Order Code RL32107

CRS Report for Congress
Received through the CRS Web

Importing Prescription Drugs — Comparison of the Drug Import Provisions in the Medicare Reform Bills, H.R. 2427, and Current Law

October 8, 2003

Blanchard Randall IV, Susan Thaul, and Donna U. Vogt
Domestic Social Policy Division

Importing Prescription Drugs — Comparison of the Drug Import Provisions in the Medicare Reform Bills, H.R. 2427, and Current Law

Summary

For years now, Congress has been concerned about the rising cost of prescription drugs in the United States. Recent international price comparisons have confirmed that American consumers, particularly the elderly and uninsured, often pay much more for pharmaceuticals than do citizens in other countries. As drug prices continue to rise, more people and some local governments are turning to online pharmacies or traveling outside the country to purchase less costly prescription drugs. However, under U.S. law only drug manufacturers can import pharmaceuticals into the United States. Despite this legal restriction, the Food and Drug Administration (FDA) has for years allowed patients to bring a 90-day supply of prescription medications into the country under its so-called "personal use" import policy.

In 2000, Congress passed the Medicine Equity and Drug Safety (MEDS) Act that would have let pharmacists and drug wholesalers import less costly FDA-approved prescription drugs from foreign countries. However, the Act included a controversial provision barring the Secretary of Health and Human Services (HHS) from implementing the law without first confirming that the drugs imported under the program would "pose no additional risk to the public's health and safety; and result in a significant reduction in the cost of covered products to the American consumer." Since then, two Secretaries have declined to implement the law, stating that these conditions could not be met.

The 108th Congress is focusing now on several new proposals that may make it easier for consumers to access cheaper prescription drugs. In June 2003, the House and Senate agreed to amendments on their respective Medicare reform bills (H.R. 1 and S. 1) that would modify the MEDS Act and make it easier for pharmacists and wholesalers to import less costly prescription drugs from Canada. The bills would also prescribe conditions under which the Secretary could allow imports of drugs for personal use. In separate action, the House passed the Pharmaceutical Market Access Act of 2003 (H.R. 2427), a measure sponsored by Representative Gil Gutknecht that would permit pharmacists, wholesalers and qualifying individuals to import prescription drugs from 25 industrialized countries, and require drug companies to incorporate various tamper-resistant technologies in all prescription drug packaging. Both Medicare reform bills would require prior HHS certification of safety and cost savings; however, H.R. 2427 includes no such mandate.

Supporters of drug importation are urging Congress to pass legislation to allow pharmacists and wholesalers to import prescription drugs commercially, and to allow consumers to bring cheaper prescription drugs into the country. Opponents insist these proposals would weaken existing import laws and make it easier for unsafe or counterfeit drugs to enter the country. Other concerns involve FDA's ability to devise and enforce regulations, the added costs, the feasibility of imports as a long-term solution to high domestic prices, and possible effects on future pharmaceutical research and development. This report will be updated as events warrant.

Contents

List of Tables

Importing Prescription Drugs — Comparison of the Drug Import Provisions in the Medicare Reform Bills, H.R. 2427, and Current Law

Introduction

For some time now, Congress has been concerned with the high cost of prescription drugs in the United States. International comparisons of drug prices have confirmed that American consumers, particularly the elderly and uninsured, often pay much more for prescription drugs than do citizens in other countries.[1] Often, this price disparity stems from the fact that some countries — especially those with nationalized health care systems — have the leverage to negotiate lower drug prices due to their market strength as a single large purchaser. Today, the lower prices in these countries have become an incentive for an increasing number of U.S. citizens to buy their prescription drugs from Internet or mail-order pharmacies, or when they travel outside the United States, especially to Canada or Mexico. According to the Food and Drug Administration (FDA), the volume of foreign drug imports is increasing rapidly.[2]

Advocates for legalizing drug imports, including many Members of Congress, feel that U.S. consumers have shouldered the rising cost of prescription drugs for too long. This is unfair, they say, particularly for consumers who lack health insurance and are forced to pay higher retail prices at pharmacies here, while citizens in other countries, especially those with national health plans, have access to much cheaper pharmaceutical products, some of which were developed through research supported by the U.S. government. Furthermore, if FDA-approved pharmaceuticals are available from foreign suppliers at prices significantly lower than in this country, they insist that consumers, pharmacists, and wholesalers must have a safe, viable, and legal way to import these drugs.

---

[1] David Gross, *Prescription Drug Prices in Canada*, AARP Public Policy Institute Issue Brief, Washington, D.C., American Association of Retired Persons, June 2003. (See Figure 3: Summary of Published Estimates of Canada-U.S. Drug Price Differences, 1990 to Present.)

[2] William K. Hubbard, Senior Associate Commissioner for Policy, Planning, and Legislation, and John M. Taylor, III, Associate Commissioner for Regulatory Affairs, Food and Drug Administration (FDA). U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, hearing on "A System Overwhelmed: the Avalanche of Imported, Counterfeit, and Unapproved Drugs in the U.S.," June 24, 2003.
(Hereafter cited as Hubbard, June 24, 2003.)

To this end, the House and Senate recently agreed to amendments to their respective Medicare reform bills (H.R. 1 and S. 1) that would modify current law to make it easier for pharmacists and drug wholesalers to import less costly prescription drugs from Canadian suppliers. In separate action, the House passed the Pharmaceutical Market Access Act of 2003 (H.R. 2427), a bill offered by Representative Gil Gutknecht that would let pharmacists, wholesalers, and qualifying individuals import prescription drugs from 25 industrialized countries. At the same time, the legislation would require drugmakers to incorporate various counterfeit-resistant technologies in all their prescription drug packaging. If Congress decides to legalize the importation of prescription drugs by pharmacists, wholesalers, and consumers, it would likely have to reconcile the major differences in these three bills.

Background

The Prescription Drug Marketing Act of 1987

In the mid-1980s, concerned that substandard or even counterfeit drugs were being reimported back into the United States as "American goods returned," events that could potentially jeopardize the health of American consumers, Congress passed the 1987 Prescription Drug Marketing Act (PDMA).[3] Since then, the Act has made it illegal for anyone other than the original manufacturer to import prescription drugs into the United States. Today, Section 801(d)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA)[4] states that no "drug ... which is manufactured in a state and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug."

The purpose of the PDMA was to keep subpotent or adulterated drugs from inadvertently ending up in retail pharmacies in the United States.[5] To prevent this from happening — and enforce the law — the FDA has adopted a host of regulations in years past that require drug companies to maintain a detailed chain of custody for every pharmaceutical product brought into this country. Today, these rules not only impose strict record keeping requirements, they also require manufacturers to ensure the safety and quality of all drugs that are exported and later reimported back into the country.

When drugs are imported into the United States — whether they are shipped commercially, carried by travelers, or arrive by mail — the Bureau of Customs and Border Protection (BCBP) (formerly the U.S. Customs Service) and the FDA have broad authority to detain and deny products that "appear" to violate U.S. law or

---

[3] P.L. 100-293.

[4] Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938).

[5] U.S. Congress, House Committee on Energy and Commerce, *Prescription Drug Marketing Act of 1987*, H.Rept. 100-76, 100th Cong., 1st Sess. Washington, GPO, Apr. 30, 1987, p. 7.

regulatory standards.[6] For regulatory enforcement purposes, FDA distinguishes between two types of imported drugs: those destined for commercial distribution, and those destined for personal use, including mail-order drugs and drugs that are brought into the country by individuals passing through U.S. customs.[7]

The Medicine Equity and Drug Safety (MEDS) Act of 2000

In an effort to take advantage of the lower prices charged by drug manufacturers in other countries, in 2000 the 106th Congress passed the Medicine Equity and Drug Safety (MEDS) Act. Part of the FY2001 agriculture appropriations bill,[8] the MEDS Act amended the FFDCA to establish a 5-year program that would have allowed pharmacists and drug wholesalers to import less costly prescription drugs from foreign suppliers.[9] Pharmaceuticals imported under the Act could come only from specific industrial countries, and the agency could suspend importation immediately if a pattern of counterfeiting emerged.

As an integral part of the program, the Secretary of Health and Human Services (HHS) was required to publish regulations to ensure the safety and effectiveness of the imported drugs. Congress further stipulated, however, that before the import provisions of the MEDS Act could go into effect the Secretary of HHS had to:

> ... demonstrate[s] to Congress that the implementation of this section will (1) pose no additional risk to the public's health and safety; and (2) result in a significant reduction in the cost of covered products to the American consumer. (Section 804(l).)

In late December 2000, then-Secretary Donna Shalala announced that she could not implement the MEDS Act because it contained several "serious flaws and loopholes."[10] According to the Secretary, the law allowed drug companies to deny U.S. importers legal access to the FDA-approved labeling required for reimportation. Second, the Act did not prohibit drug manufacturers from requiring distributors to charge higher prices, limit supply, or treat U.S. importers less favorably than foreign purchasers. She also wrote that the drug import legislation's 5-year "sunset" provision would have a chilling effect upon private-sector investment in the testing and distribution systems required under the law.

---

[6] FDA, "Information on Importation of Drugs," prepared by Marvin A. Blumberg, Division of Import Operations and Policy, Office of Regulatory Affairs, FDA, HFC-170, Apr. 3, 1998, at [http://www.fda.gov/ora/import/pipinfo.htm]. (Hereafter cited as FDA, "Information on Importation of Drugs.")

[7] The term "reimportation" means that an FDA-approved drug was exported from the United States by a U.S. manufacturer and then reimported by that manufacturer, or was produced by a U.S.-licensed drug manufacturer outside of the United States and then imported.

[8] P.L. 106-387 added new Section 804 to the FFDCA.

[9] The import provision does not cover controlled substances, biologics, infused drugs, intravenous drugs, and drugs inhaled during surgery.

[10] Letter from Donna E. Shalala, Secretary of Health and Human Services (HHS), to President William J. Clinton, Dec. 26, 2000.

In July 2001, her successor, Secretary Tommy G. Thompson, declined to implement the law as well, stating that the safety of prescription drugs could not be adequately guaranteed if drugs were allowed to be reimported under the MEDS Act.[11] Moreover, the Secretary argued that the costs associated with the documenting, sampling, and testing of imported drugs, as the statute required, would make it very difficult for consumers to recognize any noticeable price savings.

FDA's Personal-Use Import Enforcement Policy

As previously noted, only drug manufacturers can legally import prescription drugs into the United States. Despite this restriction, the FDA has maintained a "lenient" enforcement policy that lets individuals (patients) bring a small amount (i.e., a 90-day supply) of non-FDA approved drugs into this country for compassionate use.[12] In addition, individuals are supposed to affirm in writing that the drug is for their own use, and provide the name and address of their treating physician.[13] For decades, this so-called "personal use" import policy has made it easier for patients with life-threatening diseases (such as cancer and AIDS) to bring medicines into the country and be treated by their own doctors.[14] Drugs cannot be imported commercially under the policy.

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. But, where the policy once let a limited number of patients import drugs for compassionate use, today it is being used to import drugs for all kinds of medical conditions, particularly by consumers seeking cheaper prescription drugs from foreign countries. Over time, changes in the economy, lenient enforcement, and a growing use of the Internet have contributed to a dramatic upsurge in the number of drugs entering the country. Today, the majority of prescription drugs entering the country are not being brought in by individuals; instead, they come via the mail after being purchased by consumers from online mail-order pharmacies.[15] More recently, some retail pharmacies, state employee health plan members, and groups of individual citizens have started importing as well.[16] Monitoring this wave of drug

---

[11] Department of Health and Human Services, "Secretary Thompson Determines That Safety Problems Make Drug Reimportation Unfeasible," *HHS News*, press release, July 10, 2001, at [http://www.hhs.gov/news].

[12] FDA, "Information on Importation of Drugs."

[13] FDA, "Coverage of Personal Importations," Regulatory Procedures Manual, Office of Regulatory Affairs, FDA, Jan. 11, 2003, at [http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html].

[14] FDA, "Information on Importation of Drugs."

[15] FDA letters to the Kullman Firm, Feb. 12, 2003; and FDA warning letters to Rx Depot, Mar. 21, 2003 and to CanadianDiscountDrugs, June 30, 2003, at [http://www.accessdata.fda.gov/scripts/wlcfm/subject.cfm?FL=I].

[16] Letter from William K. Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation, FDA to Mr. Gregory Gonot, Deputy Attorney General, state of California, responding to questions on the importation of prescription drugs into the state of California,

(continued...)

products has become a tremendous enforcement problem for both BCBP and FDA inspectors.[17]

In 2001, the BCBP and FDA conducted a 5-week survey in Carson City, California to get a better idea of the number and types of drug products that were entering the United States by mail. According to the agencies, many of the drugs detained during the survey were for treating health conditions that normally require a doctor's diagnosis.[18] This finding has raised concerns that some patients are buying prescription drugs without a doctor's prescription and exposing themselves to serious health risks. During a June 24, 2003 congressional hearing on FDA's drug import policies, William K. Hubbard, Associate Commissioner for Policy and Planning testified that the agency was very concerned about the safety of imported drug products, and warned that foreign outlets could be dispensing expired, sub-potent, contaminated, or even counterfeit medicines.[19] He further cautioned that the labeling of some drugs may not be in English and/or lack adequate directions for use, that the drugs may not have been packaged and stored under conditions appropriate to prevent degradation, or been made under current good manufacturing practices. Moreover, according to the agency, when consumers take imported drugs, they run the risk of experiencing dangerous drug interactions and/or adverse reactions, some of which could be life threatening.[20] Furthermore, persons who unknowingly take an ineffective product forgo the opportunity to receive the appropriate treatment.

When accounts of fake Procrit, Lipitor, and Viagra were reported by the media this spring, the FDA notified pharmacists and issued consumer warnings that the drugs might be counterfeit.[21] In April 2003 the agency commended the pharmaceutical industry for helping to identify and remove counterfeit drug products from the market. Some Members of Congress felt that these actions were inadequate to ensure the safety of prescription drugs, and asked whether the FDA should consider requiring "counterfeit-proof" packaging for all prescription drugs. In partial response to their concerns, on July 16, 2003, FDA Commissioner Mark McClellan unveiled a new "Counterfeit Drug Initiative" aimed to protect U.S. consumers from

---

[16] (...continued)
Aug. 25, 2003.

[17] Hubbard, June 24, 2003.

[18] William K. Hubbard, Senior Associate Commissioner for Policy, Planning, and Legislation, FDA. Testimony before the U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health, July 25, 2002.

[19] Hubbard, June 24, 2003.

[20] "FDA Takes Action Against Companies That are Importing Unapproved, Potentially Unsafe Drugs," *FDA News*, Sept. 9, 2003.

[21] See: "FDA Statement on Counterfeit Procrit," *FDA News*, Mar. 11, 2003; "FDA Alerts Consumers and Health Professionals to Recall of Counterfeit Lipitor," *FDA Talk Paper*, May 23, 2003; and "FDA Assesses Irregularities Involving the Handling of Certain Unapproved Imported Viagra Products," *FDA Talk Paper*, May 20, 2003.

counterfeit products.[22] In addition, a task force is being appointed to explore the use of technologies that can better identify, deter, and combat the counterfeiting of prescription drugs. The task force will also look into whether stronger enforcement is necessary, how to tighten wholesaler licensing, and how to identify the risks and threats from counterfeit drugs.[23]

Pending Drug Import Legislation

On June 27, 2003, the Senate passed the Prescription Drug and Medicare Improvement Act of 2003 (S. 1), which also included Title VIII: Importation of Prescription Drugs. On the same day, the House agreed to the Medicare Modernization and Prescription Drug Act of 2003 (H.R. 1), which included Title IX: Importation of Prescription Drugs as an amendment. Both bills would completely replace existing Section 804 of the FFDCA, and require the Secretary of HHS to issue regulations allowing pharmacists and drug wholesalers to import prescription drugs from Canada into the United States.

One month later, on July 24, 2003, the House voted 243 to 186 to adopt the Pharmaceutical Market Access Act of 2003 (H.R. 2427). The bill, sponsored by Representative Gil Gutknecht, would amend parts of Section 804 only, and, in so doing, permit pharmacists, wholesalers, and qualifying individuals (i.e., consumers) to import prescription drug products from 25 industrialized countries, and not just Canada. The legislation would also require drug makers to incorporate various counterfeit-resistant technologies in the packaging and shipping containers of all prescription drugs. According to media reports, some Members want the conference to remove language from the Medicare bill that would continue to require HHS to first certify, as the MEDS Act does, that importation would pose no additional risk to public health and safety and lower the cost of prescription drugs for U.S. consumers.[24] The language requiring prior HHS certification has been called a "poison pill" provision by some observers. A letter from 142 Members of Congress to the Medicare bill conferees urges that they include "market access provisions...without the 'certification' language" in the final legislation.[25]

The following table provides a comparison of the drug import provisions of the three bills — S. 1, H.R. 1, and H.R. 2427 — and current law.

---

[22] "FDA Announces Initiative to Heighten Battle Against Counterfeit Drugs," *FDA News*, July 16, 2003, at [http://www.fda.gov/bbs/topics/NEWS/2003/NEW00926.html].

[23] FDA, "Anti-counterfeit Drug Initiative," *Federal Register*, vol. 63, no. 165, Aug. 26, 2003, p. 51270.

[24] Juliet Eilperin, "For House GOP, One Vote Came With Hefty Price," *Washington Post*, July 24, 2003.

[25] U.S. Congress, House, "Letter: Emanuel to Medicare Conferees Chairmen urging inclusion of Prescription Drug Reimportation Legislation," Rep. Rahm Emanuel press release, Sept. 18, 2003.

A Comparison of the Drug Importation Provisions in Current Law, the House and Senate Medicare Bills, and H.R. 2427

Provisions	Current Law	S. 1	H.R. 1	H.R. 2427
How the legislation would amend current law	Section 804 of the Federal Food, Drug, and Cosmetic Act — Importation of Covered Products — established under the Medicine Equity and Drug Safety Act of 2000 (P.L. 106-387).	The amendment would replace existing Section 804 entirely.	Same as S. 1.	Amends Section 804 of the Federal Food, Drug, and Cosmetic Act — Importation of Covered Products; and establishes new Section 505B — Counterfeit-Resistant Technologies.
Regulatory requirements	*Regulations.* The Secretary of Health and Human Services (HHS), after consulting with the U.S. Trade Representative and the Commissioner of Customs, must publish regulations permitting pharmacists and wholesalers to import "covered products" (i.e., prescription drugs imported from Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, the European Union [Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, Netherlands, Portugal, Spain, Sweden, and the United Kingdom], and the European Economic Area [the European Union plus Iceland, Liechtenstein, and Norway], as specified in Section 802 (b)(1)(A) of the law) into the United States.	*Regulations.* Same as current law, however, prescription drugs could only be imported from Canada.	*Regulations*. Same as S. 1, except that the U.S. Trade Representative and the Commissioner of Customs would not be involved in the rule-making process.	*Regulations.* Within 180 days, the Secretary must publish rules permitting pharmacists, drug wholesalers, and qualifying individuals to import prescription drugs from the same counties already specified under existing law, i.e., Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, the European Union, and the European Economic Area.
Assurances that imported drugs will be safe and effective	*Limitation*. The regulations must ensure that all imported prescription drugs meet the same safety and efficacy standards as drugs approved in the United States and that imported products not be adulterated or misbranded.	*Limitation.* Same as current law.	*Limitation*. Same as current law and S. 1. However, the Secretary would have to adopt additional rules requiring that all prescription drugs from Canada be contained in packaging which the Secretary judges to be reasonably tamper-	*Limitation.* Same as current law; however, the bill eliminates the Secretary's authority to adopt additional measures as necessary to either protect public health or facilitate the importation of drug products.

Provisions	Current Law	S. 1	H.R. 1	H.R. 2427
	Moreover, the Secretary is permitted to adopt such rules as necessary to safeguard public health or as a means to facilitate the importation of products.		resistant and incapable of being counterfeited. Additionally, imported drugs would have to include a statement aimed at end users noting that the product has been imported from a foreign seller other than the manufacturer. Moreover, only prescription drugs which have not left the possession of the first Canadian recipient after the original manufacturer would be eligible for import. Also, if the Secretary so decides, imported drugs could enter the United States only through designated ports of entry. Clarifies that the Secretary's regulations to facilitate imports of prescription drugs could not jeopardize the public health.	
Information and record keeping requirements for importers of prescription drugs	*Records*. Records regarding imported prescription drugs must be provided to the Secretary, and then kept for such time as the Secretary determines to be appropriate.	*Information and Records*. Similar to the information and record keeping requirements under the 'Importation' section in current law.	*Information and Records*. Similar to current law and S. 1 in the area of record keeping and documentation.	*Records*. Similar to the information and record keeping requirements in current law, but only pharmacists and wholesalers (not qualifying individuals) would have to keep and provide information about imported drugs.
	The importer is required to provide any other information that the Secretary determines is necessary to ensure the public health.	Same as current law.	Same as current law.	Deletes provision requiring public health information.
	Drug importers must provide information that includes: the name and amount of the active ingredient of the drug, the dosage form of the drug, the date the product is shipped, the quantity shipped, and information about its origin and	Same as current law except while drug importers would still have to report the prices they pay for prescription drugs, the price they charge when the drug is sold would not have to be reported.	Same as current law.	Same as current law except foreign sellers would not have to document the original source of drug products nor the amount of each lot they received.

Provisions	Current Law	S. 1	H.R. 1	H.R. 2427
	destination. The importer must also supply the price paid by the importer and the price the drug was sold by the importer; the importer's name, address, and license number; original source of the drug and the amount of each lot received from that source; and the manufacturer's lot or control number. Also, the importer or manufacturer must certify that the drug is FDA-approved and properly labeled, and provide laboratory records of authenticity testing, including data, and evidence that testing was conducted in an approved U.S. laboratory.			
	For a prescription drug imported directly from the first recipient in the foreign country, there must be documentation indicating that the drug came directly from the manufacturer, that the amount being imported is not greater than the quantity that was originally received, and verification that each batch of the drug has been statistically sampled and tested for authenticity and degradation prior to importation. Samples of subsequent shipments of these drugs must also be tested for authenticity and degradation.	Same as current law.	Same as current law except while H.R. 1 mandates that the importer or manufacturer certify that the imported drug is not adulterated or misbranded, documentation of sampling and testing of subsequent shipments from the importer or manufacturer would not be required.	Similar to current law but testing and its documentation are needed only if the imports are not in counterfeit-proof packaging.
	For a prescription drug not imported directly from the first recipient in the foreign country, there must be documentation demonstrating that each batch of the drug has been statistically sampled and tested for	Same as current law.	Only allows imports from the first Canadian recipient.	Similar to current law but see above.

Provisions	Current Law	S. 1	H.R. 1	H.R. 2427
	authenticity and degradation prior to importation and the importer or manufacturer must certify that the drug is FDA-approved and properly labeled.			
Testing requirements for imported drugs	*Testing*. By law, authenticity testing can be done by either the importer or the manufacturer. A manufacturer must give the importing pharmacist or wholesaler the information needed to authenticate the product and confirm its labeling. Also, testing information must be kept in confidence, and the Secretary may adopt rules to protect trade secrets and commercial or financial information that is privileged or confidential.	*Testing*. Similar language to current law.	*Testing*. Similar language to current law.	*Testing*. Similar to existing law, however, only drug wholesalers importing prescription drugs would have to sample and test for authenticity. [If new Section 505B for counterfeit-resistant technologies becomes law, the authenticity testing requirements would be moot.]
Requirements for tamper-resistant or counterfeit-resistant technologies	No provision.	No provision.	*Limitation.* Would require that all prescription drugs imported from Canada by domestic pharmacists or wholesalers be contained in tamper-resistant packaging which cannot be counterfeited.	*Requirements for Counterfeit-Resistant Technologies.* Would amend current law establishing a new Section 505B — Counterfeit-Resistant Technologies. Henceforth, the packaging of all prescription drugs (not just those being imported) would have to incorporate overt optically variable counterfeit-resistant technology or technologies that have an equivalent function of security. The technologies employed must provide visible identification of the product; be similar to those used by the Bureau of Engraving and Printing to secure U.S. currency; be made and distributed in a secure environment; and must integrate non-visible

Provisions	Current Law	S. 1	H.R. 1	H.R. 2427
				security features with forensic capability. Also, manufacturers must incorporate the technologies into multiple elements of the packaging for prescription drugs. Moreover, shipping containers for drugs must have labels that incorporate technologies that enable inspectors to verify the authenticity of the shipment.
Countries from which drugs could be imported	*Country Limitation*. Prescription drugs covered by the law could be imported only from countries specified in Section 802(b)(1)(A).	[Note: Elsewhere, the bill restricts imports of prescription drugs under this section to those from Canada.]	[Same as S. 1.]	*Country Limitation*. Similar to current law, but eliminates the authority of the Secretary to limit the areas for public health reasons.
Registration of foreign sellers	No provision.	*Registration of Foreign Sellers*. Requires any Canadian establishment engaged in the distribution of a prescription drug imported or offered for importation into the United States to register its name and place of business with the Secretary.	*Registration of Foreign Sellers*. Same as S. 1, but adds that the Canadian establishment also register the name of its U.S. agent.	No provision.
Secretary's authority to suspend a specific drug and a specific importer	*Suspension of Importations.* If the Secretary discovers a pattern of counterfeit or violative products, the agency must suspend importation of a specific product or a specific importer. The suspension must stay in effect until the FDA investigates and determines whether the public is being adequately protected from counterfeit and violative drug products under existing regulations.	*Suspension of Importations*. Same as current law.	*Suspension of Importations*. Same as current law.	*Suspension of Importations*. Similar to current law, except that after an investigation into the suspension of an imported drug, the Secretary would not have to make a further finding that the public was being adequately protected from counterfeit drug products before the suspension could be lifted.

Provisions	Current Law	S. 1	H.R. 1	H.R. 2427
Labeling	Requires certification from the importer or manufacturer that product is FDA-approved and meets all labeling requirements.	*Approved Labeling*. Directs drug manufacturers to allow importers to use, at no cost, the approved labeling for prescription drugs.	*Approved Labeling*. Same as S. 1.	*Approved Labeling*. Same as current law by saying "meets all requirements under the Act."
Prohibition on discrimination	*Prohibited Agreements.* Prohibits manufacturers of imported drugs from entering into contracts or agreements that include provisions to prevent the sale or distribution of imported products.	*Prohibition of Discrimination*. Makes it unlawful for a drug manufacturer to discriminate against a pharmacist or wholesaler who wants to purchase a prescription drug. Defines discrimination as any activity, such as a sales contract, that limits the supply of the drug, or any measure that provides terms or conditions that are less favorable to pharmacists or wholesalers than those provided to foreign purchasers, or that restricts their access to a prescription drug that the law allows to be imported.	No provision.	*Prohibited Agreements.* Same as current law.
Charitable contributions	*Charitable Contributions; Parenteral Drugs*. Section 801(d)(1) of the Act, which allows only the U.S. manufacturer of a drug to import it into the United States, will continue to apply to (1) a product donated by a manufacturer of a drug to a charitable organization or foreign government; and (2) a parenteral drug that the Secretary determines poses a threat to the public health.	*Charitable Contributions*. Same as current law regarding charitable contributions. No mention of parenteral drugs in this context.	*Charitable Contributions*. Same as S. 1.	*Charitable Contributions; Parenteral Drugs*. Same as current law.
Importing prescription drugs for personal use	No provision in law, but FDA policy allows individuals to bring in drugs for personal use.	*Waiver Authority for Importation by Individuals*. Declarations — Congress declares that the Secretary should use discretion when enforcing the	*Waiver Authority for Importation by Individuals*. No declarations.	*Authority for Importation by Individuals*. The bill would require the Secretary to publish rules allowing 'qualifying individuals' — along with pharmacists and wholesalers — to import prescription

Provisions	Current Law	S. 1	H.R. 1	H.R. 2427
		current legal prohibition against persons importing drugs or devices for personal use. The Secretary should focus on cases where the importing may pose a significant threat to public health or an unreasonable risk to the individual.		drugs into the United States. [A waiver of the law, therefore, would not be necessary.]
		Waiver Authority — The Secretary may grant waivers, to individuals to bring in pharmaceuticals (apparently from any country), either through rule-making or on an individual basis, of the law that only allows manufacturers to import FDA-approved drugs [Section 801 (d)(1)]. The Secretary may also decide the conditions under which waivers are given on a regular basis.	No provision for a waiver for individuals to import from countries other than Canada.	
		Moreover, the Secretary would have to publish a guidance describing the circumstances when the waivers would be granted to individuals consistently.	No guidance provision. The bill does specify, however, that imported drugs may not be adulterated or misbranded.	
		Drugs Imported From Canada — The Secretary **shall** grant waivers so persons can import a 90-day supply of an FDA-approved prescription drug from a licensed pharmacy in Canada, so long as the drug's final dosage form was made in an FDA-registered facility, came from a registered Canadian seller, was accompanied by a valid prescription, and was imported under conditions the Secretary determines were necessary to ensure public safety.	Drugs Imported From Canada — The Secretary **may** grant waivers to individuals. Waivers must meet requirements similar to those in S. 1. However, under H.R. 1, *if the Secretary grants a waiver, the imported drug or device must be in possession of the individual when the individual enters the United States.*	

Provisions	Current Law	S. 1	H.R. 1	H.R. 2427
Evaluation of the program	*Studies; Reports.* Requires the Secretary to either conduct or contract with an entity to evaluate drug importers' compliance with the new regulations. In so doing, the study must compare the number of counterfeit, misbranded, or adulterated drugs imported under this law 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 FDA must evaluate the effect that imports have had on trade and patent rights under federal law. Two years after the effective date of the implementing regulations, the Secretary must submit a report to Congress describing the study's findings. Also, 18 months after the import program goes into effect, GAO must submit to Congress a report evaluating the program's effect on retail drug prices for consumers.	*Studies; Reports*. Requires the Secretary to ask the Institute of Medicine (IOM) of the National Academy of Sciences to conduct a study evaluating drug importers' compliance with the new regulations and to submit the report to Congress. Otherwise the sections are identical.	*Studies; Reports*. Similar to S. 1 except that it does not require that the Institute of Medicine, in its evaluation of the effects on trade and patent rights, to consult with the U.S. Trade Representative and the Commissioner of Patents and Trademarks.	*Studies; Reports*. Similar to current law in that the Secretary must conduct, or contract with an entity to conduct, a study of imported drugs, evaluating importers' compliance with regulations, and the incidence, if any, of drug shipments found to be misbranded or adulterated. More specifically, the study would assess whether this level of compliance contrasts with the incidence of shipments of prescription drugs transported within the United States which have been found to be misbranded and adulterated. Not later than 18-months after the date of enactment, the Secretary must submit a report to Congress describing the findings of the above study.
No limits on the Secretary	*Construction.* Nothing in this section shall be construed to limit the Secretary's authority relating to the importation of covered products, other than with respect to Section 801(d)(1), which allows only the manufacturer to import a prescription drug.	*Construction*. Same as current law.	*Construction*. Same as current law.	*Construction*. Same as current law.

Provisions	Current Law	S. 1	H.R. 1	H.R. 2427
Definitions	*Definitions.* Under the Act, the term "covered product" means prescription drugs. The definition, however, does not include drugs listed in Schedules I, II, and III (i.e., drugs with high abuse potential) of the Controlled Substances Act, nor biological products regulated under the Public Health Service Act. Under the Act, besides drug companies themselves, only licensed pharmacists or wholesalers may import drugs. All labs that qualify for testing must be in the United States, and be approved first by the Secretary. Also, parenteral (injectable) drugs cannot be imported if the Secretary feels they might pose a threat to public health. A pharmacist is defined as a person licensed by a state to practice pharmacy and dispense and sell prescription drugs. A wholesaler means a person licensed as a wholesaler or distributor of prescription drugs in the United States, but does not include the manufacturer of the drug being imported. A prescription drug means, as described in Section 503(b) of the Act, a drug intended for use by man under the supervision of a licensed health practitioner.	*Definitions.* The term prescription drug means any drug other than a controlled substance, a biologic, an infused drug, an intravenous injection drug, or a drug inhaled during surgery. Other definitions are the same as in current law.	*Definitions*. Same as in S. 1.	*Definitions*. Similar to current law except that it includes the definition of a "qualifying individual" to mean an individual who is not a pharmacist or wholesaler.
Conditions for the Secretary to halt the import program	No provision.	*Effectiveness of Section.* Between 12 and 18 months after the regulations are implemented, if the Secretary certifies to Congress that, based on substantial evidence, in	No provision.	No provision.

Provisions	Current Law	S. 1	H.R. 1	H.R. 2427
		the opinion of the Secretary, the benefits of the implementation of the import program do not outweigh any detriment, drug imports under the section would cease 30 days after the certification is submitted. However, the certification may not be submitted unless, after a public hearing, the Secretary finds it is more likely than not that implementation will result in an increased risk to the public health; identifies, in qualitative and quantitative terms, the nature and causes of the increased risk; considers whether measures can be taken to avoid, reduce, or mitigate the increased risk; describes whether additional statutory authority is needed; identifies, in qualitative and quantitative terms, the benefits that would result from the program, including reductions in the cost of drugs to U.S. consumers, which would allow them to obtain needed medications without foregoing other necessities of life; and, in specific terms, compares the detriment with those benefits and determines the benefits do not outweigh the detriment.		

Provisions	Current Law	S. 1	H.R. 1	H.R. 2427
Conditions for the Secretary to implement the import program	*Conditions*. The drug import program could begin only if the Secretary first demonstrated 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.	*Conditions.* The Secretary must certify these conditions rather than demonstrate them.	*Conditions*. Same as current law.	*Conditions*. The bill would delete the conditions section from current law.
Authorizing appropriations	No provision.	*Authorization of Appropriations*. The bill authorizes to be appropriated such sums as are necessary to carry out this section.	*Authorization of Appropriations*. Same as S. 1.	No provision.
Conforming amendment to current law	No provision.	*Conforming Amendments*. Replaces references to "covered product" in Sections 301(aa) and 303(a)(6) in the Federal Food, Drug, and Cosmetic Act with "prescription drug."	*Conforming Amendments.* Same as S. 1.	No provision.
Sunset provision	*Sunset.* The import program would expire 5 years after the Secretary issued final regulations implementing the law.	No provision.	No provision.	*Sunset*. The bill would delete the 'sunset' provision in current law.

Issues for Consideration

Would the Cost of Drugs to U.S. Consumers Decrease?

A recent compilation of U.S. and Canadian drug-price comparisons showed that, on average, prices charged by manufacturers, wholesalers, and retailers were higher in the United States, most recently by about 70%.[26] Estimates of cross-border prescription drug sales have increased to as much as $650 million a year.[27] The purpose of the drug import bills is to give U.S. consumers the opportunity to buy drugs at the lower prices now available in other countries. Would passage of the legislation actually lower prices for prescription drugs in the months that follow? Would these prices remain lower a year or two or ten from now? It is unclear at this point whether these changes in the law would have a long term impact on the cost of pharmaceuticals to U.S. consumers primarily because the determinants of drug prices are so diverse, interdependent, and labile.

Under the terms of S. 1 and H.R. 1, imported prescription drugs could only come from Canada. However, the U.S. and Canadian pharmaceutical markets are significantly different. For example, approximately 98% of Canadian citizens over the age of 65 have some form of prescription drug coverage, mainly through their provincial government health programs.[28] This allows the government to negotiate bulk purchasing contracts for pharmaceutical products. Both public and private benefit plans actively manage costs using price and cost-effectiveness data; international price comparisons; reference pricing; substantial generic substitution; and pharmacy reimbursement policies. By federal law, Canada's Patented Medicine Prices Review Board keeps drug costs in check by regulating a drug's price based on guidelines involving the cost of alternate drugs, cost of the same drug in other countries, and changes in the Consumer Price Index.[29] Over the years, U.S. policy makers have chosen not to implement a similar policy (except in specific programs that deal with government entitlements, such as the Department of Veterans Affairs and state Medicaid programs).

Reducing Prescription Drug Costs. Supporters of the import provisions under consideration assert that a drug import program would increase competition among drug suppliers and lead to lower prescription drug prices for U.S. consumers. Representative Gutknecht, using Congressional Budget Office projections that Americans over 65 will spend $1.8 trillion on prescription drugs over the next ten years, estimates a 10 year saving of $630 billion by importing prescription drugs from abroad.[30] Some critics, however, question whether such a program would in

---

[26] Gross, 2003.

[27] Gardiner Harris, "Pfizer Moves to Stem Canadian Drug Imports," *New York Times,* Aug. 7, 2003, p. A7.

[28] Gross, 2003.

[29] Gross, 2003.

[30] Representative Gutknecht estimates a savings of 35%, based on CBO-estimates of $1.8 trillion in non-Medicare prescription drug purchases by persons over 65 for the next 10 (continued...)

reality translate into lower prices to consumers for prescription drugs. They point out that none of the proposals guarantees that pharmacists and wholesalers would pass on potential savings to consumers, and further note that increased demand and possible actions by manufacturers to limit supplies could cause pharmaceutical prices in Canada — for both U.S. and Canadian buyers — to rise.

Manufacturer Actions to Limit Supply. Under the language of H.R. 1 and S. 1, prescription drugs could only be imported from Canada; however, under H.R. 2427, they could be imported from at least two dozen industrialized countries, including Canada. One unknown factor is whether drug manufacturing facilities operating in Canada, even those currently registered with FDA, would be capable of suppling the variety and quantity of pharmaceutical products that American consumers would likely demand. Nor would sufficient supplies be assured from production plants located in the United States. In August 2003, Pfizer joined the pharmaceutical companies GlaxoSmithKline, AstraZeneca, and Wyeth in curtailing the supply of pharmaceuticals to Canadian wholesalers and pharmacists. According to reports, when these companies calculate that the amount of drugs Canadian wholesalers (and pharmacies) are ordering is above that normally needed to supply the Canadian market, they cut or withhold from future shipments the percentage they feel is destined to fill prescriptions from American consumers.[31]

On a related note, some have suggested that if Congress does pass a drug import bill, pharmaceutical companies may seek ways around the law, for instance, by exporting drugs to foreign countries with characteristics (e.g., color, size, shape, or dosages) different from those intended for retail distribution in the United States. Because these imported products might appear different than their FDA-approved counterparts, some fear they could be deemed unapproved, and not qualify for import. Another concern is that if drugmakers continue to restrict or tighten supplies of pharmaceuticals to Canadian suppliers, and adjust prices accordingly, a U.S. drug import program could, inadvertently, cause drug prices to rise in that country.

Would U.S. Consumers Face Unsafe or Ineffective Drugs?

Since 1938, the FFDCA has required that drugs sold to U.S. consumers be safe. With the 1962 Kefauver-Harris Amendments,[32] all drugs had to be proven effective as well. Today, the FDA uses its many statutory and regulatory tools to monitor domestic production and distribution of all pharmaceutical products. Generally, the agency's inspection, testing, and surveillance efforts are less extensive outside the United States than within. FDA officials have said they cannot vouch for the safety and effectiveness of imported drugs that come from unregistered and uninspected facilities.[33] Among their concerns are obvious violations such as counterfeits or intentionally diluted FDA-approved products; inadvertent changes to product quality

---

[30] (...continued)
years, available at [http://www.gil.house.gov/Issues/PDrugs/pdrugs.htm].

[31] Harris, 2003.

[32] P.L. 87-781.

[33] Hubbard, June 24, 2003.

resulting from inappropriate handling; and misuse by patients fostered by improper labeling. Another concern is that some imported drugs may not meet the United States' stringent requirements for effectiveness testing.

Product Integrity. FDA officials contend that allowing drugs to be imported by pharmacists, wholesalers, and individual consumers will only make it easier for adulterated, misbranded, subpotent, or counterfeit products to enter the U.S. distribution pipeline. They are concerned that these drugs could end up in U.S. retail pharmacies, despite the increased number of FDA inspectors hired through recent increases in bioterrorism-protection funding. Also, the increased volume of drug imports could draw FDA inspectors away from other priorities, such as food safety.[34]

To address concerns about the safety and effectiveness of the imported products, the import proposals all include requirements for packaging, inspections, sample testing, chain-of-custody documentation, and registration of participants. Similar to current law, S. 1 and H.R. 1 would require that authenticity testing be done by either the importer or the manufacturer. H.R. 2427 would eliminate the testing mandate so long as the imported drugs were contained in counterfeit-proof packaging. H.R. 1, however, would impose additional limitations to ensure the safety of the drug imports. It would require that imported drugs not have left the possession of the first Canadian recipient; include a statement verifying that the drug was imported by the seller; be in reasonably tamper-resistant packaging; and, if the Secretary so decides, enter the United States only through designated ports of entry.

H.R. 2427, however, goes significantly further to ensure safety: it would require that the packaging of all prescription drugs — not just those for importation — "incorporate overt optically variable counterfeit-resistant technologies ...." Authentication testing by drug wholesalers (defined to include importers) would only be required if the drugs are not in counterfeit-proof packaging. Nevertheless, FDA's Associate Commissioner William Hubbard has testified that the legislation would not protect against the threat of counterfeit drugs because no random sampling plan can protect against such criminal conduct.[35] According to one report, an FDA official recently claimed that the bill would cost FDA $500 million over 5 years to implement, monitor, and test imported products.[36] Further, critics predict that the testing and packaging requirements will be very costly and burdensome for drug manufacturers, costs that will likely just be passed on to consumers.

FDA Personal-Use Import Policy and Enforcement Issues. According to FDA's policy statement on importing drugs for personal use:

---

[34] "Rx Reimportation Could Divert FDA Inspectors From Food Safety-HHS," *The Green Sheet*, Feb. 25, 2002, p. 3.

[35] William K. Hubbard, Senior Associate Commissioner, Policy, Planning and Legislation, FDA, hearings before the Senate Special Committee on Aging, *Buyer Beware: Public Health Concerns of Counterfeit Medicine*, July 9, 2002, p. 14.

[36] Transcript of telephone conversation with FDA official, *FDA Week*, Aug. 1, 2003, at [www.InsideHealthPolicy.com].

> ... the intent of the personal use importation guidance is to save FDA resources and to generally permit, through the exercise of enforcement discretion, medical treatments sought by individuals that are not otherwise available in the United States (where such treatments are not promoted/commercialized in the United States). Thus foreign-made chemical versions of drugs available in the United States are not intended to be covered by the policy.[37]

Both S. 1 and H.R. 1 would authorize the Secretary, either through rule-making or on an individual basis, to grant waivers to individuals to import prescription drugs from Canada. Under the waivers, persons could bring a 90-day supply of prescription drugs into the United States for personal use so long as they were FDA-approved drugs, in final dosage form, made in FDA-registered facilities, from registered Canadian sellers, accompanied by valid prescriptions, and imported under conditions the Secretary determined were necessary to ensure public health. H.R. 1 also says that, if the Secretary grants a waiver with conditions, one condition must be that the imported drug (also includes devices) be in the possession of an individual when that person enters the United States. S. 1 would let the Secretary grant waivers for personal use imports from any source, and urges using discretion in enforcing the personal-use import policy. H.R. 2427 would amend the law to allow, within rules published by the Secretary, individuals to import drugs for personal use.

FDA continues to believe that the personal importation of drugs is a bad idea. Two years ago, in a letter to the Chairman of the House Energy and Commerce Committee, FDA's William Hubbard warned that, if any of the provisions became law, the situation would be "buyer beware" for consumers who decided to import prescription drugs under those circumstances.[38] This year, at a hearing before the same committee, he reiterated that concern, saying that consumers expose themselves to a number of risks potential risks when they purchase drugs from foreign sources.[39]

The BCBP is responsible for checking all imported goods coming into this country. When BCBP officials suspect that an FDA-regulated product is being illegally imported either by mail or in personal baggage, they often refer the package to FDA border officials. However, as the volume of imported drugs has grown exponentially in recent years — to the point where a close examination of each and every package is not feasible, some commentators have cautioned that it will become more and more difficult to keep counterfeit pharmaceuticals out of the country, especially if they look exactly like FDA-approved drugs and appear to comply with all U.S. regulations.[40]

Lack of Physician Involvement. The FDA has raised another concern about the use of imported drugs — the fact that a growing number of patients, particularly those now using Internet pharmacies, are buying and taking medications

---

[37] FDA, "Information on Importation of Drugs."

[38] Letter from William K. Hubbard, Senior Associate Commissioner, Policy, Planning, and Legislation, FDA to the Honorables W. J. "Billy" Tauzin, Chairman, and John Dingell, Ranking Minority Member, House Committee on Energy and Commerce, July 17, 2001.

[39] Hubbard, June 24, 2003.

[40] Ibid.

without the traditional safeguards of a medical diagnosis and a doctor's prescription. Safe and effective drugs can become unsafe and/or ineffective if they are not taken under the care of a physician. Also, prescription drugs can have serious side effects that the average layperson is unaware of — an issue that fuels agency doubts about a move to expand Internet or mail-order availability.

Could U.S. Regulatory Agencies Enforce Consumer Protections?

Secretary's Certification. Under the drug import provisions of S. 1 and H.R. 1, the rules governing the import of prescription drugs could be issued only if the Secretary of HHS first certified that there would be no additional risks and that the costs of the drugs would be reduced. This so-called "poison pill" or "safety provision" (depending on your point of view) was not included in H.R. 2427 mainly because the bill's supporters realized that not being able to meet these prerequisites under the MEDS Act is what has kept HHS from implementing the law to begin with. Recently, the Congressional Budget Office (CBO) declined to estimate the cost savings to U.S. consumers of the drug import titles in H.R. 1 and S. 1 based on the assumption that the Secretary would not issue the necessary regulations to implement the legislation. CBO further noted that, even if the Secretary were to implement the provisions, there would be no substantial savings to the federal government because brand-name drug companies would be unlikely to increase the supply of drugs in Canada enough to permit a significant share of their U.S. market to be imported from Canada.[41]

Cost of Protection. In addition to the initial costs of rulemaking, ongoing FDA and BCBP inspection and enforcement processes to manage the imports would be costly to the government. The pharmaceutical industry would face the cost of the development, manufacture, and ongoing maintenance of the packaging technologies called for to deter tampering and counterfeiting.[42] The U.S. consumer will likely end up bearing a significant portion of all of these costs through taxes and increased prices.

Feasibility. If Congress were to establish an expanded import mechanism for prescription drugs, its success, in all likelihood, will depend on the ability of pharmacists, drug wholesalers, and consumers to access and purchase FDA-approved drugs without any undue administrative hardships. Some feel that this is unlikely given that the agency that would administer the import regulations, the FDA, is on record with concerns over the safety of drugs from foreign sources.[43] Under S. 1, the Secretary could terminate the program by certifying to Congress, with statistical evidence, that the benefits of the import program did not outweigh its detriments.

---

[41] Congressional Budget Office, *Estimates of the Cost of S. 1 and H.R. 1*, July 22, 2003, p. 52-53, at [http://www.cbo.gov/showdoc.cfm?index=4438&sequence=0].

[42] FDA, *Federal Register*, Aug. 26, 2003.

[43] Hubbard, June 24, 2003.

What Are Possible Domestic and International Ramifications?

A number of commentators have proffered scenarios describing the intermediate and long-term implications should the drug import legislation pass. Not surprisingly, these predictions vary considerably among Members of the House and the Senate, individual pharmaceutical manufacturers, organized trade associations, consumer advocacy groups, and observers in the U.S. states and Canadian provinces.

Industry Reaction and Actions. Some have raised concerns about how the pharmaceutical industry may react to changes in market conditions, suggesting that some larger manufacturers might curtail their investments in research and development, or move their offices and plants to countries offering more favorable regulatory and financial climates perhaps. Short of such actions, companies could, as mentioned before, attempt to manipulate the supply of drugs to circumvent the purpose of the legislation.[44]

Questions about International Relationships. Administration officials have repeatedly said that the FDA will be unable to monitor the life-cycle of imported drugs — from manufacturing, packaging, and shipping — to ensure that the drugs are safe and effective. In the case of drugs imported from Canada, might the two governments consider some form of reciprocity, recognizing the validity of the other's system? Canada's drug regulatory requirements are quite similar to those of the United States, and Health Canada and the FDA operate with similar procedures when ensuring the safety and efficacy of pharmaceutical products.[45] In addition to safety, several trade issues have been raised.[46] A drug import agreement between the United States and Canada could, perhaps, present some NAFTA related issues. In addition, although there were strict requirements in the recent World Trade Organization agreement on the humanitarian import of generic versions of patented pharmaceuticals to prevent shipments of these generic drugs from entering developed countries, some have questioned whether these arrangements are enough to prevent cross-shipments of these drugs from being imported into the United States.[47]

---

[44] See John E. Calfee, "The High Price of Cheap Drugs: The House is tempted by a terrible idea," *The Weekly Standard*, July 21, 2003; and "Drug Dealing," editorial in *The Washington Post*, July 24, 2003, p. A20.

[45] See "Questions Concerning the U.S. and Canadian Regulatory Systems for Approving and Distributing Prescription Drugs," a memorandum by CRS, May 28, 2003 to Rep. Bernard Sanders, available at [http://bernie.house.gov/documents/CRS-Canadian_Rx_Drugs.pdf], visited Aug. 25, 2003.

[46] Ronald Guse, Registrar, Manitoba Pharmaceutical Association, National Association of Pharmacy Regulatory Agencies (Canada), noted out at a July 16, 2003 conference at the Center for Strategic and International Studies that should a wrong or counterfeit imported drug cause medical treatment failure, the cost of the failure would fall on the health care system rather than on the trading entity.

[47] An Aug. 2003 World Trade Organization (WTO) General Council agreement seeks to ensure that intellectual property rights do not keep countries that lack the capacity to produce medicines for themselves from obtaining them from abroad. Under the agreement,

(continued...)

Other Federal Agency Involvement. Expanding drug imports would probably involve agencies other than the FDA and the BCBP. The U.S. Postal Service, for instance, is already involved in dealing with mail-order drug purchases. The Federal Communications Commission has a role in regulating commerce over the Internet. The Treasury Department oversees tax revenues. The Department of Veterans Affairs is already involved and benefits from negotiating drug prices with pharmaceutical companies. How a new drug law might affect them is very unclear at this point.

Congressional Options for Controlling Drug Costs

Clearly, the high cost of prescription drugs is affecting the purchasing power of individual consumers and public and private entities. Not only are prices seen as too high, but the emerging trend today is toward the development of evermore sophisticated drugs, with complex dosing schedules and intense patient-monitoring requirements, which cost more to make and to administer medically. Together, these factors are ratcheting up overall healthcare spending (particularly in the United States which hasn't traditionally controlled utilization). These drug import provisions address the market prices of existing drugs, but the high cost of prescription drugs presents larger dilemmas for which importing drugs from other countries is but one possible fix.

If Congress wants to lower the cost of drugs to U.S. consumers, there are other options beyond maintaining the status quo or facilitating the limited importation of prescription drugs.[48] The options — some more feasible than others — include instituting price controls or other regulatory measures on prescription drugs in this country; encouraging more market action (such as with purchasing agreements); and promoting or providing insurance coverage for pharmaceuticals, among others.

---

[47] (...continued)
countries are expected to limit production of these generic drugs to amounts needed for public health dangers such as HIV/AIDS, malaria, and tuberculosis, and not use the opportunity for commercial ventures. *WTO News*, 2003 Press Release 350, Decision removes final patent obstacle to cheap drug imports, Aug. 30, 2003, available at [http://www.wto.org/english/news_e/pres03_e/pr350_e.htm].

[48] In its current consideration of a Medicare drug benefit, Congress may avoid a government role in price controls by including the private sector in benefit administration. See CRS Report RL31992, *Medicare Prescription Drug Provisions as Passed by the Senate, and H.R. 1, as Passed by the House*, by Jennifer O'Sullivan.