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Importation of Prescription Drugs Provisions in P.L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

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Summary

The new Medicare legislation, the Medicare Prescription Drug, Improvement, and Modernization Act (P.L. 108-173), addresses the importation of prescription drugs for all U.S. consumers, not just for Medicare-eligible individuals. These provisions are rooted in consumer and congressional concern 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 more for prescription drugs than do citizens in other countries. The importation of lower-priced prescription drugs is one strategy to reduce U.S. consumer spending.

The new Act, despite being structured as a replacement to the importation provisions in the Medicine Equity and Drug Safety (MEDS) Act of 2000, does not effectively change U.S. prescription drug importation policy. The details it adds will not be implemented unless the Secretary of Health and Human Services (hereafter referred to as the Secretary) certifies to Congress that such imports do not threaten the health and safety of the American public and do provide cost savings. That certification requirement, continued from prior law, has effectively halted implementation of existing import provisions because no Secretary has been willing to provide the required certification.

The Act changes the law in four basic ways: it (1) directs the Secretary to allow imports from Canada only (the MEDS Act had allowed imports from a specific list of industrialized countries, including Canada); (2) includes a shift in approach to the importation of prescription drugs by individuals, by codifying the discretion in enforcement that the Food and Drug Administration (FDA) has exercised to allow the "personal use" imports of prescription drugs; (3) eliminates the prohibition against a manufacturer's entering into agreements to prevent the sale or distribution of imported products; and (4) includes a mechanism, based on evidence, by which the Secretary can terminate the import program.

Following enactment of the Medicare bill in December 2003, some Members of Congress have moved to amend the importation of prescription drugs provisions. Some states and localities have set up websites to facilitate individuals' purchase of prescription drugs from Canadian pharmacies. FDA has responded. In letters to state officials, FDA has warned that states could face tort liability suits and charges of assisting in criminal activity if citizens suffer injury from these drugs. FDA, via the Department of Justice, has gone to the courts to stop the Canadian and U.S. distributors of drugs imported from Canada.

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Introduction

The new Medicare legislation, the Medicare Prescription Drug, Improvement, and Modernization Act (P.L. 108-173), addresses the importation of prescription drugs for all U.S. consumers, not just for Medicare-eligible individuals.[1] These provisions are rooted in consumer and congressional concern 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 more for prescription drugs than do citizens in other countries.[2] The importation of lower-priced prescription drugs is one strategy to reduce U.S. consumer spending.

The new Act, despite being structured as a replacement to the importation provisions in the Medicine Equity and Drug Safety (MEDS) Act of 2000, does not effectively change U.S. prescription drug importation policy. The details it adds will not be implemented unless the Secretary of Health and Human Services (hereafter referred to as the Secretary) certifies to Congress that such imports would not threaten the health and safety of the American public and would provide cost savings. That certification requirement, continued from prior law, has effectively halted implementation of import provisions because no Secretary has been willing to provide the required certification, a stance outlined in testimony from the Food and Drug Administration (FDA).[3]

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[1] The debate, resulting in House and Senate amendments to their respective Medicare bills (H.R. 1 and S. 1) and a separately passed House bill (H.R. 2427), involved varied approaches toward modifying current law to make it easier for pharmacists, drug wholesalers, and individuals to import less costly prescription drugs from foreign suppliers.

[2] 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.)

[3] 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

(continued...)

Although earlier laws restricted the importation of a prescription drug to its manufacturer, the FDA has maintained a lenient enforcement policy that lets individuals bring a small amount of non-FDA approved drugs into this country for their own use.[4] Called a "personal-use" or "compassionate-use" policy, this FDA discretion 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. The policy, as described on the FDA website, does not cover commercial imports, nor does it cover individual imports of FDA-approved drugs available in the United States.[5]

Drug Import Provisions in Current Law

The new Medicare legislation[6] entirely replaces the language in Section 804 of the Federal Food, Drug, and Cosmetic Act (FFDCA) that had been inserted by the MEDS Act of 2000. The following summarizes the prescription drug import provisions in the new Act.

Provisions

Definitions. [Section 804(a)] "Importer" is defined to mean a pharmacist or a wholesaler; "pharmacist" to mean a person licensed by a state to practice pharmacy, including the dispensing and selling of prescription drugs; and "wholesaler" to mean a person licensed as a wholesaler or distributor of prescription drugs in the United States, not including the manufacturer of the drug being imported. A "prescription drug" is defined as a drug subject to Section 503(b)[7] excluding, however, a controlled substance, a biological product, an infused drug, an intravenously injected drug, a drug that is inhaled during surgery, or a parenteral drug whose importation the Secretary determines poses a threat to the public health. "Qualifying laboratory" is defined as a U.S. laboratory that has been approved by the Secretary for the purposes of this section.

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[3] (...continued)
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.

[4] FDA, "Information on Importation of Drugs"; and 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].

[5] See also, CRS Report RS 21711, Legal Issues Related to Prescription Drug Sales on the Internet by Jody Feder. Updated March 5, 2004.

[6] Section 1121(a) of P.L. 108-173, Dec. 2003.

[7] Section 503(b) of the FFDCA defines which kind of substances the law requires to be filled for human use by prescription only. This is a drug that because of its "toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug ... shall be dispensed only upon a written prescription of a practitioner licensed by law to administer such drug ...."

Regulations. [Section 804(b)] The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, must promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

Limitation. [Section 804(c)] 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 the importer comply with all information and reporting requirements. The Secretary is permitted to adopt such rules as necessary to safeguard public health or as a means to facilitate the importation of prescription drugs.

Information and Records. [Section 804(d)] 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 drug is shipped, the quantity shipped, and information about its origin and destination. The importer must also supply the price paid by the importer; the importer's name, address, and license number; the 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, properly labeled, not adulterated, and not misbranded; and provide laboratory records of authenticity testing, including data, and evidence that testing was conducted in an approved U.S. laboratory. The importer is required to provide any other information that the Secretary determines is necessary to ensure the public health. Records regarding imported prescription drugs must be provided to the Secretary, and then kept for such time as the Secretary determines to be appropriate.

For a prescription drug imported directly from the first foreign recipient from the manufacturer, 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, that the drug was subsequently shipped by that recipient to the U.S. importer, 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. 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 authenticity and degradation prior to importation.

Testing. [Section 804(e)] The importer or the manufacturer must conduct the required authenticity testing at a qualified U.S. laboratory. If the importer conducts these tests, the 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 used only for this required import testing or to otherwise comply with this Act. The Secretary may adopt rules to protect trade secrets and commercial or financial information that is privileged or confidential.

Registration of Foreign Sellers. [Section 804(f)] Any Canadian establishment engaged in the distribution of a prescription drug imported or offered for importation into the United States must register its name and place of business

with the Secretary. The Canadian establishment also must register the name of its U.S. agent.

Suspension of Importation. [Section 804(g)] If the Secretary discovers a pattern of counterfeit or violative products, the agency must suspend importation of that specific prescription drug or that 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.

Approved Labeling. [Section 804(h)] A drug manufacturer must give the importer written authorization to use, at no cost, the approved labeling for the prescription drug.

Charitable Contributions. [Section 804(i)] Section 801(d)(1) of the FFDCA, which allows only the U.S. manufacturer of a drug to import it into the United States, will continue to apply to a product donated by a manufacturer of a drug to a charitable organization or foreign government.[8]

Waiver Authority for Importation by Individuals. [Section 804(j)] Congress declares that the Secretary should use discretion when enforcing the current legal prohibition against persons importing drugs or devices. The Secretary should focus enforcement on cases where the importing may pose a significant threat to public health. When the importation is clearly for personal use and the prescription drug or device does not appear to present an unreasonable risk to the individual, the Secretary should exercise discretion to permit the importation by the individual. The new law specifies two waiver procedures to allow individuals — other than pharmacists and wholesalers — to bring prescription drugs into the United States for their personal use.

The first deals with drugs from Canada. The Secretary is required to publish regulations that grant waivers for an individual to import for personal up to a 90-day supply of a drug from a licensed Canadian pharmacy. The drug must also be in final dosage form, be made in an FDA-registered facility, come from a registered Canadian seller, be accompanied by a valid prescription, and be imported under conditions the Secretary determines are necessary to ensure public safety.

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[8] With many drug samples being imported illegally in the early 1980s, Congress decided to restrict such imports. The 1988 Prescription Drug Marketing Act [P.L. 100-293] established, among other things, requirements for the distribution of prescription drug samples. The regulations (21 CFR part 203) addressed the practice of licensed practitioners to donate unused prescription drug samples to charitable institutions such as free clinics, nursing homes, and other charitable health care entities for dispensing to patients, or for further donation to another charity here or overseas for dispensing to its patients. These requirements also say that a drug sample donated to a charitable institution must be inspected by a licensed practitioner or registered pharmacist and that drug sample receipt and distribution records must be kept by the institution for a minimum of three years. These record keeping requirements were intended to deter illegal reimportation. See FDA website at [http://www.fda.gov/cder/guidance/4932dft.htm].

The second addresses drug imports from any other country. Here, the law gives the Secretary the option, rather than a requirement, to issue regulations allowing imports from countries other than Canada. If the Secretary were to publish such regulations, the law requires the Secretary to also publish guidance specifying the conditions under which individuals would be able to import drugs for personal use.

Construction. [Section 804(k)] Nothing in this section shall be construed to limit the Secretary's authority relating to the importation of prescription drugs, other than with respect to Section 801(d)(1), which allows only the manufacturer to import a prescription drug.

Commencement of Program. [Section 804(l)] The drug import program described above can begin *only if* the Secretary first certifies 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 covered products (prescription drugs) to American consumers.

Termination of Program. [Section 804(l)] Once an importation program is implemented, the Secretary can move to terminate it under specified conditions. If the Secretary certifies to Congress, between 12 and 18 months after the regulations are implemented, that, based on substantial evidence, in 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.[9] However, the Secretary's 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 and, if those measures would require additional statutory authority, to report to Congress describing needed legislation; 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 that the benefits do not outweigh the detriment.

Authorization of Appropriations. [Section 804(m)] The new law authorizes to be appropriated such sums as are necessary to carry out this section.

Conforming Amendments. Section 1121(b) of the Medicare Prescription Drug bill replaces references to "covered product" in Sections 301(aa) and 303(a)(6) in the Federal Food, Drug, and Cosmetic Act with "prescription drug."

Study and Report on Importation of Drugs. Section 1122 requires the Secretary, in consultation with appropriate government agencies, to conduct a study on the importation of drugs to the United States pursuant to Section 804 of the

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[9] This certification, required only in the context of the Secretary's intent to end the program, differs from the certification the Secretary must make to initiate the program.

Federal Food, Drug, and Cosmetic Act (as added by Section 1121 of the conference agreement). The Secretary shall submit the report to Congress not later than 12 months after the enactment of this Act.

Study and Report on Trade in Pharmaceuticals. Section 1123 requires the President's designees to conduct a study and report on issues related to trade and pharmaceuticals.

Discussion of Enacted Legislation

Import Provisions. It is doubtful whether the Secretary will implement these import provisions given the Act contains the provision that led both Secretaries Shalala and Thompson to decline. That provision requires that the Secretary certify that imported drugs would be safe and at reduced cost before implementing import regulations. Although significant changes were considered, the new law changes very few elements of the MEDS Act of 2000. Effectively, until the Secretary makes a certification regarding safety and cost, the law allows no one (other than the U.S. manufacturer of the drug) to legally import a prescription drug.[10] Therefore:

Until an HHS Secretary certifies to Congress that "the implementation of this section will (A) pose no additional risk to the public's health and safety; and (B) [will] result in a significant reduction in the cost of covered products to the American consumer,[11]" drug imports are illegal unless imported by the manufacturer of the drug. Neither a pharmacist nor a wholesaler may import prescription drugs. The law does not allow an individual to import a drug for personal use.[12]

If the HHS Secretary were to certify to Congress the required safety and cost savings certification, then all the mechanisms of Section 804 would go into effect. In that case, pursuant to regulations that the Secretary must promulgate:

- By law and according to regulations, a pharmacist or a wholesaler could import prescription drugs from Canada;
- Personal-use imports by an individual from any other country would remain illegal unless the Secretary chose to issue regulations allowing them; and
- The law's restrictions on personal-use imports would be waived so an individual could import a 90-day supply of a prescription drug from Canada.

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[10] FDA has published descriptions of its personal-use import policy, which is based on the Secretary's discretion in how to enforce the regulations; the MEDS Act had no provision for a personal-use waiver. See FDA, "Information on Importation of Drugs"; and 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].

[11] Section 804(l)(2) of the FFDCA.

[12] The law does not specifically address a state as an importer. See below for more information.

Studies and Reports. Unrelated to whether the Secretary certifies safety and cost savings, the Medicare Act mandates two studies with reports to Congress.

Study and Report on Importation of Drugs. The law directs the HHS Secretary, within 12 months of enactment, to study and report on "the importation of prescription drugs into the United States pursuant to Section 804 of the FFDCA (as added by Section 1121 of this Act)." The conference report provides the detailed instructions for that study. These include consideration of the pharmaceutical distribution chain; anti-counterfeiting technologies and their costs; the scope, volume, and safety of unapproved drugs; participation of foreign health agencies in ensuring product safety; the impact of importation on the drug prices that consumers face; the impact on research and development; agency resources; liability protections; and intellectual property rights.

Study and Report on Trade in Pharmaceuticals. The new law also directs that "[t]he President's designees shall conduct a study and report on issues related to trade and pharmaceuticals." Here, too, the conference report provides detail not stated in the bill, including the naming of the Secretary of Commerce, the International Trade Commission, the HHS Secretary, and the United States Trade Representative as responsible for the conduct of the study and report. Topics to be covered include how other countries use price controls and what this costs U.S. consumers; the impact of price controls and intellectual property laws on price, innovation, generic competition, and research and development; and whether these are appropriate topics for trade negotiations with other countries.

Changes in Law

The following table provides a comparison of the drug import provisions of the recently passed Medicare legislation and the MEDS Act provisions that it replaced.

Comparison of the Importation of Prescription Drug Provisions in the New Law and What They Replace

Topic	Old Law (Medicine Equity and Drug Safety Act of 2000, P.L. 106-387)	New Law (Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173)
	Section 804 of the Federal Food, Drug, and Cosmetic Act — Importation of Covered Products — was established under the Medicine Equity and Drug Safety Act of 2000 (P.L. 106-387).	Section 1121(a). The provision replaces the existing Section 804 entirely.
Definitions	*Definitions.* Under the Act, the term "covered product" means prescription drugs. 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. 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. Also, a parenteral (injectable) drug cannot be imported, other than by its U.S. manufacturer, if the Secretary feels its importation might pose a threat to public health.	Replaces the term "covered product" with "prescription drug." Maintains the definition of "prescription drug" as a drug subject to Section 503(b), but expands the list of prescription drugs that would not be eligible for import (other than by each drug's U.S. manufacturer) under this law. In addition to prohibiting the importation of a biological product, a parenteral drug whose importation the Secretary determines poses a threat to the public health, and Schedule I, II, and III controlled substances, the new law prohibits importing of an infused drug, an intravenously injected drug, a drug that is inhaled during surgery, and any controlled substance.
	"Importer" is not directly defined, although the law states that besides drug companies themselves, only licensed pharmacists or wholesalers may import drugs.	804(a). *Definitions.* Explicitly defines "importer" to mean a pharmacist or a wholesaler.
	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.	Same.
	"Qualifying laboratory" is defined as a laboratory in the United States that has been approved by the Secretary for the purposes of this section.	Same.
Regulations	*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.	804(b). *Regulations.* Requires the Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, to promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

Topic	Old Law (Medicine Equity and Drug Safety Act of 2000, P.L. 106-387)	New Law (Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173)
Limitation	*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. 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.	804(c). *Limitation.* Same, although includes requirement that the importer comply with all testing requirements.
	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 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.	804(d)(1)(A,B,C,D,E,F,G,H,I) and 804(d)(1)(K,L,M). *Information and Records.* Same, except although the importer must supply the price the importer paid to acquire the drug, the importer is not required to provide price at which the importer sells the drug.
	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; 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.	804(d)(1)(J)(i). Same, although requires, in addition to documentation that the drug came directly from the manufacturer, documentation that the drug was subsequently shipped by that recipient to the importer, and that it is not adulterated or misbranded.
	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 authenticity and degradation prior to importation and the importer or manufacturer must certify that the drug is FDA-approved and properly labeled.	804(d)(1)(J)(ii) and 804(d)(1)(K). Same, except also requires importer certification that the drug is not adulterated or misbranded.
	The importer is required to provide any other information that the Secretary determines is necessary to ensure the public health.	804)d)(1)(N). Same.
Records	*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.	804(d)(2). Same.

Topic	Old Law (Medicine Equity and Drug Safety Act of 2000, P.L. 106-387)	New Law (Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173)
Testing	*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.	804(e). *Testing.* Same, although states that the required authenticity testing be done at a qualified laboratory (defined earlier as being in the United States and approved by the Secretary).
Registration of foreign sellers	No provision.	804(f). *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. Also requires that the Canadian establishment register the name of its U.S. agent.
Suspension of importations	*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.	804(g). *Suspension of Importations.* Same.
Approved labeling	Requires certification from the importer or manufacturer that product is FDA-approved and meets all labeling requirements.	804(h). *Approved Labeling.* Requires a drug manufacturer to give the importer written authorization to use, at no cost, the approved labeling for the prescription drug.
Charitable contributions	*Charitable Contributions; Parenteral Drugs.* Despite the import provisions in Section 804, only the U.S. manufacturer of a drug may import into the United States (1) a product donated by a manufacturer of a drug to a charitable organization or foreign government; or (2) a parenteral drug whose importation the Secretary determines poses a threat to the public health.	804(i). *Charitable Contributions.* Same.
Waiver authority for importation by individuals	No provision in law, but FDA policy allows individuals to bring in drugs for personal use.	804(j). *Waiver Authority for Importation by Individuals.* Congress declares that the Secretary should use discretion when enforcing the current legal prohibition against persons importing drugs or devices. The Secretary should focus enforcement on cases where the importing may pose a significant threat to public health. When the importation is clearly for personal use and the prescription drug or device does not appear to present an unreasonable risk to the individual, the Secretary should exercise discretion to permit the importation by the individual. The Secretary is authorized to grant waivers, either through rule-making or on an individual basis, of the law that only allows manufacturers to

Topic	Old Law (Medicine Equity and Drug Safety Act of 2000, P.L. 106-387)	New Law (Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173)
		import FDA-approved drugs [Section 801 (d)(1)] to allow individuals to bring in pharmaceuticals from any country. The Secretary may also decide the conditions under which waivers are given on a regular basis. The Secretary must publish guidance describing the consistent circumstances in which waivers would be granted to individuals. The Secretary is required to grant waivers, by regulation, so persons can import for personal use up to 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.
Construction	*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.	804(k). *Construction.* Same.
Commencement of 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.	804(l)(2). *Commencement of Program.* Same, although uses the term "certify" rather than "demonstrate."

Topic	Old Law (Medicine Equity and Drug Safety Act of 2000, P.L. 106-387)	New Law (Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173)
Termination of program	No provision.	804(l)(2). *Termination of Program.* The authority of the Secretary to terminate the program is restricted to the procedure in this section. Between 12 and 18 months after the regulations are implemented, if the Secretary certifies to Congress that, based on substantial evidence, in 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 and, if those measures would require additional statutory authority, to report to Congress describing needed legislation; 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.
Authorization of appropriations	No provision.	804(m). *Authorization of Appropriations.* Authorizes to be appropriated such sums as are necessary to carry out this section.
Conforming amendments	No provision.	1121(b). *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."

Topic	Old Law (Medicine Equity and Drug Safety Act of 2000, P.L. 106-387)	New Law (Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173)
Studies; reports	*Studies; reports.* Two reports are required.	Also requires two reports, but changes content and timetable required.
	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.	No provision.
	No provision.	*Study and Report on Importation of Drugs.* Section 1122 requires the Secretary, in consultation with appropriate government agencies, to conduct a study on the importation of drugs in the United States pursuant to Section 804 of the FFDCA (as added by Section 1121 of the conference agreement). The Secretary shall submit the report to Congress not later than 12 months after the enactment of this Act.
	Also, 18 months after the import program goes into effect, the General Accounting Office must submit to Congress a report evaluating the program's effect on retail drug prices for consumers.	No provision.
	No provision.	*Study and Report on Trade in Pharmaceuticals.* Section 1123 requires the President's designees to conduct a study and report on issues related to trade and pharmaceuticals.
Country limitation	*Country Limitation.* Prescription drugs covered by the law could be imported only from countries specified in Section 802(b)(1)(A).	No provision; however, elsewhere, the conference agreement restricts imports of prescription drugs under this section to those from Canada.
Prohibited agreements	*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.	No provision.
Sunset	*Sunset.* The import program would expire five years after the Secretary issued final regulations implementing the law.	No provision.

House- and Senate-passed Bills in the 108th Congress Leading to the Medicare Bill Conference Agreement

In June 2003, the Senate and the House each passed drug importation provisions as part of their Medicare bills. Both the Senate-passed Prescription Drug and Medicare Improvement Act of 2003 (S. 1) and the House-passed Medicare Modernization and Prescription Drug Act of 2003 (H.R. 1) would have required the Secretary of HHS to issue regulations allowing pharmacists and drug wholesalers to import prescription drugs from Canada into the United States. These two bills were sent to conference.

One month later, the House voted 243 to 186 to adopt the Pharmaceutical Market Access Act of 2003 (H.R. 2427), which contained broader provisions, such as permitting qualifying individuals (i.e., consumers) as well as pharmacists and wholesalers to import prescription drug products from 25 industrialized countries, including Canada. This bill, introduced by Representative Gutknecht, differed strikingly from the then-current law and the subsequently enacted Medicare legislation in that it would have eliminated the provision that requires the Secretary to first certify that importation would pose no additional risk to public health and safety and would lower the cost of prescription drugs for U.S. consumers.

H.R. 2427 would also have required drug makers to incorporate various counterfeit-resistant technologies in the packaging and shipping containers of *all* prescription drugs. The bill would have created a new section in the law called Counterfeit-Resistant Technologies. It would have required that all prescription drugs (not just those being imported) be packaged to incorporate overt optically variable counterfeit-resistant technology or technologies that have an equivalent function of security; provide, with those technologies, 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 integrate non-visible security features with forensic capability.[13]

Post-Passage Activity

Drug importation is attracting attention in the legislative, executive, and judicial branches of government.

States and Municipalities

Because expenditures for pharmaceuticals continue to increase and are taking a larger portion than previously of public funds used for health care, some states are

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[13] By requiring manufacturers to incorporate the technologies into multiple elements of the packaging for prescription drugs, the shipping containers for drugs would have had to incorporate technologies into labels so inspectors could verify the authenticity of the shipment.

trying various ways to legally import lower cost prescription drugs from Canada in order to control the rate of growth of this portion of the state budget. Government officials from several states have petitioned HHS Secretary Tommy Thompson to grant waivers from the current law prohibiting imports; allow pilot projects; or promulgate regulations, as would be allowed under the new Section 804 of the FFDCA, if the Secretary issued the required certification, to authorize programs for the safe importation of prescription drugs from Canada. They cite potential savings, in one case, of over $90 million a year.[14]

Coinciding with the National Governors Association meeting in Washington, D.C., a bipartisan group of Governors, accompanied by a bipartisan group of Members of Congress, held a February 24, 2004 hearing preceded by a press conference in which they spoke of collective action to take advantage of lower priced pharmaceuticals from Canada.[15]

Food and Drug Administration

The FDA, which is charged with ensuring the safety and effectiveness of prescription drugs sold in the United States, has responded swiftly. Rather than single out individuals for punishment for breaking the law, the agency has sent warning letters and has sought to close down the websites and facilities that are illegally supplying prescription drugs.[16] In January 2004, FDA reported on its second "blitz examination" of import courier hubs. It found that 87% of the almost 2,000 examined parcels containing prescription drugs, mostly from Canada, contained unapproved drugs. Because, by law, any prescription drug imported by anyone other

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[14] Ram Kamath and Scott McKibbin, Office of Special Advocate for Prescription Drugs, Illinois Department of Central Management Services, *Report on Feasibility of Employees and Retirees Safely and Effectively Purchasing Prescription Drugs From Canadian Pharmacies*, Oct. 27, 2003, at [http://www.affordabledrugs.il.gov/pdf/SpecialAdvocateCanadian10-27-03Final.pdf]. News Release by Olympia Snowe, U.S. Sen. for Maine, "Snowe Requests Meeting for Two Main Seniors Groups, Penobscot Nation with HHS Secretary Tommy Thompson," Dec. 11, 2003. Thomas F. Reilly, Attorney General of the State of Massachusetts, letter to Tommy G. Thompson and Mark B. McClellan, Oct. 13, 2003.

[15] "Dorgan May Delay McClellan Nomination Over Drug Imports," *Congress Daily*, Feb. 25, 2004; and Robert Pear, "Senators Threaten to Delay Action on Medicare Nominee," *The New York Times*, Feb. 25, 2004. Collective action was also the topic of a Dec. 2003 meeting of representatives of nine state governments with five Canadian drug suppliers ("States Call for Prescription Drug Reimportation Pilot Programs," *Inside Health Policy*, Jan. 12, 2004). Two cities — Springfield, Massachusetts and Montgomery, Alabama — have set up programs to facilitate the purchase by employees and retirees of drugs from Canada. Springfield estimated that it could save between $4 to $9 million annually. Montgomery, which for the last year has allowed its 4,100 city employees and retirees to buy drugs from Canada, reported saving up to $500,000 so far. Also, Minnesota and Wisconsin unveiled, in Feb. 2004, websites to guide citizens to Canadian pharmacy sites.

[16] See also, CRS Report RS21711, *Legal Issues Related to Prescription Drug Sales on the Internet*, by Jody Feder..

than the drug's manufacturer is illegal, the FDA considers it unapproved.[17] FDA continues to object to these websites and states in a letter to Governor Pawlenty of Minnesota that the states could face tort liability suits and charges of assisting in criminal activity if citizens suffer injury from these drugs.[18]

Congress

Following passage of the Medicare bill, some Members have introduced bills that seek to allow the importation of prescription drugs. S. 1974, introduced by Senator Daschle on November 25, 2003, includes the importation and anti-counterfeiting provisions that the House had passed in the Gutknecht bill, as does S. 2137, introduced by Senator Dorgan on February 26, 2004. Senator Kennedy introduced S. 1992 on December 9, 2003, one section of which would amend the new law's importation provisions to include registration, inspection, and reporting requirements for Canadian wholesalers and pharmacists who export prescription drugs to the United States; restore the prohibition of manufacturer discrimination against importers provisions from the MEDS Act; replace the report requirements now assigned to the Secretaries of HHS and Commerce with reports involving the Institute of Medicine and the General Accounting Office; and remove the requirement that the Secretary certify safety and reduced cost to U.S. consumers before implementing the importation provisions.

It remains unclear whether Congress will act in the second session of the 108th Congress to ease the restrictions on prescription drug imports. It confronts a dilemma in that several Governors, local officials, and the AARP support the importation of drugs from Canada and possibly other countries and other stakeholders, including the FDA, the pharmaceutical manufacturers, and pharmacists are opposed to such importation.

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[17] FDA considers as unapproved any drug that is a foreign version of, mislabeled, or inappropriately handled FDA-approved drug; counterfeit version of an FDA-approved drug; and a drug that FDA has not tested for safety and effectiveness. "Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments," *FDA News*, Jan. 27, 2004, pp. 4-7, at [http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html]. Joining FDA in expressing opposition to state prescription drug import programs are the National Association of Boards of Pharmacy, the American Pharmacists Association, and the National Association of Chain Drug Stores.

[18] Letter from William K. Hubbard, FDA Associate Commissioner for Policy and Planning, to Hon. Tim Pawlenty, Governor of Minnesota, Feb. 23, 2004, at [http://www.fda.gov/oc/opacom/hottopics/importdrugs/pawlenty022304.html].