Importing Prescription Drugs: Objectives, Options, and Outlook

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Summary

Can purchases from abroad lower the cost of prescription drugs to U.S. consumers? Current law allows pharmacists and wholesalers to import prescription drugs from Canada commercially, and codifies the Food and Drug Administration's (FDA) current practice of allowing imports of prescription drugs by individuals under certain defined circumstances. There is, however, one proviso. The Secretary of Health and Human Services (HHS) must first certify that the drugs to be 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"—a step no Secretary has been willing to take.

FDA has argued that it is impossible to monitor the millions of transactions and guarantee that these drugs would be safe. Meanwhile, some states and municipalities, looking at ways to control their expenditures for prescription drugs, have created websites to direct U.S. consumers to Canadian sources, and several state Governors have proposed pilot import programs. In October 2006, Congress took limited action regarding personal-use importation. The Department of Homeland Security Appropriations Act, 2007, blocks Customs and Border Protection from using those funds to stop an individual's importing, for personal use, a limited supply of a drug that meets FDA standards.

Drug importation was addressed in three pairs of comprehensive bills in the 109th Congress, none of which saw legislative action. To date, two revised versions have been introduced in the 110th (S. 242/H.R. 380 and S. 251). All would allow commercial and personal-use imports and replace the need for HHS Secretary certification with different ways to assure safety and effectiveness, among them requiring tamper-resistant and anti-counterfeit packaging; inspecting samples of imported drugs; requiring registration of importers, exporters, and Internet pharmacies; and enforcing extensive chain-of-custody monitoring and documentation. They also present different approaches for influencing industry response. Updates of this report will address bills and continuing discussions in the 110th Congress.

Opponents of the legislation raise concerns about safety, added costs, the feasibility of imports as a long-term solution to high domestic prices, and whether, beyond the short term, U.S. consumers would pay less for their prescription drugs. Other points of contention include issues of patent law and international trade agreements.

This report examines these issues, spells out how they are treated from bill to bill, and refers to the following alternatives to importation that might ease the burden of prescription drug costs on consumers: use of generics and disease management techniques; research and development incentives to industry; study of the drugs' comparative effectiveness and judicious application of the findings to benefit package and prescribing decisions; and assumption of some of the consumers' cost.

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Introduction

In 2003, U.S. consumers bought more than $1 billion in prescription drugs from Canada—twice as much as the year before, by some estimates.[1] Although the 2004 and 2005 increases slowed,[2] congressional efforts to allow American consumers to buy prescription drugs from foreign sellers did not. Many U.S. residents use the Internet or mail-order pharmacies; others simply go to a drug store when they travel outside the United States, especially to Canada or Mexico.[3] The reason is clear. Brand-name prescription drugs often cost less abroad—particularly for the uninsured and many of the elderly who pay retail prices.[4]

Under current law, only the manufacturer of a prescription drug may legally bring it into the United States. The law allows U.S. pharmacists and wholesalers to do so only if the Secretary of Health and Human Services (HHS) first certifies that those drugs would be safe and that the program lowered drug costs for U.S. consumers. After issuing that certification, the Secretary must issue regulations allowing individuals to import prescription drugs. Because no HHS Secretary has ever taken that step, consumers, pharmacists, and wholesalers are prohibited from importing prescription drugs.

Given the difference between prices in the United States and elsewhere, many Americans, including some Members of Congress, want legislation eliminating the restrictions on imports.

This report does not address whether drug prices are too high or unfair.[5] It does focus on the issues recent legislative proposals raise in attempting to help U.S. consumers—themselves or through importing pharmacists and wholesalers—gain access to safe and less expensive Food and Drug Administration (FDA)-approved prescription drugs from abroad.

The report begins with an overview of the domestic drug distribution system and how Congress has handled prescription drug importation.[6] It then discusses the current situation following its

[1] IMS Health, "IMS Reports 11.1 Percent Dollar Growth in '03 U.S. Prescription Sales," press release, February 17, 2004, at http://www.imshealth.com. Later that year, the report from the Department of Health and Human Services (HHS) Task Force on Drug Importation put its estimate at about $700 million. HHS, *Report on Prescription Drug Importation*, December 2004, at http://www.hhs.gov/importtaskforce/Report1220.pdf.

[2] In 2005, Internet pharmacy sales from Canada to the United States totaled $349 million, down from $456 million in 2004. IMS Health, "IMS Reports 8.3 Percent Dollar Growth in 2004 U.S. Prescription Sales," press release, February 14, 2005; and IMS Health, "IMS Reports 5.4 Percent Dollar Growth in 2005 U.S. Prescription Sales," press release, February 22, 2006; both at http://www.imshealth.com.

[3] Testimony of 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), in U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *A System Overwhelmed: the Avalanche of Imported, Counterfeit, and Unapproved Drugs in the U.S.*, 108th Cong., 1st sess., hearings, June 24, 2003 (hereinafter "Hubbard, June 24, 2003").

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

[5] For a discussion of health care costs, see CRS Report RL32545, *Health Care Spending: Context and Policy*, by (name redacted).

[6] The term "reimportation" has been used to mean an FDA-approved drug that was exported from the United States by a U.S. manufacturer and then imported back into this country. The law applies to those drugs and to others, such as a drug produced by a U.S.-licensed drug manufacturer outside of the United States and then imported or one produced by a foreign manufacturer. In this report, the term "importation" applies to all these activities.

upsurge in the volume of drug imports, state and local government initiatives, the drug industry and FDA's reactions, and the legislative proposals introduced to consider this issue. It goes on to examine three broad sets of issues surrounding importation. The first involves ensuring drug safety and effectiveness, by attending to product integrity and appropriate use. The next set explores whether a drug import program would be feasible administratively and in the context of international trade and pharmaceutical research and development. The report concludes by discussing the likelihood that a drug import program would save U.S. consumers money. (A separate CRS report provides a detailed side-by-side comparison of current law and selected major importation bills introduced but not passed during the 109th Congress. Other CRS reports focus in more detail on legal and drug price issues.[7])

Background

Since 1938, the Federal Food, Drug, and Cosmetic Act (FFDCA, P.L. 75-717) has required that drugs sold to U.S. consumers be safe. With its 1962 Kefauver-Harris Amendments (P.L. 87-781), all drugs had to be proven effective as well. The FFDCA is the major law that set up the current U.S. system of drug regulation; subsequent legislation amends it. In the last 17 years, congressional and FDA actions have addressed the importation of prescription drugs by, in turn, limiting imports, establishing exceptions to those restrictions, and attempting to broaden access to imports.

Distributing Prescription Drugs: The Current System

FDA supervises the approval, production, and distribution of prescription drugs. It works to prevent unsafe, ineffective, subpotent or adulterated drugs from reaching retail pharmacies in the United States—whether on purpose or inadvertently.[8]

Before it approves a prescription drug for sale, FDA requires that a manufacturer demonstrate that its product is safe and effective for its intended use, that directions on the label are clear and appropriate, and that the drug has been manufactured in specific production lines that have been registered and approved by FDA. After approval, the manufacturer must continue production according to FDA-approved "good manufacturing processes."[9] The drug companies must periodically open their production facilities to rigorous FDA inspection.

After production, the manufacturer sends the drug to FDA-registered U.S. drug wholesalers or secondary drug wholesalers for further distribution. States license or authorize the pharmacists

[7] CRS Report RL33175, *Importation of Prescription Drugs: A Side-by-Side Comparison of Current Law, S. 109/H.R. 328,S. 184/H.R. 753, and S. 334/H.R. 700*, by (name redacted) and (name redacted). See also CRS Report RL32191, *Prescription Drug Importation: A Legal Overview*, by (name redacted); and CRS Report RL33781, *Pharmaceutical Costs: An International Comparison of Government Policies*, by (name redacted).

[8] For a fuller discussion, see CRS Report RL32797, *Drug Safety and Effectiveness: Issues and Action Options After FDA Approval*, by (name redacted).

[9] A drug production term used by FDA and the pharmaceutical industry. See, for example, FDA, *Guidance for Industry: Q7A Good Manufacturing Practice: Guidance for Active Pharmaceutical Ingredients*, August 2001, at http://www.fda.gov/cder/guidance/4286fnl.htm; FDA, *Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach*, September 2004, at http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm; and FDA, "Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations," September 2006, at http://www.fda.gov/cder/guidance/7260fnl.htm.

and wholesalers who sell and distribute pharmaceuticals within their borders and also license the physicians and dentists who prescribe the drugs.

Influence of the Prescription Drug Marketing Act of 1987

The structure of today's distribution system is based on changes made in the 1980s when Congress determined that the drug distribution system was not sufficiently "closed" to prevent abuse of drug samples. The Prescription Drug Marketing Act of 1987 (PDMA, P.L. 100-293)[10] banned the sale, trade, and purchase of drug samples; mandated storage, handling, and accounting standards for drug samples; and required that drug wholesalers be licensed by the states. To enforce the law, the FDA drafted regulations that would require drug companies to maintain a detailed "chain of custody" (known as a pedigree) for every pharmaceutical product sold in this country. By imposing strict recordkeeping requirements, FDA hoped, among other things, to ensure the safety and quality of all drugs that are exported and later imported back into the country.[11] The recorded pedigree would allow manufacturers to trace back suspected counterfeit shipments.

However, the law excluded manufacturers' authorized distributors from this recordkeeping requirement. Because most drugs are sold from authorized distributors into secondary drug wholesale distribution markets (not authorized distributors of record), the recordkeeping requirement created a dilemma. Because secondary distributors (authorized and unauthorized) receive no records or pedigree with the drugs they purchase, they do not have the information necessary to show a chain of custody. For that reason, when FDA published final regulations to implement this section of the PDMA in December 1999, the Small Business Administration petitioned the agency, arguing that enforcement of the provision would drive 4,000 or more secondary distributors out of business. Subsequently, FDA delayed the effective date of this provision's enforcement repeatedly,[12] most recently because it believed that industry voluntary conversion to an electronic pedigree was imminent, in which case the rule would be superfluous. In 2006, seeing that industry's progress toward the technology change was slow, FDA announced and then finally implemented the rule on December 1, 2006. One week later, a court issued a preliminary injunction to prohibit FDA's implementing key pieces of the rule.[13]

Department of Homeland Security Appropriations Act, 2007

For the past few years, Members have tried to use the agriculture appropriations bill (which includes FDA) to get around administrative blocks to prescription drug importation. The House-

[10] 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, April 30, 1987, p. 7.

[11] FDA, "The Prescription Drug Marketing Act: Report to Congress," 2001, at http://www.fda.gov/oc/pdma/report2001/report.html.

[12] FDA, "Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date," *Federal Register*, February 23, 2004 (21 CFR 203). For PDMA history, see http://www.fda.gov/oc/pdma/report2001/report.html, p. 7.

[13] FDA, "Addendum to FDA's 'Guidance for Industry: PDMA Pedigree Requirements—Questions and Answers' Related to the Preliminary Injunction ordered 12/5/06 in RxUSA Wholesalers, Inc. v. HHS," December 15, 2006; and FDA, "Prescription Drug Marketing Act Pedigree Requirements under 21 CFR Part 203 Compliance Guide and Guidance for Industry: Prescription Drug Marketing Act Pedigree Requirements Questions and Answers; Notice of availability and guidances," *Federal Register*, November 15, 2006 (21 CFR 203 and 205).

passed FY2007 agriculture appropriations bill would prohibit FDA from using funds to prevent individuals, pharmacists, or wholesalers from importing prescription drugs that comply with the core requirements of the FFDCA.[14] The Senate-reported bill contains no similar provision.

Importation's supporters had more success in applying this strategy to the Department of Homeland Security FY2007 appropriations bill that became law. It prohibits the use of those funds by CBP to prevent "individuals not in the business of importing a prescription drug" from importing a prescription drug that complies with the FFDCA.[15]

The Senate Committee on Commerce, Science, and Transportation of the 109th Congress reported its Federal Trade Commission (FTC) reauthorization bill (S. 1392) and included the text of Senator Dorgan's separate drug importation bill (S. 334). Although the bill did not see further activity in that Congress, the Congressional Budget Office (CBO) issued cost estimates of the import provisions that provide additional data for the ongoing debate.[16]

Importing Prescription Drugs: The Current System

The PDMA limits importation of a prescription drug into the United States to the manufacturer. Further, when importing a drug, the manufacturer must present records indicating that the product is the same as an FDA-approved drug being distributed in the United States, that the imported product was handled properly and, if necessary, is re-labeled for the U.S. market. 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 (CBP) (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 regulatory standards.[17]

FDA's Practice Concerning Personal-Use Imports

Since the PDMA's restrictions went into effect, the FDA has chosen to leniently enforce that ban and has allowed individuals to bring into the United States a small amount (i.e., a 90-day supply) of non-FDA-approved drugs for personal use.[18] This FDA enforcement policy requires that those individuals affirm in writing that the drugs are for their own use, and provide the name and address of their treating physician.[19]

When FDA's personal use import policy began, it was not envisioned as a way for consumers to bring lower-priced prescription drugs into the United States. According to FDA's policy statement on importing drugs for personal use:

[14] Section 749, H.R. 5384 in the 109th Congress.

[15] P.L. 109-295, Section 535.

[16] Congressional Budget Office (CBO), "Cost Estimate: S. 1392, FTC Reauthorization Act of 2005," September 8, 2006, at http://www.cbo.gov/ftpdocs/66xx/doc6634/s1392.pdf.

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

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

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

> ... 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.[20]

But where the policy once compassionately let a few people import—for personal use—cancer or AIDS drugs that were not available for sale in the United States, today that policy is used by consumers seeking lower foreign prices for FDA-approved drugs available in the United States.

CBP Practice Concerning Personal-Use Imports

The U.S. Customs and Border Protection (CBP) is responsible for enforcing the FFDCA prohibition on prescription drug importation. Hence, despite FDA's continuing "exercise of enforcement discretion" regarding personal-use importation by individuals, from November 2005 until October 2006, CBP could implement a policy to detain prescription drugs entering U.S. international mail branches. In a notification letter, CBP would ask the intended recipient to choose between abandoning the shipment or requesting "an admissibility determination from the FDA."

In October 2006, CBP amended this policy and stopped detaining these drugs, referring all identified imports to FDA. (FDA would, presumably, continue its practice of enforcement discretion.) CBP, in conjunction with this change, planned to focus its actions on "high risk threats to the health and safety of the American public."[21] The revised CBP policy specified that CBP would not block an individual personally carrying from Canada a 90-day supply of a prescription drug that otherwise met FFDCA requirements. The policy does not apply to mail shipments, imports from countries other than Canada, or any controlled substances (drugs, such as narcotics, covered by the Controlled Substances Act).

The Medicine Equity and Drug Safety Act of 2000

With drug costs rising and more and more consumers importing less expensive prescription drugs for their own use, the 106th Congress passed the Medicine Equity and Drug Safety (MEDS) Act (P.L. 106-387) in an effort to take advantage of the lower prices drug manufacturers charged in other countries. The MEDS Act of 2000 amended the FFDCA to authorize a five-year program allowing pharmacists and drug wholesalers to import less costly prescription drugs from foreign suppliers.[22] 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.

HHS did not implement the import program. The act required that, before publishing implementing regulations to put the import provisions into effect, the Secretary must first:

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

[21] Darren Mackaly, CBP Congressional Liaison, personal communications, December 10, 2006.

[22] Part of the FY2001 agriculture appropriations bill (P.L. 106-387), the MEDS Act added new Section 804 to the FFDCA. The import provision does not cover controlled substances, biologics, infused drugs, intravenous drugs, and drugs inhaled during surgery.

> ... 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 2000, then-Secretary Donna Shalala announced that she could not implement the MEDS Act because it allowed drug companies to deny U.S. importers legal access to the FDA-approved labeling required for reimportation; did not prohibit drug manufacturers from requiring distributors to charge higher prices, limit supply, or treat U.S. importers less favorably than foreign purchasers; and the five-year "sunset" provision would have a chilling effect upon private-sector investment in the testing and distribution systems required under the law.[23] In 2001, her successor, Secretary Tommy G. Thompson, declined to implement the law as well, stating that to import drugs under the MEDS Act would make it impossible to adequately guarantee the safety of prescription drugs.[24] 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. Consequently, FDA has never implemented that section of the law, and there is no legal program in effect for importing prescription drugs other than by the manufacturer.[25]

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The 108th Congress also addressed consumer burden. Provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (hereinafter referred to as the MMA for Medicare Modernization Act, P.L. 108-173) entirely replaced the 2000 MEDS Act language in the FFDCA (Section 804). This new Section 804, however, requires conditions for implementing a prescription drug import program that are similar to the 2000 MEDS Act. It, too, states that before promulgating regulations concerning importation the HHS Secretary must certify 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." Until that certification, drug imports are illegal unless imported by the manufacturer of the drug. Now, therefore, neither a pharmacist nor a wholesaler may import prescription drugs. The law does not allow an individual to import a drug for personal use.

If the HHS Secretary were to give Congress the required safety and cost savings certification, then all the mechanisms of Section 804 would go into effect. The Secretary would have to promulgate regulations that:

- allow a pharmacist or a wholesaler to import prescription drugs from Canada;

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

[24] U.S. 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.

[25] Letters from FDA, written on behalf of HHS Secretary Michael Leavitt, decline state and municipal requests for importation waivers under MMS, citing, among other arguments, Secretaries Shalala and Thompson's declining to offer this certification of safety and cost savings (e.g., letters dated November 2005 and March 2006 from Randall W. Lutter, FDA Associate Commissioner for Policy and Planning, at http://www.fda.gov/oc/opacom/hottopics/importdrugs/duncan110805.html and http://www.fda.gov/oc/opacom/hottopics/importdrugs/saxe031706.html).

- waive the law's restrictions on personal use imports, so an individual could import a 90-day supply of a prescription drug from Canada; and
- continue the ban on the importation of personal-use drugs from any other country unless the Secretary granted, by regulation or on a case-by-case basis, personal-use waivers to individuals.[26]

The MMA directed the HHS Secretary to study and report to Congress on the importation of prescription drugs into the United States. This requirement was addressed when the HHS Task Force on Drug Importation released its *Report on Prescription Drug Importation* in December 2004.[27]

Current Situation

Although Congress passed the MMA with provisions to permit drug imports from Canada, the act contained the requirement that, to implement the program, the Secretary first must certify that all imports would be safe and at reduced cost to U.S. consumers. (See **Appendix**, Drug Regulation in Canada.) The current Secretary refused to make this determination, therefore, absent a change in his position, the program cannot take effect.

Price Differentials

A 90-day supply of 20 mg. Lipitor, a statin drug used to control high cholesterol, sells in the United States for about $346 and is available from Canada for about $165.[28] This type of discrepancy is not unique. A recent compilation of U.S. and Canadian drug-price comparisons showed that, on average, brand-name drug prices charged by manufacturers, wholesalers, and retailers were higher in the United States, most recently by about 70%.[29] This was consistent with the Canadian pharmaceutical pricing board's 67% finding.[30] The differentials between Canadian and U.S. retail prices are much less for generic drugs[31] and, not surprisingly, they constitute only a small portion of what individuals import to the United States from Canada.[32]

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[26] The Secretary could choose, for example, to allow one specific individual or any individual to import, for personal use, (1) an FDA-approved prescription drug from a specified country other than Canada; or (2) a drug not available in the United States (and not FDA-approved) from Canada or another country.

[27] HHS Task Force on Drug Importation, *Report on Prescription Drug Importation*, December 2004, at http://www.hhs.gov/importtaskforce/Report1220.pdf.

[28] Estimates compiled from http://www.canadapharmacy.com, http://www.cvs.com, and http://www.walgreens.com, visited January 14, 2007.

[29] Gross, 2003.

[30] Abigail Zugar, "Rx:Canadian Drugs," *New England Journal of Medicine*, vol. 349, no. 23, December 4, 2003, pp. 2188-2190.

[31] Patricia M. Danzon and Michael F. Furukawa, "Prices and Availability of Pharmaceuticals: Evidence from Nine Countries," *Health Affairs* Web exclusive, October 29, 2003, at http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.521v1.pdf, visited March 8, 2004; "U.S./Canada Price Gap Closing Thanks to Generics, Express Scripts Says," *The Pink Sheet*, March 8, 2004; and Mark B. McClellan, Commissioner of Food and Drugs, FDA, statement before the U.S. Congress, Senate Committee on Commerce, Science and Transportation, March 11, 2004.

[32] Comparing prices across products, places, or purchasers is a complex activity. Complicating the debate are the government, industry, and consumer affiliations of some of the analysts and varying definitions. In a simple transaction chain, the price at which a manufacturer sells a drug to a wholesaler (point A) differs from the price at which that (continued...)

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, while consumers in other countries, especially those with national health plans, have access to the same pharmaceutical products at much lower prices. Consumer dissatisfaction is magnified, they argue, because some of these drugs were developed through research supported by U.S. taxpayers. If foreign suppliers offer FDA-approved pharmaceuticals at prices significantly lower than in this country, advocates insist that consumers, pharmacists, and wholesalers must have a safe, viable, and legal way to import these drugs.[33]

Drug Import Volume

Growing Internet use by individuals contributed to the dramatic upsurge in 2003 in the importation of prescription drugs through links to pharmacies abroad. The typical importer used to be an individual traveling to a Canadian pharmacy and carrying a personal supply back into the United States; now, it is becoming a U.S. consumer ordering from an online mail-order pharmacy that ships the prescription drug to the United States.[34] Looking at 2005 and 2006 data, however, IMS Health reports that the rate of increase of U.S. Internet drug purchases from Canada was slowing. Its analysts attribute some of this to the new Medicare prescription drug benefit.[35] The Canadian news media mention additional reasons for the decrease: the strong Canadian dollar, manufacturers' actions to restrict supply, and package seizures by U.S. border agents.[36]

Encouragement from States and Municipalities

Several states and municipalities are looking at ways to control expenditures for prescription drugs in their Medicaid budgets and for employees and retirees. They are pursuing legislative, judicial, and administrative approaches.

(...continued)

wholesaler sells that drug to a neighborhood drug store (point B), which will differ from the price the store charges the individual for whom the drug was prescribed (point C). Comparing prices at point A in Canada to prices at point C in the United States would muddle the question. Adding markups by secondary wholesalers, chainstores or other shared purchasing arrangements, rebates, discounts, differences in shipping costs or charges, and health insurance payments yields more price points. Although these difficulties weaken the usefulness of some price comparison reports, other reports appear to be based on reasonable and defined methodologies.

[33] Donald L. Barlett and James B. Steele, "Why We Pay So Much for Drugs; How the Clamor for Cheap Canadian Imports is Heating Up the 2004 Campaign and Giving Washington a Headache," *Time Magazine*, February 2, 2004.

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

[35] Because no comprehensive surveillance of drug importation activity exists, estimates vary. Numerous news accounts refer to the volume and dollar value of drugs that individuals in the United States import from Canada. These include $1.3 billion (Christopher Rowland, "Canada Looks to Curb Drug Exports," *Boston Globe*, June 30, 2005); $1.5 billion (Judith Graham, "Canada to ban bulk drug imports, allow Internet sales," *Chicago Tribune*, June 30, 2005; and Steve Hymon, "Council Considers Offering Data on Canadian Drugs," *Los Angeles Times*, February 17, 2005). IMS Health has reported a range of figures, including "the equivalent of $1.1 billion U.S. dollars (based on U.S. prices) last year" [2003]; for Internet pharmacy sales from Canada, $346 million in 2005, and $456 million in 2004. IMS Health, "IMS Reports 8.3 Percent Dollar Growth in 2004 U.S. Prescription Sales," press release, February 14, 2005; and IMS Health, "IMS Reports 5.4 Percent Dollar Growth in 2005 U.S. Prescription Sales," press release, February 22, 2006; both at http://www.imshealth.com.

[36] "Minnesota-based Internet drug company shuts down," *Canadian Press NewsWire*, December 28, 2006.

In 2004, state legislators introduced 51 bills and resolutions—in 24 states plus the District of Columbia—that addressed state importation of prescription drugs, with most focusing on imports from Canada.[37] The count in 2005 was 56 bills and resolutions in 22 states; in 2006, it was 29 in 13 states.[38] One 2004 measure in Louisiana would make illegally importing drugs a crime; and, in 2005, a Virginia law prohibited sales by nonresident pharmacies not registered with the Commonwealth. Other states' proposals generally encourage importation by asking Congress to legalize the practice or explore its feasibility or by authorizing purchases from Canadian mail-order pharmacies. Connecticut, Mississippi, Vermont, and West Virginia Governors signed bills into law in 2004, and the Mayor of the District of Columbia signed a bill that needs ratification by the U.S. Congress; and a Rhode Island bill became law without the Governor's signature. Governors of Maine, Nevada, Texas, Vermont, and Washington signed laws in 2005. In 2006, the only enacted law was in California.

On another front, the Minnesota Attorney General (AG) is investigating whether GlaxoSmithKline (GSK) violated state anti-trust laws when it blocked sales to Canadian pharmacies selling prescription drugs to U.S. consumers. The AG has asked the court to compel GSK to release the Minnesota-requested documents that are located in Canada and England, which GSK has refused to do, citing the Ontario Business Records Act.[39] Other states are using the courts in attempts to change a larger range of pharmaceutical industry pricing practices.[40]

Some states—such as Minnesota and Wisconsin—have created websites to direct U.S. consumers to Canadian sources; several Governors have proposed pilot import programs to gain information about the savings benefits.[41] FDA opposes these activities, arguing they are both illegal and unfeasible. An FDA letter to Minnesota Governor Pawlenty, for example, opposed the state government's endorsement of Canadian Internet sites, arguing that U.S. consumers could enter into a "'buyer beware' gray zone" and risk receiving counterfeit drugs. The letter also "noted the potential tort liability that a state could be subject to if a citizen purchases an unapproved, illegal drug on your advice, and suffers an injury as a result."[42] Earlier, in response to the Illinois Governor's report on importation of drugs for state employees, an FDA official wrote that the

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[37] National Conference of State Legislatures, "2004 Prescription Drug State Legislation," revised November 2006, at http://www.ncsl.org/programs/health/drugdisc04.htm.

[38] National Conference of State Legislatures, "2005 Prescription Drug State Legislation," revised November 15, 2006, at http://www.ncsl.org/programs/health/drugdisc05.htm; and NCSL, "2006 Prescription Drug State Legislation," updated January 3, 2007, at http://www.ncsl.org/programs/health/drugbill06.html.

[39] State of Minnesota Office of the Attorney General, "Hatch Takes Dual Action on Pharmaceutical Industry Front," press release, September 30, 2003; and David Phelps, "Hatch Says Glaxo Is Hindering Probe," *Star Tribune* (Minneapolis, MN), November 18, 2003, p. D1; and John Carreyrou, "Seizures of Canadian Drugs Rise as Congress, Customs Spar," *Wall Street Journal*, July 24, 2006.

[40] Reed Abelson and Jonathan D. Glater, "New York Will Sue Two Big Drug Makers On Doctor Discount," *The New York Times*, February 13, 2003, p. A1.

[41] Letter from William K. Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation, FDA, to Deputy Attorney General Gregory Gonot, state of CA, responding to questions on the importation of prescription drugs into CA, August 25, 2003. Minnesota RxConnect Online, at http://www.state.mn.us/cgi-bin/portal/mn/jsp/home.do?agency=Rx and the state of Wisconsin Prescription Drug Resource Center, at http://www.drugsavings.wi.gov, both visited March 19, 2004.

[42] Letter from William K. Hubbard, FDA Associate Commissioner for Policy and Planning, to Governor Tim Pawlenty of Minnesota, February 23, 2004, at http://www.fda.gov/oc/opacom/hottopics/importdrugs/pawlenty022304.html, visited March 25, 2004. Also see "FDA Sends Wisconsin Letter Over Use of Canadian Internet Pharmacies," *PharmaLive.com*, July 26, 2004. Some legal experts observe that it is not at all clear that a state would be liable in tort ("Trial lawyer threat is latest FDA ploy to stop Rx reimportation," Inside Washington Publishers, February 27, 2004).

state substantially overstated the likely effect of an importation program by omitting costs for pharmacists, shipping, and liability.[43] As of January 2007, the states of Illinois, Kansas, Missouri, Vermont, and Wisconsin participate in the I-SaveRx program "that allows consumers to purchase safe and affordable prescription refills from licensed, inspected pharmacies in Canada and the United Kingdom."[44]

Cities, too, have set up programs to facilitate the purchase by employees and retirees of drugs from Canada. One—Springfield, Massachusetts—reported saving about $3 million a year.[45] In December 2003, Montgomery, Alabama, reported saving up to $500,000 so far that year by allowing its 4,100 city employees and retirees to buy drugs from Canada.[46] In July 2004, the Mayor of Boston launched a pilot program to permit about 14,000 city employees and retirees to purchase prescription drugs from Canada. By waiving copayments for selecting the Canadian option, but keeping copayments for domestic orders at $10, the city creates only a small incentive for individuals to participate.[47]

Some states are exploring other avenues to influence their drug costs. North Dakota has proposed a "Prairie Prescriptions Pilot Project," asking the HHS Secretary to waive the current legal restrictions and allow pharmacies to import less expensive drugs from Canadian pharmacies. Senator Dorgan, a proponent of this proposal, has stated that the project could save the state $81 million annually by licensing Canadian pharmacies and wholesalers, and selling imported drugs only within the state.[48] Illinois, Iowa, and New Hampshire have also sought waivers under the MMA from HHS for drug importation programs.[49]

Opposition from FDA and the Pharmaceutical Industry

Both FDA and the drug industry have continued to oppose the idea of unlimited importation of drugs. FDA officials assert that FDA cannot vouch for the safety and effectiveness of imported drugs that come from unregistered and uninspected facilities, particularly those overseas. Without the safety net of FDA's "closed" distribution system, they believe U.S. consumers would not be able to verify where a drug is made, would not be notified if there is a recall of the product, and could easily be defrauded with counterfeit drugs. Furthermore, they argue that importing drugs

[43] Letter from William K. Hubbard, FDA Associate Commissioner for Policy and Planning, to Ram Kamath and Scott McKibbon, Special Advocates for Prescription Drugs, Chicago, IL, November 6, 2003.

[44] I-SaveRx: Safe and Affordable Prescription Drugs, at http://www.i-saverx.net/general.htm.

[45] When Springfield ended its own health insurance coverage for municipal employees and retirees, enrolling them, instead, in Massachusetts's state plan, it ended its Canadian drug importation program. See Christopher Rowland, "Mass. city ends drug plan that defied US; Springfield joins state, halts Canadian imports," *Boston Globe*, August 26, 2006; Christopher Rowland, "FDA Tells Supplier to Halt Canadian Drug Orders; Springfield Mayor Defiant on Import of Prescriptions," *The Boston Globe*, September 17, 2003, p. D1; and Jarrett T. Barrios, Massachusetts State Senator, remarks to health leaders seminar, National Conference of State Legislators, Washington, DC, December 10, 2003.

[46] Julie Appleby, "More Cities, States Opt for Canadian Drugs," *USA Today*, December 23, 2003; and Kim Chandler, "Montgomery's been quietly buying drugs from Canada," *Birmingham News* (Alabama), December 31, 2003.

[47] Christopher Rowland, "City Launches Program to Buy Imported Drugs Impact is Seen as Mainly Political," *The Boston Globe*, July 22, 2004, p. A1.

[48] "Sen. Dorgan Pushes for Drug Import Pilot Program in North Dakota," *Inside Health Policy*, April 1, 2004.

[49] Cyril Zaneski, "Support Grows on Hill to Allow Drug Imports," *Baltimore Sun*, June 3, 2004, at http://www.baltimoresun.com.

would have a minimal impact on domestic drug prices while opening the borders to potential counterfeit products.[50]

Selected Legislative Proposals

In the first week of the 110th Congress, Members introduced drug importation bills: S. 242 and H.R. 380, the Pharmaceutical Market Access and Drug Safety Act of 2007 (introduced January 10, 2007, by Senators Dorgan and Snowe and Representatives Emanuel and Emerson); and S. 251, the Pharmaceutical Market Access Act (introduced January 10, 2007, by Senator Vitter). Members of the 109th Congress had introduced three pairs of bills, none of which was reported. Because numerous academic and policy panels, news and professional journals, and committee hearings discussed them, this report uses the provisions in the bill pairs of the 109th in its presentation of issues that this Congress faces.[51] As public discussions of the bills introduced in the 110th Congress build, updates of this report will reflect them. The bills from the 109th Congress are:

- **The Pharmaceutical Market Access Act of 2005**: **S. 109**, introduced by Senator Vitter on January 24, 2005, and **H.R. 328**, introduced by Representative Gutknecht on January 25, 2005; referred to in this report as the Vitter-Gutknecht bills.
- **The Safe Importation of Medical Products and Other Rx Therapies Act of 2005, or the Safe IMPORT Act of 2005**: **S. 184**, introduced by Senator Gregg on January 26, 2005, and **H.R. 753**, introduced by Representative Bradley on February 10, 2005; referred to in this report as the Gregg-Bradley bills.
- **The Pharmaceutical Market Access and Drug Safety Act of 2005**: **S. 334**, introduced by Senator Dorgan on February 9, 2005, and **H.R. 700**, introduced the same day by Representative Emerson; referred to in this report as the Dorgan-Emerson bills. On July 21, 2005, Senator Dorgan successfully offered the drug importation provisions as an amendment to the Federal Trade Commission reauthorization bill (S. 1392) approved by the Senate Commerce, Science and Transportation Committee (but there was no further action on that bill).[52]

All the bills seek to balance the availability of imported prescription drugs—for both commercial and personal use—with the assurance that those imports would be safe and effective. The underlying goal is to reduce or restrain the growth of the financial burden that prescription drugs place on U.S. consumers. They all would act primarily by replacing or amending Section 804 of the FFDCA. A striking difference between these bills and current law is their elimination of the provision that has so far been the chief obstacle to imports: HHS Secretary certifications about

[50] Tom McGinnis, FDA, comments made February 27, 2004 at a session on the "Reimportation Debate" at the National Medicare Prescription Drug Congress, Washington, D.C., February 25-27, 2004. On June 30, 2004, FDA and Pfizer began alerting pharmacists and the public about confirmed counterfeit Viagra sold at two California pharmacies (FDA, "FDA is Alerting the Public to Counterfeit Viagra Found in Two California Pharmacies," *FDA Statement*, June 30, 2004, at http://www.fda.gov/bbs/topics/news/2004/NEW01083.html) [It is not clear whether the Viagra was imported]; and Hubbard, June 24, 2003.

[51] See CRS Report RL33175, *Importation of Prescription Drugs: A Side-by-Side Comparison of Current Law, S. 109/H.R. 328,S. 184/H.R. 753, and S. 334/H.R. 700*, by (name redacted) and (name redacted).

[52] Elaine S. Povich, "Drug Importation Tacked to FTC Bill," July 21, 2005, at http://nationaljournal.com.

risk and cost. Throughout the following discussion of issues, this report refers to provisions in these bills.

Issues for Congressional Consideration

An individual imports a drug for personal use. A pharmacist or wholesaler imports a drug for commercial use. A manufacturer imports one of its own drugs. Each of these situations involves two issues that are at the heart of congressional debate:

- Can we ensure that imported drugs—and how they would be used—would be safe and effective; and
- If Congress chooses to proceed, how could it craft an administratively feasible statutory and regulatory drug import framework that results in U.S. consumers' gaining access to lower priced prescription drugs.

Drug Safety and Effectiveness

Health concerns, summarized as safety and effectiveness, focus on two domains. The first is product integrity—Is the product what the seller purports it to be? The second is appropriate use—Does this individual need this drug at this time?

Product Integrity

Would an import program make it easier to sell to U.S. consumers drugs that are adulterated, misbranded, of inaccurate or variable dose, counterfeit, or not manufactured safely? Opponents of legalization say it would. They are concerned, as well, that, with the current level of regulatory scrutiny and oversight of overseas manufacturing, FDA could not guarantee the integrity of each shipment, particularly those that arrive by mail. As the volume of imported drugs has greatly increased in recent years, some commentators have cautioned that inspectors, who cannot closely examine each and every package, will find it 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. While less concerned with drugs obtained from Canadian pharmacies, they worry that some counterfeit drugs produced elsewhere could be shipped to Canada and then on to U.S. consumers.

Aside from such intentional acts, FDA is concerned with actions that might inadvertently affect the safety and effectiveness of imported drugs. It cautions that the labeling of some drugs may not be in English or otherwise lack adequate directions for use; not have been packaged and stored under conditions appropriate to prevent degradation; or not have been made under current good manufacturing practices—all related to requirements for FDA-approved products. If the drugs are subpotent or ineffective, patients "may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause."[53]

[53] Testimony of FDA Associate Commissioner for Regulatory Affairs John Taylor, in U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *Importation of Prescription Drugs*, hearings, 108th Cong., 2nd sess., May 20, 2004 (hereinafter "Taylor, May 20, 2004").

Although each of these circumstances could adversely affect a U.S. consumer, the FDA has—or could be given—options with which to address many of these threats that are less drastic than a total ban on drug importation. It could define and require appropriate labeling in English; it could set a certification standard; it could enforce the law's requirement that prescription drugs require prescriptions, adding that the prescriber must be licensed in the United States; and it could encourage anticounterfeiting technology or increase border and mail inspections. The expense of these activities, however, would diminish the apparent price differential between U.S. and foreign-dispensed drugs. To what degree is a matter of debate.

All this raises the question: To ensure the safety and effectiveness of drugs sold to U.S. consumers, how can the Congress and FDA decide which drugs could be eligible for import?

Drug Eligibility and FDA-Approval Status

Most proposals would require that the drugs be FDA-approved, meaning that they have gone through the rigorous, FDA-required and substantiated process of safety and effectiveness testing and are, therefore, approved by the FDA for sale in the United States. These bills would prohibit the importation of biologics and controlled substances; imported pharmaceuticals that do not meet these U.S. standards and are not manufactured under FDA regulatory oversight would be considered "unapproved" drugs and could not be imported legally.

Current law and the Vitter-Gutknecht and Gregg-Bradley bills explicitly require that an imported drug be approved for sale by the FDA. The Dorgan-Emerson bills allow different administrative requirements for importation, while maintaining the substantive elements of FDA approval prior to importation. The Dorgan-Emerson bills require that a manufacturer notify the HHS Secretary when a drug that could be imported differs from the version FDA had approved for sale in the United States (the "U.S. label drug"). They require extensive information about whether the difference, if it were to be made to a U.S. label drug, would require a supplemental application to FDA and whether FDA would require that the application be processed before the drug could be marketed.

The Gregg-Bradley bills require that imported drugs be labeled as imported and not be commingled with actual FDA-approved drugs. A U.S. drug store could then have two supplies of one pharmaceutical: the imported drug and the one that came through the U.S. distribution system. Some have characterized this as a "two-tiered system," implying an actual or perceived difference in quality.

Permitted Countries

With product integrity in mind, legislators could look to limit permitted countries to those with regulatory approval systems similar to those in the United States. The three bill pairs and current law vary in the countries from which they would permit importation. The most inclusive are the Vitter-Gutknecht bills,[54] which include Australia, Canada, Israel, Japan, New Zealand, South Africa, Switzerland, members of the European Union,[55] Iceland, Liechtenstein, and Norway. They

[54] In one of the very few differences between S. 109 and H.R. 328, the Gutknecht bill restricts European Union members to those included as of December 31, 2003.

[55] When the importation bills were drafted in 2003 and early 2004, the 15 member countries of the European Union were Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, Netherlands, Portugal, (continued...)

also allow the Secretary to designate additional countries that have equivalent regulatory requirements regarding safety and effectiveness or to remove a country that does not.

The Dorgan-Emerson bills differ from the Vitter-Gutknecht bills by excluding Israel, South Africa, and members of the European Economic Area that are not also members of the European Union (excluded are Iceland, Liechtenstein, and Norway), and, for European Union countries, by adding a reference to their Annex to the Treaty of Accession that essentially disqualifies the ten countries admitted to membership in May 2004 (excluded are Cyprus, the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia, and the Slovak Republic).

The Gregg-Bradley bills include Canada and allow the Secretary, three years after enactment, to designate as eligible any members of the European Union as of December 2003. Current law, subject to the Secretary's certification, includes only Canada, although it allows the Secretary to grant waivers permitting personal-use importation from other countries.

Ensuring Drug Identity

What procedures might help verify that the drugs are what they say they are? The approaches vary and include registration, testing, monitoring and inspections, packaging and labeling, recordkeeping that could include chain-of-custody pedigrees, and penalties, in varying degrees.

Registration . All three bill pairs require that commercial participants (be they owners, operators, agents, wholesalers, pharmacies, or pharmacists) register with FDA, providing information such as the name and address of the importer and what they are importing, the name and addresses of every place of business of the exporter that relates to the drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter. The Vitter-Gutknecht bills require that only exporters register; the Gregg-Bradley and Dorgan-Emerson bills would have both exporters and commercial importers register. These registration requirements would enable regulatory enforcement and establish responsibility for consumer and government inquiries.

Recordkeeping . To ensure that imported drugs come from safe sources, the legislative proposals require extensive recordkeeping of transactions involving a drug. Current law contains elaborate requirements: drug importers would have to provide 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, information about its origin and destination, the price paid by the importer, the original source of the drug, the amount of each lot received from that source, the manufacturer's lot or control number, and the importer's name, address, and license number. There are other tracking records that must be kept. The importer is required to provide any other information that the Secretary determines is necessary to ensure the public health.

The Vitter-Gutknecht bills have almost identical requirements to current law. The Gregg-Bradley and Dorgan-Emerson bills require that chain-of-custody records be kept for two years. They also require that the wholesale distributor of record provide to the recipient of an imported drug, information regarding all previous sales, purchases, or trades of the drug including the identity of the distributors and provide information such as dates and names and addresses of all parties to

(...continued)

Spain, Sweden, and the United Kingdom. On May 1, 2004, ten additional countries joined: Cyprus, the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia, and the Slovak Republic.

each transaction. The wholesaler must also maintain for Secretarial inspection for two years records of all previous and all subsequent transactions. The point of this required detailed information is to make it more difficult for counterfeit drugs to slip into the distribution chain. The Dorgan-Emerson bills also require that the Secretary randomly review records of exports to individuals for personal use.

Product Testing and Facility Monitoring and Inspection . The Customs and Border Protection Service (CBP) is responsible for checking all imported goods coming into this country. When CBP 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. FDA officials report that the monitoring of even the current wave of drug products has become a tremendous enforcement problem for both CBP and FDA inspectors.[56]

To demonstrate how difficult enforcement has become, FDA released on January 27, 2004, a report on a second import "blitz" it conducted with the U.S. Bureau of Customs and Border Protection (CBP) in six courier hubs and mail centers around the country. They examined almost 2,000 mailed packages (about 80% of them came from Canada) that appeared to contain FDA-regulated products and found that 87% did. The FDA reported finding recalled drugs, foreign-versions of FDA-approved drugs, drugs requiring close physician monitoring, and addictive controlled substances.[57] The FDA and CBP press statements did not provide sufficient detail to allow an assessment of the validity of the operation's methodology or the agencies' conclusions. Without that, the extent to which these products were indeed a health threat to U.S. consumers is unclear. What is clear is that any pharmaceutical product imported by anyone other than the manufacturer is considered to be an unapproved drug. Therefore, since only FDA-approved drugs can be sold in the United States, all drugs currently being imported for personal use or that would be imported under some of the state initiatives would be unapproved and deemed illegal.

Current law requires that the importer or manufacturer certify that the drug is FDA-approved, properly labeled, not adulterated, and not misbranded, provide laboratory records of authenticity testing, including data, and evidence that testing was conducted in an approved U.S. laboratory. The Vitter-Gutknecht bills reflect similar requirements to current law, and also include that the importer certify that the drug is FDA-approved and provide laboratory records of authenticity testing if the drugs were not in counterfeit-proof packaging.

The Gregg-Bradley and Dorgan-Emerson bills approach this differently. Rather than call for laboratory testing of drug samples, they start with the assertion that the FDA-approved manufactured product has passed inspection as safe and effective and then require chain-of-custody documentation covering every transfer until the drug reaches the importer. Enforcement includes ongoing and onsite physical monitoring of a drug's manufacturer, registered exporters and importers, and records of all transactions involving the drug.

The Dorgan-Emerson bills require that the exporter permit the Secretary to assign one or more employees to conduct day-to-day on-site continuous monitoring of warehouses or other exporter owned, controlled, or operated facilities that relate to qualifying drugs; to have day-to-day access to records including financial records; to verify the chain of custody of each qualifying drug,

[56] Taylor, May 20, 2004.

[57] U.S. Food and Drug Administration, "Recent FDA/US Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments," press release, January 27, 2004, pp. 4-7.

monitor markings, and sample the exported drugs to assure compliance; and to carry out other functions that the Secretary determines necessary regarding compliance. The Secretary may allow periodic, rather than day-to-day, inspections of a business with sufficient history of compliance.

In addition, both bill pairs would authorize the federal government to sample and inspect drugs to prevent the importation of adulterated, misbranded, or non-FDA-approved drugs from entering the country. The Gregg-Bradley bills also allow the Secretary to form an agreement with another federal agency or a state for its employees to conduct examinations and investigations to enforce compliance. However, the Secretary would also need to give adequate training and reimbursement, with required reporting to Congress of the joint activities.

Regulating Internet Pharmacies

Use of the Internet—which poses challenges for all kinds of drug distribution—creates some special difficulties when it comes to imports.[58] Existing laws that govern mail-order, out-of-state, or nonresident pharmacies cannot effectively protect consumers because some "rogue" pharmacies and distributors operate one day and disappear the next. Online questionnaires can jeopardize the legal privacy protections of a patient's medical records and could lead to a misdiagnosis.[59]

Current law does not address use of the Internet to sell or purchase imported prescription drugs. The Vitter-Gutknecht bills have no provisions specifically related to Internet pharmacy procedures, but include qualified Internet pharmacies among other registered exporters and the extensive associated requirements. The Gregg-Bradley and Dorgan-Emerson bills do address Internet sales. Their provisions address registration, posted information, prescriptions, and relationship to medical care.

The Gregg-Bradley bills present an extensive statutory and regulatory structure for Internet pharmacies, placing it in the FFDCA but set apart from the importation sections. In addition to registration, the bills require that Internet pharmacies provide specific professional services, including confidential patient medication profiles, "interactive and meaningful consultation by a licensed pharmacist," and verification of prescription validity. They require advance notice of commercial shipments of prescription drugs and include a licensing fee. Providers of interactive computer services are liable if they accept advertising for a prescription drug from an unlicensed Internet pharmacy or accept advertising stating that a physician's prescription is not needed to obtain a prescription drug. The Gregg-Bradley bills also require policies and procedures to

[58] The Internet is a potent modality for the efficient sale and purchase of all types of merchandise, including pharmaceuticals. Advantages include cost savings because of comparative shopping for consumers and bulk purchases by mail order pharmacies; consultations with the pharmacist in the privacy of the home; privacy of prescriptions sent over secure lines; alternative source for information about a drug; and, potentially, more accurate records. For consumers, the comfort of anonymity in purchasing certain drugs is a plus as often is the range of products offered over those of the local pharmacy. For websites, the same anonymity works to the retailer's advantage as does the ability to interact with many more consumers. Many analysts believe the movement toward electronic prescribing meshes well with Internet sales. Electronic prescribing has given physicians, pharmacists, and consumers convenience by saving the time it takes to answer calls and faxes to verify unclear prescriptions; reducing the number of prescribing errors with the use of computer software programs that can check for conditions that contraindicate certain medications, patient history of allergic reactions, adverse drug interactions, and confusion between similarly named drugs; quickly determining if the drug is on an insurer's formulary (an approved list of drugs for reimbursement); and eliminating problem handwriting recognition.

[59] See CRS Report RS21711, *Legal Issues Related to Prescription Drug Sales on the Internet*, by (name redacted).

prevent payments for unlawful Internet pharmacy requests. FDA would establish a fee system based on anticipated costs of enforcing these requirements.

The Dorgan-Emerson bills require that detailed information be accessible on the Internet site, covering pharmacist credentials, address and telephone contacts, and the name and professional licensure information of the person, if any, who provides for medical consultations through the site for purposes of providing prescriptions. No one can dispense or sell a drug if the purchaser or patient communicated through the Internet did not have a valid U.S. prescription. The dispenser must also have a "qualifying medical relationship with the patient."

Several other bills were introduced in the 109th Congress to ensure the integrity of drugs purchased over the Internet.[60] Not all of these deal specifically with imports.

Controlling Advertising and Credit on Online Search Engines

Some online search engines, such as Yahoo, Microsoft's MSN, and Google, announced in 2003 that they would not accept advertising from certain Internet pharmacies.[61] The House Energy and Commerce Committee asked credit card and courier companies, such as Visa, MasterCard, FedEx, and UPS, to investigate ways to stop illegal marketers from using their services.[62] The Gregg-Bradley bills make providers of advertising services on the Internet liable if they accept advertising for a prescription drug from an unlicensed Internet pharmacy or accept advertising stating a physician's prescription is not needed to obtain a prescription drug. The bills require regulations for a payment system that could prevent or block restricted transactions and exempt from liability any actions blocking or refusing to honor a restricted transaction. They also require that FDA develop regulations to prevent payments for unlawful Internet pharmacy requests and set up a system through grants or contracts to identify unlicensed Internet pharmacy websites or those in violation of federal or state laws. Finally, they require that FDA promulgate regulations consistent with the National Association of Boards of Pharmacy Verified Internet Pharmacy Practice Sites program, known as VIPPS, which certifies, based on on-site inspections and record reviews, that a pharmacy meets state licensure and registration requirements and follows procedures appropriate for Internet practice.[63]

The Dorgan-Emerson bills state that a provider of an interactive computer service or of advertising services would not be held liable for the selling or dispensing of drugs in violation of this section if that provider does not own or exercise corporate control over the person selling or dispensing drugs. They also direct the Secretary to review practices of public and private entities

[60] Bills in the 109th Congress: H.R. 578 (Prescription Drug Affordability Act, introduced by Rep. Paul on February 2, 2005); H.R. 840 (Ryan Haight Internet Pharmacy Consumer Protection Act of 2005, introduced by Rep. Davis on February 16, 2005); H.R. 3608 (Internet Drug Sales Accountability Act, introduced by Rep. Sweeney on July 28, 2005); and S. 399 (Internet Pharmacy Consumer Protection Act or the Ryan Haight Act, introduced by Sen. Coleman on February 16, 2005).

[61] Gilbert M. Gaul and Mary Pat Flaherty, "Google to Limit Some Drug Ads; Web Giants Asked to Help Discourage Illicit Online Pharmacies," *The Washington Post*, December 1, 2003, p. A1.

[62] Gilbert M. Gaul and Mary Pat Flaherty, "Firms Pressed on Internet Drugs: Senate Panel Writes to Credit Card Companies, Shippers," *The Washington Post*, December 10, 2003, p. A4; and "Credit Card Firms, Shippers Willing To Help Stop Illegal Online Rx Sales," March 2004, at http://www.InsideHealthPolicy.com.

[63] Testimony of Executive Director/Secretary Carmen A. Catizone, National Association of Boards and President and CEO Craig Fuller, National Association of Chain Drug Stores, in U.S. Congress, House Committee on Government Reform, March 18, 2004.

that certify Internet businesses. Authorizing appropriations, they direct the Secretary to have the Clearinghouse on Internet Prescribing identify sites that appear to violate drug dispensing laws.

Packaging and Labeling

To reduce risks to safety such as adulterated and counterfeit drugs, some suggest requiring tamper-resistant and anti-counterfeit packaging, along with proper use instructions on the labeling. Others suggest that the agency also educate the public on counterfeit packaging detection. Critics of these proposals argue that the pharmaceutical industry would pass the cost of the new packaging requirements to consumers, cutting down the amount saved from imports.[64]

The HHS-appointed Counterfeit Drug Task Force explored a multi-pronged approach to the use of technologies that can better identify, deter, and combat the counterfeiting of prescription drugs. The major recommendation in its February 2004 final report was for the use of an electronic pedigree using radio frequency identification (RFID) technology to "track and trace" drugs from manufacturing plant to local pharmacy.[65] RFID places electromagnetic chips and tags containing a unique serial number onto cartons and individual drug products.[66] FDA is encouraging, not requiring, use of RFID, which in addition to blocking counterfeit drugs could help companies more accurately manage their inventories.[67] Drugmakers are considering whether to adopt the technology, albeit cautiously because of its cost.[68]

Several bills require that medications from overseas come in anti-tampering and anti-counterfeit packaging. The Vitter-Gutknecht bills include extensive prescription drug packaging—not only for imports.[69] The Gregg-Bradley bills take a different tack. They require the drug container to have a prominent and conspicuous label that includes the lot number; the name, address, and phone number of the drug importation facility; a statement that the drug was imported, naming the country from which it came; and a unique, identification code indicating that the drug has been imported, based on the national drug code of the prescription drug. In addition, it requires that the FDA establish a "Counterfeit Alert Network" to notify health professionals and the public of counterfeit drugs; develop, publish, and keep up-to-date an Internet accessible reference document to identify prescription drugs marketed in the United States, Canada, and other countries as the Secretary permits. The Dorgan-Emerson bills mandate that the FDA, during inspections, verify the chain of custody of a statistically significant sample of the drugs that are to

[64] Comments made by Ronald Guse, Registrar, Manitoba Pharmaceutical Association, National Association of Pharmacy Regulatory Agencies (Canada) at a conference on "Safety and Security in North American Trade," Center for Strategic and International Studies, July 16, 2003.

[65] "HHS takes new steps to protect consumers from counterfeit drug threats," *HHS News*, February 18, 2004; and FDA, "Combating Counterfeit Drugs: A Report of the Food and Drug Administration," February 2004, at http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html.

[66] "Protecting Consumer From Counterfeit Drugs," *FDA Consumer*, May-June 2004.

[67] John Wilkerson, "FDA Won't Require 'Paper Pedigree' Under New Plan To Combat Counterfeit Drugs," February 18, 2004 at www.InsideHealthPolicy.com.

[68] "FDA Sees Promise of RFID Technology; Drugmakers Question Feasibility," March 2004, at [fdanews@enewsletters.fdanews.com].

[69] The Vitter-Gutknecht bills require manufacturers to incorporate overt optically variable counterfeit-resistant technology or those equally effective. The technologies employed must provide visible identification of the product and be similar to those used by the Bureau of Engraving and Printing to secure U.S. currency. Also, manufacturers must incorporate the technologies into multiple elements of the packaging for prescription drugs, and shipping container labels must incorporate technologies that enable inspectors to verify the authenticity of the shipment.

be imported. This sampling and compliance with the chain-of-custody requirements may be accomplished by the use of anticounterfeiting or track-and-trace technologies.

In addition to their concern about packaging costs being transferred to the consumer, critics argue that this technological solution may take years to implement.

Appropriate Use

At hearings and in letters, FDA has raised a concern about the growing number of patients, particularly those now using Internet links to pharmacies based either in the United States or overseas, who are buying and taking medications without the traditional safeguards of a medical diagnosis and a doctor's prescription. The FFDCA defines a prescription drug as one 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."[70] FDA has outlined the risks to consumers who get drugs without the knowledge of a physician, such as through Internet purchases from illegitimate pharmacies. For example, the "patient may be practicing what amounts to self-diagnosis. Consequently, the risk of negative outcomes such as harmful drug interactions, contraindications, allergic reactions or improper dosing is potentially magnified."[71] Furthermore, persons who unknowingly take an ineffective product forgo the opportunity to receive the appropriate treatment.[72]

Safe and effective drugs can be unsafe or ineffective if they are not taken appropriately. This potential danger accompanies any medication used without adequate instruction and follow-up, even if dispensed domestically according to a valid prescription. If an import program inadvertently were to give individuals easier access to prescription drugs through the Internet, its design, many feel, should prevent unsupervised or otherwise inappropriate use of those safe and effective drugs.

Even though since 1988 it has been technically illegal for anyone other than the manufacturer to import prescription drugs, a large number of people (especially seniors, according to popular belief) are doing it. Congress declared in the MMA that the Secretary should use discretion when enforcing the current legal prohibition against persons importing drugs or devices. The MMA also added to current law a requirement to take effect if the Secretary certifies the safety and cost savings of the commercial importation sections. It would then require FDA 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 that ensure public safety. The Secretary may also grant waivers in other circumstances.

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[70] Section 503(b) of the Federal Food, Drug, and Cosmetic Act.

[71] William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, statement before the U.S. Congress, House Committee on Government Reform, March 18, 2004.

[72] The Internet Pharmacy Consumer Protection Act (H.R. 3880) would, among other things, prohibit sales when the patient did not have a valid U.S. prescription before communicating with the Internet dispenser and when the prescriber did not have a qualifying medical relationship with the patient, which must include at least one in-person medical examination.

The Vitter-Gutknecht bills also use the waiver mechanism for personal-use imports, but they require the Secretary to do so within 180 days of enactment without the certification requirement. Rather than using a waiver, the Gregg-Bradley and Dorgan-Emerson bills allow an individual to import up to a 90-day supply of a qualifying drug if the drug is accompanied by: a copy of a prescription that is valid under federal and state laws and was issued by a practitioner who, under the law of the state in which the individual resides, is authorized to administer drugs. To prevent duplicative filling by another pharmacist, all prescriptions must be marked to indicate they have been filled. The Gregg-Emerson bills also allow an individual to import a 90-day supply prescription drug from Canada or a permitted country for their personal use if the drug is purchased from a licensed pharmacy and is accompanied by a copy of a valid prescription signed by a prescribing physician in a state. The Gregg-Emerson bills add that the prescription must be cosigned by a prescribing physician in Canada or the permitted country. If the imported prescription drug is an over-the-counter (OTC) drug in the country of purchase, then the purchaser would have to have a valid prescription signed by the pharmacist in Canada or a permitted country. This bill pair is the only one that mentions "compassionate use," permitting an individual to import up to a 90-day supply of a drug that is not approved by FDA if it is to be used to continue treatment begun in a foreign country for a serious medical condition.

Program Feasibility

Design of a successful import policy would need to overcome several obstacles, chiefly those involving cost and pharmaceutical industry response.

Costs of a New Import Regulatory Program

An import program would entail initial costs of rulemaking and continuing costs of managing the product and information from both exporters and importers. HHS would need to develop two sets of oversight protocols. The first would help legitimate consumers get safe and effective medications as prescribed by their physicians. The second would prevent and deter individuals from purchasing drugs that FDA has not monitored—and for whose safety and effectiveness it cannot, therefore, vouch—for unsupervised use.

At a March 2004 congressional hearing, one FDA official estimated that a drug import program's cost would compare to what FDA spends on regulating food imports under the bioterrorism law which amounts to several hundred million dollars.[73] Another FDA official reportedly stated at a May 2004 congressional hearing that FDA's estimated costs for a program are "hundreds of millions of dollars to ... ensure the safety of products coming into the U.S."[74] According to one FDA official, the cost of a program could be much greater than anticipated. He contends that FDA

[73] "$58 million for Canadian Rx Reimportation Based on Outdated Estimate," *Inside Washington's FDA Week*, March 19, 2004. At a House Appropriations subcommittee hearing regarding the President's proposed FY2005 FDA budget, FDA's deputy commissioner estimated it would cost FDA $58 million to start a program to ensure import safety (Lester M. Crawford, Deputy Commissioner, FDA, response to questions at House Appropriations Committee hearing, March 11, 2004; and John Wilkerson and Veena Menon, "Crawford Says Drug Importation Program Would Cost $58 Million," *InsideHealthPolicy.com Daily Updates*, March 11, 2004).

[74] Comment was made by John Taylor, FDA Associate Commissioner for Regulatory Affairs at the Senate Health, Education, Labor and Pensions Committee hearing on May 20, 2004 (Lise Richwine, "Drug Import Plan Would Be Costly—Officials," *Reuters*, May 20, 2004, at http://www.reuters.co.uk).

would need enough funding to inspect all 55,000 U.S. pharmacies and 7,000 U.S. wholesalers that would have to register with the agency.[75]

Current law includes no explicit funding mechanism other than authorizing appropriations of such sums as necessary to implement the prescription drug importation provisions, and FDA uses appropriated funding to inspect and monitor imports. Alternative funding options to cover inspection, recordkeeping, and quality control costs include fees charged to the exporter and the importer.[76]

The Vitter-Gutknecht bills not only authorize appropriations but also would provide for exporter fees to cover the cost of administering the import provisions. The Gregg-Bradley and Dorgan-Emerson bills provide for both exporter and commercial importer fees designed to cover all costs of the program.

All three bills link the aggregate total of all fees to the estimated costs of the importation program, setting a limit of 1% of the total price of drugs imported. The Secretary would collect from each exporter (and importer, except in the Vitter-Gutknecht bills) both a flat registration fee and a fee calculated to represent the estimated proportion of the aggregate amount for which the individual importer or exporter's activity accounted. The bills require that these fees be used only for the administration of the importation provisions that the bills would add.

Supporters argue that the broader based user fee system could give the agency resources necessary to police the imports. Critics contend, however, that the fee proposals are excessive and likely to preclude the participation of many small pharmacies.[77] Furthermore, the importers who do pay registration costs and annual fees may pass these costs on to consumers.

Drug Industry Behavior

Pharmaceutical companies have opposed proposed legislation permitting drug imports, claiming that the safety of these drugs cannot be assured. How would they react to the new laws?

Limiting Supplies

Several companies have begun to manipulate the supply of drugs, particularly to Canada, which some see as actions to circumvent the purpose of any legislation.[78] In May of 2004, the Minnesota

[75] "Rx Import Plan Would Require Funds to Inspect All U.S. Pharmacies—FDA," *The Pink Sheet*, vol. 66, no. 25, June 21, 2004, p. 35.

[76] These costs are for monitoring foreign facilities; developing, implementing, and maintaining a system to mark shipments to indicate registration compliance; and conducting inspections within the United States to determine compliance with required conditions for importers and for imports for personal use.

[77] In comments made public, former FDA Commissioner, David Kessler, concluded that the 1% could result in up to $100 million in new resources which would double FDA's current drug center field budget ("Kessler: Kennedy Bill Would Give FDA Enough Money to Run Rx Imports," *InsideHealthPolicy.com Daily Updates*, June 3, 2004 [Letter from David Kessler, M.D., Dean, University of California San Francisco School of Medicine, to Senator Edward M. Kennedy, May 19, 2004, available from CRS]).

[78] John E. Calfee, "The High Price of Cheap Drugs: the House Is Tempted by a Terrible Idea," *Weekly Standard*, July 21, 2003; "Drug Dealing," editorial in *Washington Post*, July 24, 2003, p. A20; "Merck Targets Drug Reimports," *Washington Post*, January 21, 2005; Al Swanson, "Analysis: Govs lobby for cross-border Rx," *UPI*, January 20, 2005; David Gram, "Vt. may sue pension funds in fight for Canadian drugs," *Associated Press*, November 30, 2004; and (continued...)

Seniors Foundation filed a class action suit in federal court against nine pharmaceutical companies (Abbott Laboratories, Boehringer Ingelheim, GlaxoSmithKline, AstraZeneca, Pfizer, Eli Lilly, Merck, Novartis, and Wyeth) claiming they were curtailing the supply of pharmaceuticals to Canadian wholesalers and pharmacists and had acted together to impede the importing of brand drugs from Canada to keep prices high for American consumers.[79] In September 2005, a federal judge dismissed that suit, although a similar lawsuit filed by the Minnesota attorney general is still pending in state court.[80] According to reports, when these companies calculate that the amount of drugs Canadian wholesalers (and pharmacies) are ordering is above the normally needed supply to the Canadian market, they cut or withhold from future shipments the percentage they feel is destined to fill prescriptions from American consumers.[81] Perhaps in response to a threat to their supply of pharmaceuticals, the Canadian International Pharmacy Association decided in December 2003 that its 27-member mail-order pharmacy association would not sign formal agreements with U.S. states and cities.[82] The Minister of Health in the previous Canadian government proposed a legislative package to ban Canadian commercial exports of prescription drugs and to more tightly regulate sales to foreign individuals.[83] New bills are pending in Canada, but the current government is waiting to act until it sees that Canadian supplies are threatened.[84] If drugmakers do restrict or tighten supplies of pharmaceuticals to Canadian suppliers, some anticipate that a U.S. drug import program could, inadvertently, cause drug prices to rise in Canada and reduce Canadian residents' access to some drugs.

The Vitter-Gutknecht and Dorgan-Emerson bills would restrict drug companies from controlling their sales to foreign pharmacies. Some argue that these provisions would be unconstitutional and would probably violate both the takings clause of the Fifth Amendment and the patent clause of Article 1 of the Constitution.[85] The Gregg-Bradley bills also would permit the Secretary to decide after three years whether supplies are the hindering factor for imports, and to permit drug imports from the 15-member European Union three years after enactment.

The American Association of Retired Persons (AARP) believes that provisions in the Dorgan bill would hinder the ability of drug companies to limit the supply of pharmaceuticals to foreign

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"Reimportation: Canadian pharmacy, patient groups call for ban," *American Health Line (National Journal Group, Inc.)*, October 19, 2004.

[79] Tom Majeski, "Seniors Sue Drug Makers; Federal Suit Seeks Class-Action Status," *Saint Paul (Minnesota) Pioneer Press*, May 20, 2004.

[80] David Phelps, Tom Buckingham, and staff writers, "Business Insider; Inside Track," *Star Tribune (Minneapolis, Minnesota)*, September 5, 2005.

[81] "Pfizer Halts Supply to Canadian Pharmacies Reimporting Drugs to U.S.," *Drug Industry Daily*, vol. 1, no. 28, March 3, 2004 at [fdanews@enewsletters.fdanews.com].

[82] "Large Scale Reimportation Efforts Rebuffed by Canadian Mail-order Group," *Washington Drug Letter*, vol. 36, no. 1, January 5, 2004.

[83] David Struck, "Canada to Restrict Exports to U.S. of Prescription Drugs; Bulk Prescription Sales Would Be Banned," *Washington Post*, June 30, 2005; and Alan Freeman and Gloria Galloway, "Congress planning new stab at drug legislation; Bill would allow importation from Canada, Europe," *The Globe and Mail (Canada)*, December 23, 2006.

[84] Michelle Macafee, "Groups ask Ottawa to ban drug exports before U.S. Congress legalizes trade," *Canadian Press*, November 23, 2006.

[85] "Gregg Reimportation Bill Enters Fray," *Medicine and Health*, June 7, 2004.

pharmacies and that the Gregg bill would not. AARP has, therefore, come out with strong support for the Dorgan bill.[86]

Changing Formulations

Pharmaceutical companies have other ways to circumvent what they view as the adverse financial impact of legal importation. For example, companies may export drugs that have different nonpharmacologic characteristics (e.g., color, size, shape, or dosages) than the FDA-approved counterpart product intended for retail distribution in the United States. Because these exported products would, literally, appear different from their FDA-approved domestic counterparts, they would be deemed unapproved and therefore not qualify for import under current law and regulations.

The Vitter-Gutknecht and Dorgan-Emerson bills would make it unlawful for a manufacturer to make a drug for distribution in a permitted country so that it differs from the drug made for U.S. distribution "for the purpose of restricting importation of the drug...." Provisions describe involvement of the FTC and the state attorneys general. The extensive notification requirements in the Dorgan-Emerson bills regarding differences between a drug a manufacturer produces for sale in a permitted country and the drug it produces for U.S. distribution could serve, in addition to addressing safety, to influence industry decisions.

Corporate Investment

Other concerns have been that the larger manufacturers might curtail their investments in research and development. Industry spokespeople have not sought to allay those fears, stating, for example, "It is widely understood that these policies will limit patient choices and stifle the incentives for research and development of the innovative medicines patients need to treat diseases like Alzheimer's, diabetes, heart ailments and cancers."[87] Some economists point out that while substantial lost income would lead to lower investment, the tipping point is unknown and difficult to estimate because industry data and internal discussions are not public. One approach to alter manufacturers' incentives is tax penalties pegged to certain actions. None of the currently pending bills includes such provisions; bills of the 108th Congress did.[88]

Influencing Behavior with Rewards and Penalties

Implementation of the importation provisions in current law is restricted by the requirement that the Secretary certify safety and cost savings. Even were the Secretary to issue the certification necessary to begin the drug importation section in the FFDCA, many analysts and Members of Congress anticipate manufacturer resistance.

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[86] "AARP Backs Prescription Drug Import Legislation," at http://www.aarp.org/legislative/prescriptiondrugs/rxprices/watchdog/Articles/a2004-06-29-importlegislation.html; and "Prescription Drug Importation: Can it Help America's Seniors?," speech by AARP CEO William Novelli, June 22, 2005, at http://www.aarp.org/research/intl/comparisons/prescription_drug_affordability_importation_and_sa.html, visited October 25, 2005.

[87] Alan F. Holmer, President and CEO, Pharmaceutical Research and Manufacturers of America, statement on the introduction of importation legislation by Sen. Charles Grassley, April 8, 2004, at http://www.phrma.org/mediaroom/press/releases/08.04.2004.955.cfm.

[88] S. 2307 of the 108th Congress, introduced by Sen. Grassley, provided for a research and development tax incentive.

Patent, Intellectual Property, and Trade Issues

A host of questions have been raised concerning how importation relates to a patent holder's rights. Variables concerning patent law[89] and international trade agreements[90] may influence decisions despite being seemingly unrelated to FDA's responsibility for drug safety and efficacy and some Members of Congress and the public's concerns about drug cost to consumers. The interplay of all the diverse factors will affect importation policy and practice.[91]

In February 2005, the negotiations concluded on the U.S.-Australia Free Trade Agreement. The language of the agreement raised concerns among certain Members of Congress that the agreement would be used to prevent the importation of prescription drugs into the United States by limiting a source of supply of drugs and possibly setting a precedent for other international free trade agreements.[92]

Australia is listed as a "permitted country" in two of the three pairs of import bills discussed in this report. The FTA specifically contains a protection for the rights of patent holders over their patented products including pharmaceuticals. The agreement reads:

> Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means. [Article 17:9:4].

This provision means that no drug can be imported to the United States from Australia without permission of the U.S. patent holder.[93] If pharmaceutical companies contractually or otherwise

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[89] CRS experts in foreign trade and law have produced reports relevant to this discussion; for example, CRS Report RL32400, *Patents and Drug Importation*, by (name redacted); and CRS Report RS21129, *Pharmaceutical Patent Term Extensions: A Brief Explanation*; CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, and CRS Report RL32377, *The Hatch-Waxman Act: Legislative Changes Affecting Pharmaceutical Patents*, by (name redacted) and (name redacted).

[90] 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.

[91] An August 2003 World Trade Organization (WTO) General Council decision seeks to ensure that intellectual property rights do not keep countries lacking the capacity to produce medicines for themselves from obtaining them from abroad. Under the agreement, countries that provide medicines covered by this decision 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. This decision was incorporated as an amendment to the WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement in December 2005. *WTO News*, "Decision Removes Final Patent Obstacle to Cheap Drug Imports," press release 350, August 30, 2003, at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm. See also CRS Report RL33750, *The WTO, Intellectual Property Rights, and the Access to Medicines Controversy*, by (name redacted).

[92] See CRS Report RL32375, *The U.S.-Australia Free Trade Agreement: Provisions and Implications*, by (name redac ted).

[93] In reaction to reports that the draft agreement would "prohibit the re-importation to the United States of medicines covered by Australia's pharmaceutical benefits scheme," Senator Grassley charged, in February 2004, that by including this language in the agreement, the executive branch "intruded on the congressional debate over access to drugs for U.S. seniors" (Martin Vaughan, "Grassley Says Australian Drug Provision Intrudes on Hill Debate," *Congress Daily*, February 10, 2004). The U.S. free trade agreements with Morocco and Singapore have similar provisions.

place restrictions on sales, a common industry practice, they would have the right to control the sales of their drugs within and outside the United States. The Vitter-Gutknecht and Dorgan-Emerson bills would prohibit such behavior.

Australia subsidizes the cost of pharmaceuticals to its residents. To control its own costs, the government, through its Pharmaceutical Benefits Scheme (PBS), selects the lowest priced brand among competing producers of a specific drug in a therapeutic class and pays only that amount. Australia's PBS already prohibits export of the prescription drugs it subsidizes (about 90 to 95% of Australian drug purchases).[94] Only for U.S.-patented drugs that PBS does not cover would this agreement add restrictions. Of broader concern, though, is the precedent that this FTA may set in prohibiting certain kinds of imports.[95]

A 2004 CBO report describes the purpose of patents. While the manufacturer holds the patent on a new product, it is allowed to set the price high where feasible and adjust the price in response to price sensitivities elsewhere.[96] In a 2001 court case, *Jazz Photo Corporation v. International Trade Commission*, the judge in the U.S. Court of Appeals for the Federal Circuit ruled that if a company has a U.S. patent on a product and sells it abroad, the company retains its U.S. patent rights.[97] The ruling might prevent importation of drugs under the proposed bills because, under it, drug companies would be able to sue another importer for patent infringement if the importer was bringing in U.S. patented drugs first sold abroad. This principle would apply to either U.S. patented drugs made here or those made under license in foreign manufacturing facilities. According to FDA estimates, foreign-made FDA-approved drugs account for about 40% of the drugs sold here.[98] Consequently, unless legislative proposals to import drugs address this patent issue, implementing them might be difficult.[99]

The Vitter-Gutknecht and Dorgan-Emerson bills address the issue and would reverse judicial precedent holding that sales of patented goods outside the United States do not exhaust the U.S. patent. Under the bills' provision, goods that were the subject of authorized foreign sales by the U.S. patent holder may be imported into the United States without regard to the U.S. patent. Currently, the owner of the U.S. patent can sue if a product first sold abroad is imported without the consent of the patent holder. Critics complain that this would deny these companies recourse to the courts if drug imports were made legal.[100] The Gregg-Bradley bills would not penalize pharmaceutical companies for discriminating against foreign pharmacies who export drugs to U.S. consumers.

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[94] "U.S.-Australia Trade Pact Lacks Language Banning Drug Exportation," *The Pink Sheet*, March 15, 2004, p. 5; and telephone conversation with Lisa Cohen, Office of the U.S. Trade Representative, July 2004.

[95] John Wilkerson, "Reimportation Ban in Australia Pact Could Affect Domestic Policy," *Inside Health Policy*, February 10, 2004, at http://insidehealthpolicy.com/secure/health_docnum.asp?f=health_2001.ask&docnum=FDA-10-7-5.

[96] CBO, "Would Prescription Drug Importation Reduce U.S. Drug Spending?" CBO Economic and Budget Issue Brief, April 29, 2004, at http://www.cbo.gov.

[97] 264 F.3d 1094 (Fed. Cir. 2001).

[98] "Rx Drug Importation Foes Argue Plan Would Cause U.S. Job Loss," *Inside Health Policy*, May 11, 2004, at http://www.insidehealthpolicy.com.

[99] See CRS Report RL32400, *Patents and Drug Importation*, by (name redacted).

[100] Letter from Biotechnology Industry Organization, to Sen. Bill Frist, M.D., June 7, 2004.

Cost Savings from Drug Importation

Would an import program save U.S. consumers money? Would it increase access to lower priced foreign drugs? Would it actually lower prices in the months that follow implementation? Would these prices remain lower a year or two or 10 from now? It is unclear at this point to what extent these changes in the law if implemented 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.

Market and Competition

Proponents of a more tolerant policy assert that a drug import program would not only widen U.S. consumers' access to lower-priced drugs abroad, but would also increase competition among drug suppliers and lead to lower domestic prices. Critics argue that an import program is unfeasible, given industry and FDA opposition. Other critics assert that there is no guarantee that any savings would be passed on to consumers.

Whether an import program would succeed in lowering the financial burden on U.S. consumers poses a difficult set of concerns. Even some economists who support lowering the ban on drug imports believe that prices here and abroad would converge, leaving U.S. consumers somewhat better off in the intermediate time frame and foreign consumers worse off.[101] Potential changes in drug development policy and longer term markets are hot topics of debate.

It is unclear how much a new program might lower prices of pharmaceuticals for U.S. consumers—or if it would. Any program would create greater transaction costs for all drug importers. Studies of the parallel import trade in the European Union show that traders, rather than consumers, profit most from the transactions.[102] The recent CBO study concluded that any cost savings to U.S. consumers would likely be minimal because some of the difference in prices would accrue to wholesalers and other intermediaries to pay for new packaging and labeling, and to pay insurance for liability risks associated with the safety and quality of the shipped drugs. Foreign governments may limit the supply of drugs that could be exported and the drug industry could limit the volume shipped and exercise other maneuvers. CBO, therefore, estimated that the savings from a new import program would be "modest," reducing total drug spending by about 1% ($40 billion over 10 years).[103]

[101] Roger Pilon and John E. Calfee, remarks at debate, "Resolved: Congress Should Remove the Ban on Drug Reimportation," The CATO Institute, Washington, DC, March 30, 2004.

[102] Mattias Ganslandt and Keith E. Maskus, "The Price Impact of Parallel Trade in Pharmaceutical Products: Evidence from the European Union," *World Bank Policy Research Working Paper 2360*, July 2001, cited by Jim Furniss at session on "Drug reimportation: Learning from the experience in Europe," National Medicare Prescription Drug Congress, Washington, D.C., February 27, 2004 (available from CRS).

[103] CBO, April 29, 2004.

Others estimate significant savings to U.S. consumers. Using the 2004 CBO estimate that Americans over age 65 will spend $1.8 trillion on prescription drugs over the next 10 years, Representative Gutknecht estimated a 10-year savings of $630 billion (35%) by importing drugs.[104] Other estimates include Americans' saving $59.7 billion if, during 2004, they purchased all brand-name drugs at Canadian prices.[105]

Because Senator Dorgan successfully amended the FTC reauthorization bill (S. 1392) that the Committee on Commerce, Science, and Technology reported in 109th Congress, CBO cost estimates of that bill included the prescription drug importation provisions that he had first introduced in his stand-alone bill (S. 334). CBO estimated that the provisions, if enacted, would lower total U.S. spending on prescription drugs from 2006-2015 by $50 million (about 1%), a small proportion of which would be savings to federal programs.[106]

At least one economic analysis challenges the widespread expectation that drugmakers would cut supplies to Canada rather than allow U.S. customers access to Canada's lower prices. It describes two kinds of purchases under a legalized import program: drugs that the consumer had been and would have continued buying at U.S. market prices, and drugs that the consumer would begin to purchase at the lower price but had forgone or would forgo at the U.S. price. If the second group accounts for 45% of U.S. consumer purchases in Canada, the drug manufacturers' loss from the first group would be balanced by the gain from the second.[107] The authors anticipate that manufacturers would not cut supply. If this source of revenue is available, others question, why has the pharmaceutical industry not adjusted domestic prices to take advantage of the demand?

Government Influence on Pricing

Comparisons of U.S. prices to those in Canada and, more recently, Australia are complicated by differences in approach to regulation. In Canada, the federal and provincial governments play key roles in negotiating or setting prices. Australian policy differs: the government decides what price it would be willing to pay and then subsidizes purchasers to that amount. As the United States—whose consumers account for one-half of worldwide pharmaceutical sales—makes small or large adjustments in its approach to international drug markets, other countries may well adjust their policies in the interest of their consumers.

Industry Pricing

In a country where the government works to control prices, the seller has some leeway in setting the price. One recent study, comparing U.S. drug prices with those in eight other countries, found that the wealthier the country, the higher the price of drugs. The authors discuss whether this reflects buyers' sensitivity to price, something manufacturers may include in pricing decisions.[108]

[104] Rep. Gutknecht includes this estimate in material on his website, at http://www.gil.house.gov/Issues/PDrugs/pdrugs.htm.

[105] Alan Sager and Deborah Socolar, "Do Drug Makers Lose Money On Canadian Imports?" *Data Brief No. 6*, Boston University School of Public Health, April 15, 2004, at http://www.healthreform/program.org.

[106] CBO, "S. 1392: FTC Reauthorization Act of 2005," September 8, 2005.

[107] Sager and Socolar, 2004.

[108] Danzon and Furukawa, 2003.

Congressional Options for Controlling Drug Costs

Clearly, the high cost of prescription drugs affects the purchasing power of individual consumers and public and private entities. Also, the trend 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 has not traditionally controlled utilization). In addition, the new outpatient prescription drug benefit for Medicare beneficiaries began on January 1, 2006. It is too early to draw conclusions about its long-term prospects for reducing drug cost burden on U.S. consumers (Medicare-covered and others). What impact it will have on costs for the elderly is uncertain; it will provide coverage that many have not had. Because the government will now be paying for a larger proportion of drugs used by people in the United States, many believe that the government will have a stronger interest in the comparative costs, safety, and effectiveness of various available drugs.

If Congress wants to lower the cost of drugs to U.S. consumers, there are options—some more feasible than others—other than importation. These include encouraging the use of generics and disease management techniques, providing research and development incentives to industry, studying the comparative effectiveness of similar drugs and applying that information judiciously in benefit package and prescribing decisions, instituting price controls or other regulatory measures on prescription drugs in this country, encouraging more market action (such as with purchasing agreements), encouraging reciprocal arrangements with other nations' regulatory authorities, and promoting or providing insurance coverage for pharmaceuticals to a wider population than have it today. Such steps are beyond the scope of this report.

Appendix. Drug Regulation in Canada

Current law and the various pending bills designate Canada as the first or only country from which U.S. consumers or commercial importers could import if the program were implemented.

Safety and Effectiveness

Canada's drug regulatory requirements are quite similar to those of the United States, and Health Canada and FDA operate with similar procedures when ensuring the safety and efficacy of pharmaceutical products.[109] In a February 12, 2004 letter to Health Canada, then FDA Commissioner McClellan stated that:

> ... we have no reason to doubt the safety of Canadian drugs regulated by Health Canada and distributed within the regulated distribution systems in Canada. Rather, it is the practice of cross-border Internet pharmacies in Canada that primarily, or entirely, serve Americans—not Canadians—and the associated gaps between our two drug regulatory systems that remain of great concern to us.[110]

Canadian officials seem to concur that there is a gap between the two countries' responsibilities. Health Canada has already said that it does not assume regulatory oversight of drugs exported to U.S. addresses and is therefore neither willing nor able to guarantee the safety of those drugs.[111] On November 18, 2003, the United States and Canada signed a Memorandum of Understanding to share information on (1) pharmacies that export drugs to either nation, (2) quality defects or product recalls, (3) new regulations or policies regarding drugs, and (4) post-market surveillance results.[112]

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[109] CRS Memorandum, *Questions Concerning the U.S. and Canadian Regulatory Systems for Approving and Distributing Prescription Drugs*, by Blanchard Randall IV and Donna Vogt to Rep. Bernard Sanders, available at http://bernie.house.gov/documents/CRS-Canadian_Rx_Drugs.pdf, visited March 5, 2004.

[110] Letter from Mark B. McClellan, Commissioner of Food and Drugs, FDA, to Diane C. Gorman, Assistant Deputy Minister, Health Products and Food Branch, Health Canada, February 12, 2004.

[111] In the letter, Commissioner McClellan confirmed his commitment to work with Canada on inspections, enforcement, information, and risk communication and expressed concern about the regulation of Canadian Internet pharmacies that primarily serve Americans. The letter commented on findings of Minnesota pharmaceutical officials who had inspected eight Canadian pharmacies that supply U.S. citizens with drugs and that agreed to pre-arranged inspections by state officials. It cited practices that Minnesota officials found that would violate current Minnesota standards. The Minnesota pharmacy surveyors also found that some of the Canadian pharmacies "should be as good or better than the U.S. mail order pharmacies that we currently license" (Michele Mattila and Stuart Vandenberg, Pharmacy Board Surveyors, memorandum to David Holmstrom and Minnesota Board of Pharmacy Members, "Visits to Canadian Pharmacies; Summary of Findings," December 24, 2003, at http://www.phycybrd.state.mn.us/canada_memo.pdf, visited March 19, 2004). The Minnesota Board of Pharmacy, after considering these documents, noted in its minutes that "since the importation of prescription drugs from Canada remains a violation of federal law, the Board cannot recommend that anyone use pharmacies outside of the United States for obtaining prescription medications" (Minutes of the Minnesota Board of Pharmacy, January 6-7, 2004 meeting, at http://www.phcybrd.state.mn.us/minutes/2004/jan.pdf, visited March 19, 2004). Using the same information from the Minnesota pharmacy surveyors, the state's pharmacy program manager wrote to the Minnesota Commissioner of Human Services with details and his first, second, and third choice rankings of Canadian pharmacies that the state should consider for the Minnesota Program (Cody Wiberg memorandum to Kevin Goodno, "Report on the Survey of Canadian Pharmacies," undated copy, available from CRS).

[112] "Memorandum of Understanding Between the Food and Drug Administration, Department of Health and Human Services, of the United States of America and the Health Products and Food Branch, Health Canada, of Canada Regarding Sharing and Exchange of Information About Therapeutic Products," November 18, 2003, at (continued...)

Canadian pharmacies are regulated by provincial and federal authorities and are required to have licenses. These pharmacies cannot dispense a prescription drug without a prescription written by a physician licensed in Canada. Even though legitimate Internet or mail-order pharmacies require faxed or e-mailed prescriptions from a U.S.-licensed health care provider, there are some Canadian pharmacies (called "rogue" by FDA) that have apparently been set up only to dispense pharmaceuticals by mail.[113] For some of these, Canadian physicians rewrite a U.S. prescription or initiate a Canadian original, not necessarily following whatever regulations Canada might require nor being available for the level of monitoring required in the United States.[114]

Canadian pharmacies may soon find it difficult to hire physicians to write prescriptions for U.S. patients. The Canadian Medical Protective Association, a large malpractice insurance company for physicians (about 95% of the doctors licensed to practice in Canada are members), has notified Canadian doctors that it would no longer provide coverage to "risky activity" meaning if the physician did not originate the prescription but instead co-signed it for Americans in search of cheaper drugs without examining the patients in person.[115] The co-signing has been denounced by provincial and territorial licensing bodies.[116] It also is illegal, according to Canadian law, for any Canadian entity to import drugs in finished dosage form from a foreign country for the purpose of subsequent export, according to the Canadian International Pharmacy Association.[117]

Cost and Price

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.[118] This allows the government to negotiate bulk purchasing contracts for pharmaceutical products. By federal law, Canada's Patented Medicine Prices Review Board keeps drug costs in check by regulating a

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http://www.fda.gov/oia/agreements/HCFDAMOU111803.pdf.

[113] John Henkel, "Buying Drugs Online: It's Convenient and Private, but Beware of 'Rogue Sites,' *FDA Consumer*, January-February 2000, updated March 2001, at http://www.fda.gov/fdac/features/2000/100_online.html, visited August 3, 2004.

[114] Paul Pringle, "Not-So Corner Drugstore; Canadian Web firms are supplying low-cost prescription to many elderly Americans. But manufacturers and regulators are chafing," *The Los Angeles Times*, February 21, 2003, p. A1; Bernard Simon, "Pressure on Canada's Online Drug Sellers," *The New York Times*, December 10, 2003, p. W1; and "Health Canada says it cannot ban sale of Rx drugs to U.S. consumers," *InsideHealthPolicy.com*, May 6, 2004.

[115] James Sproule, "CMPA assistance in Internet and cross-border prescribing to non-patients—General principles," Canadian Medical Protective Association Information Sheet, February 2004 (IS0440E), at http://www.cmpa-acpm.ca, visited January 15, 2007; and "Cross-Border Prescriptions Put MDs at Legal Risk," February 3, 2004, at http://www.theglobeandmail.com.

[116] Marc Kaufman and Gilberg Gaul, "Canadian Group Seeks Drug Export Ban," *The Washington Post*, November 15, 2003, p. A6; The Nova Scotia College of Pharmacists, "Council Position Statement [on] Internet/Mail-Order Pharmacy Services: International Prescription Industry," updated December 2002, National [Canada] Association of Pharmacy Regulatory Authorities, at http://www.napra.org; "Joint Statement of the American Pharmacists Association (APhA) and the Canadian Pharmacists Association (CPhA)," May 13, 2003, at http://www.pharmacists.ca/content/media/newsroom/news_releases, visited April 19, 2004; "Position Statement on Cross-Border Prescription Drug Trade," Canadian Pharmacists Association, February 2004.

[117] "Canadian Pharmacy Group Says Transshipment Illegal in Canada," *InsideHealthPolicy.com*, June 3, 2004. The Canadian International Pharmacy Association was created in November 2002 to promote the growth and viability of the Canadian Internet pharmacies that provide international services; see http://www.ciparx.ca.

[118] Gross, 2003.

drug's price based on guidelines involving the cost of alternate drugs, cost of the same drug in other developed countries, and changes in the Consumer Price Index. In addition, 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.

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