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The Prescription Drug Import Provisions of the FY2001 Agriculture Appropriations Act, P.L. 106-387

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Summary

The FY2001 Agricultural Appropriations bill [P.L. 106-387] included two amendments to the Federal Food Drug and Cosmetic Act (FFDCA): one that would have required the Food and Drug Administration (FDA) to establish a 5-year drug import program that would allow pharmacists and wholesalers to import FDA-approved prescription drugs into the United States; and a second that placed conditions on FDA sending warning letters regarding the importation of drugs for personal use. When the 106th Congress was unable to reach a consensus on a new prescription drug benefit under Medicare, it looked for other ways to increase the availability of lower cost prescription drugs. Under the new law, pharmacists and drug wholesalers who import drugs would have to provide FDA with specific information that would allow the agency to monitor the program. All imported drugs would have to be FDA-approved, tested for authenticity, and be properly labeled before they could be distributed. Drug companies would be prohibited from entering into contracts and agreements that would limit or interfere with the program's implementation. The import program could not begin until the Secretary of Health and Human Services (HHS) certified to Congress that its implementation would pose no additional public health risk and would significantly reduce the cost of drugs for American consumers. However, on December 26, 2000, Secretary Shalala advised the President that she could not implement the program because of what she termed "serious flaws and loopholes" in the legislation. Nevertheless, the conditions on warning letters are effective immediately. This report will be updated as events warrant.

Introduction

The cost of prescription drugs, particularly for the elderly and the uninsured, became a major concern of the 106th Congress. The issue grew contentious when U.S. consumers began asking why they were paying more for prescription drugs than citizens in other countries. According to an editorial in the *New England Journal of Medicine*, Americans

regularly pay up to twice as much as Europeans and Canadians for the same drug.¹ This anomaly has led some Americans to travel outside the United States, particularly to Canada, to purchase prescription drugs.² Some believe that these price disparities are unfair, and are a major contributor to the rising cost of health care in America.³ The U.S. pharmaceutical industry argues, however, that U.S. patients benefit from a steady flow of new therapies, and asserts that revenues generated from drug sales are necessary to support drug research and development, which benefit all consumers world-wide.⁴

Background

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), all drugs must be proven safe and effective before they are approved for marketing in the United States. All imported drugs, whether they are originally made in the United States or manufactured in another country, must be FDA-approved and be properly labeled. Also, imported drugs must come with information indicating where they were made, the name of the importer, and evidence that they were made following good manufacturing practices. Imported pharmaceuticals that do not meet U.S. standards are considered “unapproved” drugs and cannot be imported legally. To reduce the risk of adulterated or subpotent drugs from reentering this country, Congress in 1987 made it illegal for anyone other than the manufacturer to import a drug into the United States.⁵

FDA’s Personal Use Import Policy. Even though the FFDCA prohibits non-approved drugs from entering the United States, for years the FDA has maintained a policy that allows patients to bring a 90-day supply of prescription drugs for their personal use. The reason for this policy was to let patients with serious diseases (such as AIDS) bring non-FDA approved therapies into this country, so that they could continue to be treated by their own physician.⁶ Under the policy, patients must affirm in writing that the drug is for their own use, provide the name and address of their attending physician, or provide evidence that the medication is necessary to continue treatment. Today, drugs brought in for personal use are often purchased in person, by mail, or through the Internet. At the time the personal use import policy was adopted, it was never intended as a way for

¹ Angel, Marcia. The Pharmaceutical Industry – To Whom Is It Accountable? *New England Journal Of Medicine*, v. 342, no. 25, June 22, 2000. p. 1902-1904.

² Patented Medicine Prices Review Board. Trends in Drug Prices and Expenditures, Figure 8, Average Foreign-to-Canadian Price Ratios All Patented Drug Products in 1999. *1999 Annual Report*, Canada.

³ Pear, Robert. Rise in Health Care Costs Rests Largely on Drug Prices. *The New York Times*. November 14, 2000. p. A12.

⁴ Pharmaceutical Research and Manufacturers of America. Why do Prescription Drugs Cost so Much? [<http://www.phrma.org/publications/publications/brochure/questions/>] October 19, 2000.

⁵ Prescription Drug Marketing Act of 1987, P.L. 100-293.

⁶ U.S. Food and Drug Administration. Information on Importation of Drugs Prepared by the Division of Import Operations and Policy. [<http://www.fda.gov/ora/import/pipinfo.htm>]. FDA usually refrains from taking enforcement actions when: the drug is for a serious condition and no domestically approved treatment exists; the drug has not been advertised in the United States; and the product poses little or no risk.

patients to purchase lower priced drugs in foreign countries. Recently, however, the number of patients who are importing drugs for personal use under this policy has been growing.⁷ This policy was not changed by the FY2001 Agriculture Appropriations Act.

Changes in the Law to Allow Drug Imports

During consideration of the FY 2001 agriculture appropriations bill, Congress agreed on two amendments to the FFDCA that would ease restrictions on imported drugs. The first amendment, called the Medicine Equity and Drug Safety Act of 2000, required FDA to promulgate regulations implementing a new drug import program which would allow pharmacists and drug wholesalers to import prescription drugs from certain countries. The second amendment, called the Prescription Drug Import Fairness Act of 2000, prevents FDA from sending warning letters to individuals who import drugs for personal use unless the agency specifies how the imported drug violates the law.

The following points summarize the legislation's major clauses as enacted:

Regulations and Limitations. Under the Act, the Secretary of Health and Human Services (HHS)⁸ must promulgate regulations allowing pharmacists and wholesalers to import prescription drugs (referred to as "covered products" in the Act) into the United States. The statute does not specify a time frame for establishing these regulations. Before these rules can be published, however, the Secretary must consult with the U.S. Trade Representative and the Commissioner of Customs. The Act requires that all drugs imported under the new law must meet the same safety and efficacy standards as drugs approved in the United States. In addition, imported products cannot be adulterated or misbranded. Furthermore, the Act allows the Secretary to adopt rules as necessary to protect public health or to facilitate the import program.

Records Maintained by Pharmacists and Wholesalers. The Act requires that all records regarding imported prescription drugs must be kept for whatever period the Secretary determines as necessary. The records must also be made available for inspection purposes. Nothing in the Act, however, requires these records be made available to the General Accounting Office (GAO) to conduct the study required by the law. (See "Studies and Reports" below.)

Importation. Importers must provide FDA with records that include: the name and amount of the drug, its active ingredients and dosage, the date on which it was shipped, and information about its origin and destination. They must also supply information about the drug's resale price, the quantity of each lot, and the manufacturers' control number.

Certain other requirements must be met before drugs can be reimported. For drugs entering the United States directly from the first holder of the drug overseas, there must be documents indicating who has had control over the drug, that it is the same quantity of a drug that was originally received, and verification that each batch of the drug has been

⁷ If U.S. patients want to get their drug prescriptions filled in Canada, they must first get a prescription from a Canadian physician before it can be filled by a Canadian pharmacy.

⁸ The Secretary of HHS delegates to the FDA the responsibility for carrying out the statute.

statistically sampled and tested in the United States for authenticity and degradation prior to importation. Subsequent shipments of these drugs must also be tested for authenticity and degradation, and be certified as FDA-approved and be properly labeled.

For reimported drugs that are not coming directly from the first foreign holder, the imports must have documents accompanying them that demonstrate that a batch of the product has been statistically sampled and tested for authenticity and degradation. The importer or manufacturer must also certify that the product is FDA-approved and meets all U.S. labeling requirements. In addition, there must be documents verifying that the required authenticity testing was conducted in an approved U.S. laboratory.

Testing. Either the manufacturer or the importer can conduct the required testing. Manufacturers must supply to the importing pharmacist or wholesaler information needed to authenticate the product and its labeling. Testing information must be kept in confidence, and the Secretary may adopt rules to protect commercial or financial information, and confidential and privileged trade secrets.

Imports from Designated Countries. Prescription drugs covered by the law can be imported only from: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the European Union. Additional countries can be added to the list at the Secretary's discretion.

Suspension of Importations and Enhanced Penalties. If FDA discovers a pattern of counterfeit or violative products, the agency can suspend importation of a specific product or a specific importer. The suspension stays in effect until the agency completes an investigation and determines that the public is adequately protected. Those who knowingly violate the terms of the Act can receive up to 10 years in prison and fines not to exceed \$250,000 or both.

Prohibited Contract or Agreements. Manufacturers of imported drugs may not enter into contracts or agreements that include provisions to prevent the sale or distribution of imported products.

Studies and Reports. FDA is required to evaluate drug importers' compliance with the new regulations. In doing this, the agency has to compare the number of counterfeit, misbranded, or adulterated imported drugs with the number of drugs shipped domestically that are counterfeit, misbranded, or adulterated. After consulting with the U.S. Trade Representative and the Commissioner of Patents and Trademarks, the study must evaluate the effect the imports have had on trade and patent rights under federal law. Two years after the effective date of its implementing regulations, FDA has to give Congress a report describing the study's findings. In addition, 18 months after the program goes into effect, GAO must submit to Congress a report that evaluates whether the program has been effective in lowering drug prices for consumers.

Definitions. Under the Act, the term "covered product" refers to imported prescription drugs. However, the scope of the definition does not include Schedule I, II, and III controlled substances (drugs with a high abuse potential), nor biological products regulated under the Public Health Service Act. Also, donated drugs, or free drugs supplied to foreign-based charitable organizations or foreign governments cannot be imported. Further, parenteral (injectable) drugs may not be imported if FDA feels that they may be

a “threat to the public health.” Under the Act, in addition to manufacturers, only licensed pharmacists or wholesalers may import drugs. All labs that qualify for testing have to be approved by the Secretary.

Conditions. Before the import program can begin, the Secretary must demonstrate to Congress that its implementation will pose no additional risk to public health and safety, and will result in a significant reduction in the cost of drugs for U.S. consumers.

Sunset Provision. The import program is set to expire 5 years after FDA issues its final implementation regulations.

Appropriation. Congress appropriated \$23 million for implementation of the Act in FY2001. However, this appropriation becomes available only when the President submits an official budget request and justification to Congress.

Warning Notices. A second amendment (Section 746) prevents FDA from sending warning notices to individuals who import prescription drugs for personal use unless the agency provides a detailed explanation of why the warning notice is being sent.⁹

Issues and Concerns Raised by the New Statute

On December 26, 2000, Secretary of HHS, Donna Shalala, said in a letter to the President that she could not request the \$23 million that was conditionally appropriated to implement the drug reimportation program because of flaws and loopholes in the legislation that she claimed would not provide cost savings for consumers and could pose unnecessary risks to public health.¹⁰

Costs of Prescription Drugs. By expanding the supply of drugs available to U.S. consumers, the drug reimportation program might, through increased competition, reduce the cost of some prescription drugs. However, some have questioned this assumption. It has been argued that since the program has no built-in price guarantees, consumers may never actually benefit from lower priced drugs. For example, there was no provision in the law that required importers to pass savings on to consumers. Further, some questioned whether drug wholesalers and pharmacists would choose to invest in the required authenticity testing unless they could pass their added costs through to the consumer. In addition, broad categories of drugs frequently prescribed in the United States, such as controlled substances, parenterals and biologics, were exempt under the Act. In her letter advising against the law’s implementation, Secretary Shalala asserted that a drop in drug prices would be unlikely because the law did not prohibit manufacturers from requiring distributors to charge higher prices, limit supply, or otherwise treat U.S. importers less favorably than foreign purchasers.

Prohibited Contracts and Agreements. The Act prohibited manufacturers from entering into contracts or agreements with foreign buyers that would interfere with the sale

⁹ Section 746 established Section 801(g) in the FFDCA. This provision was introduced as the Drug Import Fairness Act of 2000 (H.R. 3240) and passed the House on June 29, 2000. Its provisions were incorporated into the FY2001 agriculture appropriations bill during conference.

¹⁰ Donna E. Shalala, Letter to President William J. Clinton, December 26, 2000.

or distribution of reimported drugs. Supporters of the Act felt this prohibition would prevent drug companies from circumventing congressional intent and rendering the program ineffective. Critics noted, however, that drug manufacturers could simply get around the prohibition by demanding that distributors promise to sell only the drug at the more expensive U.S. price.¹¹

Limit Supplies. Another concern was that drug companies could choose to reduce the amount of drugs they export in order to limit the number of drugs available for reimportation. Further, some suggested that manufacturers could also thwart the intent of the statute by exporting prescription drugs made with different identifying features (such as color, size, shape, or dosage) than those approved for sale in the United States. Because these drugs would not be exactly like their FDA-approved counterparts, from a regulatory perspective, they might be considered “non-approved” and be ineligible for reimportation. It was Congress’ belief, however, that the strong penalties imposed by the Act – \$250,000 or 10-years in jail or both – would deter such occurrences.

Drug Testing and Labeling. When pharmacists and wholesalers conduct the testing required for imported products, the Act required that drug manufacturers to supply them with the information needed to authenticate the drug, and confirm that it was properly labeled. The Act, however, does not entitle reimporters to use manufacturers’ FDA-approved labeling so that their imported drugs could be sold legally in the United States. Since most drug manufacturers consider their brand names and formulas to be proprietary under copyright and trademark laws,¹² there would be a good chance that they might seek remediation in the courts if they were required to make this kind of information available to drug importers.

Product Integrity and Inspections. The statute contained provisions that intended to create a more diversified and open program for importing prescription drugs. For this reason, some raised concerns that the import program would make it easier for adulterated, misbranded, sub-potent, or counterfeit drugs to enter the U.S. distribution pipeline and eventually end up in retail pharmacies. There were also concerns that FDA’s already overloaded drug import monitoring system, even with a \$23 million increase in funding, would be stretched even further if the agency had to monitor additional testing and conduct more inspections of overseas facilities.

Sunset Provision. Another controversial issue was the law’s 5-year sunset provision. According to Secretary Shalala, this time limitation would have given drug companies little incentive to invest in the required testing and distribution systems without some positive long-term financial return. Nor did the law provide much incentive for the U.S. government to set up a monitoring system for drug imports, if it would not result in lower cost drugs for consumers. It is unclear whether Congress and the Bush Administration will interpret these requirements differently.

¹¹ “White House, Dems: Label, Contract Loopholes Weaken Drug Import Bill.” *Inside Washington’s FDA Week*, v. 6, no. 41, October 13, 2000. p. 1 and 14-16.

¹² Claiming that the person holding a patent has the “exclusionary right” to decide whether or not to sell the product under patent or even to set conditions for a sale, some feel that the clause in the drug import legislation prohibiting contracts may be challenged under the “takings clause” of the Constitution.