be approved, and then prove that the imported drug was not FDA-approved before denying entry. This could make it more difficult for the agency to keep adulterated or counterfeit drugs from entering the country if they appear to be FDA-approved and comply with U.S. regulations.⁸ The Senate bill, on the other hand, would require FDA to keep records of all prescription drugs imported for personal use. In addition, the agency would have to compile and make public a list of FDA-approved drugs, manufactured both inside and outside the United States, that can be imported into the country. FDA contends that these requirements would add extensive monitoring responsibilities for the agency and might not necessarily increase the safety of imported prescription drugs.

⁸ Hubbard, William K., Senior Associate Commissioner for Policy, Planning, and Legislation, Food and Drug Administration. Letter to the Honorables W.J. “Billy” Tauzin, Chairman, and John Dingell, Ranking Minority Member, Committee on Energy and Commerce, House of Representatives, July 17, 2001.