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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 argues that with the likely exponential increase in imports — right now it tolerates some imports for personal use — it is impossible to monitor 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 Governors have proposed pilot import programs.

This issue is addressed in elements of four bills: S. 2493 (introduced by Senator Gregg), S. 2328 (introduced by Senator Dorgan), S. 2307 (introduced by Senator Grassley), and H.R. 2427 (introduced by Representative Gutknecht and passed by the House).

All four 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, ranging from tax incentives to penalties for noncompliance.

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.

The report examines these issues, spells out how they are treated from bill to bill, and refers to alternatives to importation to ease the burden of prescription drug costs on consumers: use of generics and disease management techniques; research and development incentives to industry; studying the drugs' comparative effectiveness and then judiciously applying the findings in benefit package and prescribing decisions; and assuming some of the consumers' cost.

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Introduction

In 2003, U.S. consumers bought over $1 billion of prescription drugs from Canada — twice as much as the year before.[1] The increase is one sign of how popular it has become for American consumers to buy prescription drugs from foreign sellers. Many 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.[2] 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.[3]

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. 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 FDA-approved prescription drugs from abroad.

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[1] IMS Health, "IMS Reports 11.1 Percent Dollar Growth in '03 U.S. Prescription Sales," press release, Feb. 17, 2004 at [http://www.imshealth.com], visited Mar. 12, 2004.

[2] 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. (Hereafter cited as Hubbard, June 24, 2003.)

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

The report begins with an overview of the domestic drug distribution system and how Congress has handled prescription drug importation.[4] It then discusses the current situation with its upsurge in the volume of drug imports, state and local government initiatives, the drug industry and FDA's reactions, and the legislative proposals introduced in the last few months 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 companion CRS report provides details of the old and new law and some history of the issues.[5])

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

The U.S. prescription drug production and distribution system as it currently exists is a "closed" system.[6] That is, FDA supervises the approval, production, and distribution of prescription drugs. Many levels of safety try to prevent unsafe, ineffective, subpotent or adulterated drugs from reaching retail pharmacies in the United States — whether on purpose or inadvertently.

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

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[4] 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.

[5] CRS Report RL32271, *Importation of Prescription Drugs Provisions in P.L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, by Susan Thaul and Donna U. Vogt. See also CRS Report RL32191, *Prescription Drug Importation and Internet Sales: A Legal Overview*, by Jody Feder.

[6] The concept of a "closed" system is outlined at [http://www.fda.gov/oc/pdma/report2001/report.html].

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."[7] 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 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)[8] banned the sale, trade, and purchase of drug samples purchased by health care entities; 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. 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 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 has delayed the

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[7] 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*, Aug. 2001 at [http://www.fda.gov/cder/guidance/index.htm]; and FDA, *Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach; A Science and Risk-Based Approach to Product Quality Regulation Incorporating an Integrated Quality Systems Approach*, 2000 at [http://www.fda.gov/oc/guidance/gmp.html].

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

effective date of its enforcement repeatedly;[9] the delayed effective date is now December 1, 2006.[10]

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.[11]

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.[12] 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.[13]

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:

> ... 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.[14]

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[9] For PDMA history, see [http://www.fda.gov/oc/pdma/report2001/report.html] p. 7.

[10] FDA, "Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date," *Federal Register*, Feb. 23, 2004 (21 CFR 203).

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

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

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

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

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.

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.[15] 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, the Secretary must first ensure the safety and effectiveness of the imported drugs. Congress further stipulated that before the import provisions of the MEDS Act could go into effect the Secretary of HHS had to:

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

In 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.[16] 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.[17] 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, that section of the law has never been

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[15] 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.

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

[17] 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].

implemented and there is no legal program in effect for importing prescription drugs other than by the manufacturer.

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 (hereafter 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;
- 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.[18]

Unrelated to whether the Secretary certifies safety and cost savings and, thereby, puts the new Section 804 into effect, the act mandates two studies. The HHS Secretary must study and report to Congress, within 12 months of enactment (due December 8, 2004), on the importation of prescription drugs into the United States.[19]

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[18] 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.

[19] The conference report provides the detailed instructions for that study. These include consideration of the pharmaceutical distribution chain; anti-counterfeiting technologies and their costs; the scope, volume, and safety of unapproved drugs; participation of foreign health agencies in ensuring product safety; the impact of importation on the drug prices that consumers face; the impact on research and development; agency resources; liability protections; and intellectual property rights. In Feb. 2004, HHS Secretary Tommy G. (continued...)

It also directs that "[t]he President's designees shall conduct a study and report on issues related to trade and pharmaceuticals."[20]

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 1**, 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 $320 and is available from Canada for about $180.[21] 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,

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[19] (...continued)
Thompson announced that he was forming a task force, to be headed by then FDA Commissioner Mark McClellan, to advise and assist HHS in carrying out this requirement. After some Members of Congress and state Governors vehemently objected because of Dr. McClellan's active role in opposing legislation to allow importation, the Secretary named Surgeon General Richard Carmona to head the panel. The Secretary filled out the rest of the task force with officials in the current Administration. (Hence, in his role as administrator of the HHS Centers for Medicare and Medicaid, Dr. McClellan will serve as a panel member). Although the panel membership includes well-qualified individuals in the areas the panel will examine, its Administration-only membership has raised concerns among some Members of Congress that an independent examination might be hampered or that panel recommendations might lose credibility due to that perception. According to these Members, the House- and Senate-passed Medicare bills (Section 804(k) in H.R. 1 and Section 804(l) in S. 1), which would have required the Secretary to arrange with the Institute of Medicine of the National Academies to conduct the study, would have minimized this potential conflict.

[20] Legislative language gives no more detail; the accompanying conference report, however, names the Secretary of Commerce, the International Trade Commission, the HHS Secretary, and the United States Trade Representative as responsible for the conduct of the study and report. Topics to be covered include how other countries use price controls and what this costs U.S. consumers; the impact of price controls and intellectual property laws on price, innovation, generic competition, and research and development; and whether these are appropriate topics for trade negotiations with other countries.

[21] Estimates compiled from [http://www.canadapharmacy.com], [http://bernie.house.gov/prescriptions/drugsheet.asp], and [http://pricecomparison.medicare.gov/compare_mail_summary.asp], visited July 9, 2004.

most recently by about 70%.[22] This was consistent with the Canadian pharmaceutical pricing board's 67% finding.[23] The differentials between Canadian and U.S. retail prices are much less for generic drugs[24] and, not surprisingly, they constitute only a small portion of what individuals import to the United States from Canada.[25]

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.[26]

Upsurge in Drug Import Volume

Growing Internet use by individuals has contributed to the dramatic upsurge 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

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[22] Gross, 2003.

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

[24] Patricia M. Danzon and Michael F. Furukawa, "Prices and Availability of Pharmaceuticals: Evidence from Nine Countries," *Health Affairs* Web exclusive, Oct. 29, 2003 at [http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.521v1.pdf], visited Mar. 8, 2004; "U.S./Canada Price Gap Closing Thanks to Generics, Express Scripts Says," *The Pink Sheet*, Mar. 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, Mar. 11, 2004.

[25] 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 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.

[26] 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*, Feb. 2, 2004.

ordering from an online mail-order pharmacy that ships the prescription drug to the United States.[27]

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.

So far in 2004, state legislators have introduced 42 bills and resolutions — in 22 states plus the District of Columbia — that address state importation of prescription drugs, with most focusing on imports from Canada. One measure in Louisiana would make illegally importing drugs a crime. 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, Vermont, and West Virginia Governors have signed bills into law; the Mayor of the District of Columbia signed a bill that still needs ratification by the U.S. Congress; and a Rhode Island bill became law without the Governor's signature. (See **Appendix 2**, Proposed State Laws or Resolutions in 2004 Regarding Importation of Prescription Drugs.)

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.[28] Other states are using the courts in attempts to change a larger range of pharmaceutical industry pricing practices.[29]

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.[30] 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

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

[28] State of Minnesota Office of the Attorney General, "Hatch Takes Dual Action on Pharmaceutical Industry Front," press release, Sept. 30, 2003; and David Phelps, "Hatch Says Glaxo Is Hindering Probe," *Star Tribune* (Minneapolis, MN), Nov. 18, 2003, p. D1.

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

[30] 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, Aug. 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 Mar. 19, 2004.

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."[31] Earlier, in response to the Illinois Governor's report on importation of drugs for state employees, an FDA official wrote that the state substantially overstated the likely effect of an importation program by omitting costs for pharmacists, shipping, and liability.[32]

Cities, too, have set up programs to facilitate the purchase by employees and retirees of drugs from Canada. One — Springfield, Massachusetts — estimated that it could save between $4 to $9 million annually.[33] Montgomery, Alabama, which for the last year has allowed its 4,100 city employees and retirees to buy drugs from Canada, reported saving up to $500,000 so far.[34] On July 22, 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.[35]

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.[36] Illinois, Iowa, and New Hampshire have also sought waivers under

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[31] Letter from William K. Hubbard, FDA Associate Commissioner for Policy and Planning, to Governor Tim Pawlenty of Minnesota, Feb. 23, 2004 at [http://www.fda.gov/oc/opacom/hottopics/importdrugs/pawlenty022304.html], visited Mar. 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, Feb. 27, 2004).

[32] 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, Nov. 6, 2003.

[33] Christopher Rowland, "FDA Tells Supplier to Halt Canadian Drug Orders; Springfield Mayor Defiant on Import of Prescriptions," *The Boston Globe*, Sept. 17, 2003, p. D1; and Jarrett T. Barrios, Massachusetts State Senator, remarks to health leaders seminar, National Conference of State Legislators, Washington, D.C., Dec. 10, 2003.

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

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

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

the MMA from Secretary Thompson for drug importation programs.[37] The MMA, however, may constrain the Secretary's granting such requests.

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 would have a minimal impact on domestic drug prices while opening the borders to potential counterfeit products.[38]

Selected Proposals Under Debate

Before the end of the session, the Congress may consider elements proposed in four pending bills, three in the Senate, one in the House:[39]

- S. 2307, the Reliable Entry for Medicines at Everyday Discounts through Importation with Effective Safeguards (REMEDIES) Act of 2004, introduced by Senator Grassley on April 8, 2004 [the Grassley bill];

- S. 2328, the Pharmaceutical Market Access and Drug Safety Act of 2004, introduced by Senator Dorgan[40] on April 21, 2004 [the Dorgan bill];

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

[38] Tom McGinnis, FDA, comments made Feb. 27, 2004 at a session on the "Reimportation Debate" at the National Medicare Prescription Drug Congress, Washington, D.C., Feb. 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.

[39] CRS General Distribution Memorandum, *Prescription Drug Importation*, May 17, 2004, and CRS General Distribution Memorandum, June 25, 2004, *Senate Prescription Drug Importation Legislation [updated]*, both by Susan Thaul and Donna U. Vogt.

[40] Co-sponsors of S. 2328 at its introduction were Sens. Snowe, Kennedy, McCain, Daschle, Lott, Stabenow, Chafee, Johnson, Pryor, and Feingold; by Aug. 2, 2004, it had 30 co-sponsors.

- S. 2493, the Safe Importation of Medical Products and Other Rx Therapies (IMPORT) Act of 2004, introduced by Senator Gregg[41] on June 2, 2004 [the Gregg bill]; and

- H.R. 2427, the Pharmaceutical Market Access Act of 2003, introduced by Representative Gutknecht on June 11, 2003, and passed by the House on July 21, 2003 [the Gutknecht bill].

All four 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 risk and cost. Throughout the following discussion of issues, this paper will refer 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 to 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

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[41] Co-sponsors of S. 2493 at its introduction were Sens. Smith, Collins, Coleman, Sessions, Lott, and Enzi; by Aug. 2, 2004, Sen. Voinovich also had joined as a co-sponsor.

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."[42]

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 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 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.

The MMA, the Gutknecht bill, and the Gregg bill all require that imported drugs be FDA-approved. The Grassley and Dorgan bills allow different administrative requirements for importation while maintaining that any imported drug must have substantive elements of FDA approval prior to importation. The Grassley bill also

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[42] 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. (Hereafter cited as Taylor, May 20, 2004.)

requires that the imported drug be manufactured in the same facility as the equivalent FDA-approved drug. It allows not only a drug with FDA-approval, but also a drug without it — as long as it has the same active ingredients, dosage strength, and route of administration as an FDA-approved drug; is produced by the same manufacturer; and is approved by the exporting country. The bill provides a procedure for the manufacturer of the FDA-approved drug to petition the Secretary if the manufacturer claims that the foreign version is not bioequivalent (the petitioning manufacturer would then be responsible for FDA's costs in testing that claim).

The Gregg bill requires 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 looked to limit permitted countries to those with regulatory approval systems similar to those in the United States. The bills and current law (MMA) vary in the countries from which they would permit importation. The most inclusive is the Gutknecht bill (H.R. 2427), which incorporates the language in the MEDS Act to permit imports from 25 countries: Australia, Canada, Israel, Japan, New Zealand, South Africa, Switzerland, members of the European Union,[43] and Iceland, Liechtenstein, and Norway. The Grassley bill (S. 2307) differs by excluding Israel and South Africa from that list but allows imports from the other countries three years after enactment. For commercial imports, the Dorgan bill (S. 2328), in addition to excluding Israel and South Africa, also excludes Iceland, Liechtenstein, and Norway, and specifies the 15 European Union countries as of January 2003, thereby excluding the 10 admitted to membership in May 2004. The Dorgan bill, alone, distinguishes between commercial and personal-use imports, allowing only Canada for the latter. The Gregg bill includes Canada and allows the Secretary, three years after enactment, to designate any members of the European Union as of December 2003. Current law, the MMA, subject to the Secretary's certification, includes only Canada, although it allows the Secretary to grant waivers permitting personal-use importation from other countries.

Documenting Chain of Custody. All the legislative proposals have provisions to verify that the drugs are what they say they are. The approaches vary and include registration, testing, monitoring and inspections, packaging and labeling, recordkeeping, and penalties, in varying degrees.

Registration. All three Senate bills 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

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[43] 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, 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.

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 Grassley bill requires that only exporters register while the Dorgan bill would have both exporters and importers register. The Gregg bill requires registration of a drug importation facility, pharmacy, or wholesaler engaged in the importation; it also includes any Internet pharmacy involved in importation. 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 all transactions involving a drug. The MMA 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 Grassley bill (S. 2307) requires the manufacturer to provide a chain-of-custody statement to the exporter. The Dorgan (S. 2328) and Gregg (S. 2493) bills require that chain of custody records be kept for two years. The Gregg bill (S. 2493) also requires 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 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.

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.[44]

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

[44] Taylor, May 20, 2004.

substances.[45] 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 Gutknecht bill (H.R. 2427) reflects the same requirements found in the MMA, and also includes that the importer or manufacturer certify that the drug is FDA-approved and provide laboratory records of authenticity testing if the drugs were not in counterfeit-proof packaging.

The Grassley, Dorgan, and Gregg 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 Grassley and Dorgan 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, 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 bills 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. In the Gregg bill, the Secretary could require owners of Internet pharmacies to permit inspections by the Secretary and could restrict ports of access. This bill also allows 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

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

it comes to imports.[46] 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.[47]

The Gregg bill sets out extensive requirements for licenses, including identification numbers for all Internet pharmacies in the United States, Canada, and permitted countries. It requires that FDA keep an up-to-date list of licensees and make the list available to the public by an Internet website and a toll-free telephone number. The Gregg bill requires a pharmacy to document in its license application its compliance with all federal and state laws and the manufacturing and distribution of controlled substances requirements whether in the United States or a permitted country.[48] In addition, the owner must permit FDA inspections and declare that any agreement of a patient releasing liability for negligence is null and void.

Besides identification requirements similar to those of importers, the Gregg bill (S. 2493) requires Internet pharmacies to maintain patient medication profiles, conduct prospective drug use reviews, ensure patient confidentiality, offer "interactive and meaningful consultation by a licensed pharmacist," establish a mechanism to report errors and possible adverse reactions and verify prescription validity by mail or electronic mail receipt from the treating provider. If the treating provider does not respond within 72 hours or informs the pharmacy that prescription is inaccurate or expired, the Internet pharmacy may not fill the prescription. In addition, the Gregg bill requires the Internet pharmacy to maintain records of direct

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[46] 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.

[47] See CRS Report RS21711, *Legal Issues Related to Prescription Drug Sales on the Internet*, by Jody Feder. Some Members of Congress have introduced bills that would regulate aspects of Internet-selling of prescription drugs (e.g., H.R. 3870 and H.R. 3880).

[48] In addition to the FDA, the Drug Enforcement Agency has regulatory interest in controlled substances; see, for example, U.S. Department of Justice, Drug Enforcement Administration, "Importing Controlled Substances From Canada and Other Foreign Countries," 69 *Federal Register* 38920, June 29, 2004.

communications with treating providers. FDA would establish a fee system based on anticipated costs of enforcing these requirements.

Several other bills have been introduced in the second session of the 108th Congress to ensure the integrity of drugs purchased over the Internet.[49] 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, have announced they will not accept advertising from certain Internet pharmacies.[50] The House Energy and Commerce Committee has asked credit card and courier companies, such as Visa, MasterCard, FedEx, and UPS, to investigate ways to stop illegal marketers from using their services.[51] The only bill that considers this issue directly, the Gregg bill (S. 2493), makes 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 bill requires 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. It also requires 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, it requires FDA to 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

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[49] H.R. 3870 (Prescription Drug Abuse Elimination Act of 2004), introduced by Reps. Norwood and Strickland on Mar. 2, 2004, addresses state prescription drug monitoring program grants, chain-of-custody procedures, and data collection requirements for Internet pharmacies, among other topics. H.R. 3880 (Internet Pharmacy Consumer Protection Act), introduced the next day by Reps. Davis and Waxman, and as S. 2464 by Sen. Coleman, would also regulate the Internet sales of prescription drugs, by requiring the persons dispensing through an Internet site to identify on the webpage each pharmacist and person who provides prescription consultations along with contact information and a list of states in which that person is licensed to practice pharmacy or medicine. Other provisions would require a valid U.S. prescription and would prohibit the sale if the dispenser knew that the prescription was issued without an in-person examination of the patient by the prescribing practitioner. H.R. 4612 (Safe Online Drug Act of 2004), introduced on June 18, 2004 by Reps. Walden and Davis, would create a uniform certification standard for Internet pharmacies, prohibit these pharmacies' selling a prescription drug without a prescription, and prohibit them from accepting links or advertising from an uncertified or illegal Internet pharmacy.

[50] 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*, Dec. 1, 2003, p. A1.

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

pharmacy meets state licensure and registration requirements and follows procedures appropriate for Internet practice.[52]

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.[53]

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.[54] RFID places electromagnetic chips and tags containing a unique serial number onto cartons and individual drug products.[55] FDA is encouraging, not requiring, use of RFID, which in addition to blocking counterfeit drugs could help companies more accurately manage their inventories.[56] Drugmakers are considering whether to adopt the technology, albeit cautiously because of its cost.[57]

Several bills require that medications from overseas come in anti-tampering and anti-counterfeit packaging. The Gutknecht bill (H.R. 2427) includes extensive prescription drug packaging — not only for imports.[58] The Grassley bill (S. 2307)

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[52] 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, Mar. 18, 2004.

[53] 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.

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

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

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

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

[58] H.R. 2427 requires 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

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also states that markings of imported drugs may include anti-counterfeiting or track-and-trace technologies and must be designed to prevent unauthorized affixation. The Dorgan bill (S. 2328) mandates that FDA, during inspections, verify the chain of custody of a statistically significant sample of the drugs that are to 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. The Gregg bill (S. 2493) takes a different tack. It requires 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 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.

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."[59] 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."[60] Furthermore, persons who unknowingly take an ineffective product forgo the opportunity to receive the appropriate treatment.[61]

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[58] (...continued)
must incorporate technologies that enable inspectors to verify the authenticity of the shipment. Two other bills have since been introduced with similar language: S. 1974 (Medicare Preservation and Drug Price Fairness Act), introduced by Sen. Daschle on Nov. 25, 2003, and S. 2137 (Pharmaceutical Market Access Act of 2003), introduced by Sens. Dorgan, Snowe, Stabenow, McCain, and Daschle on Feb. 26, 2004 state that all medications should be packaged and shipped using anti-counterfeit technologies.

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

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

[61] 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
(continued...)

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, are doing it. The pending bills all propose to establish legal channels for drug imports. The MMA requires 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.

Both the Grassley (S. 2307) and Dorgan (S. 2328) 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. The Grassley bill further specifies that a statement must accompany the drug that gives sufficient information to determine whether the prescription meets those regulations, including the prescriber's licensure; and the documentation required by the exporting country to dispense a drug. All prescriptions must be marked to indicate they have been filled to prevent duplicative filling by another pharmacist. The Dorgan bill allows personal-use imports from Canada alone, whereas the Grassley bill would allow these drug imports from permitted countries.[62] The Gregg bill (S. 2493) also allows 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 bill adds 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 is the only one that mentions "compassionate use," permitting an individual

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[61] (...continued)
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.

[62] The Grassley bill (S. 2307) provides for two additional personal import circumstances: an individual returning to the United States with up to a 30-day supply of a U.S.-dispensed prescription drug that the individual brought to the foreign country; and an individual entering the United States with up to 10 days remaining in the course of treatment begun with a prescription drug that was purchased in the foreign country where it was approved for commercial distribution.

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.

The House Appropriations Committee included in its report on the FY2005 USDA/FDA appropriations bill an amendment that would bar FDA from using its appropriated funds to enforce the prohibition on importing drugs for personal use.

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 product and information from both exporters and importers. HHS would need to develop two sets of oversight activities. 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.

In March 2004, one FDA official, speaking at a congressional hearing, 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.[63] 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."[64] According to one FDA official, the cost of a program could be much greater than anticipated. He contends that FDA 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.[65]

FDA uses appropriated funding to inspect and monitor imports. Under the Gutknecht bill, normal appropriations would continue to be the only funding

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[63] "$58 million for Canadian Rx Reimportation Based on Outdated Estimate," *Inside Washington's FDA Week*, Mar. 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, Mar. 11, 2004; and John Wilkerson and Veena Menon, "Crawford Says Drug Importation Program Would Cost $58 Million," *InsideHealthPolicy.com Daily Updates*, Mar. 11, 2004).

[64] 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]).

[65] "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.

mechanism.[66] Alternative funding options to cover inspection, recordkeeping, and quality control costs include fees charged to the exporter and the importer. The Grassley bill (S. 2307) calls for exporter fees that, in the aggregate, would cover the cost of administering the import provisions. The manufacturer would, through semi-annual fees similar to those established for supplemental applications under the Prescription Drug User Fee Act (PDUFA, P.L. 102-571), pay the expense of the Secretary's review.[67] The Dorgan bill (S. 2328) requires that an importer pay a $10,000 fee along with the submission of the registration application. In addition, a required semi-annual fee would be based on the share of volume of imports and adjusted annually so it does not exceed 1% of the price of drug imports. 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.[68] Under the Gregg bill (S. 2493), FDA would require a $5,000 initial fee and an annual fee from a drug importation facility, pharmacy, Internet pharmacy, or wholesaler and only once for each facility. The amount of the annual fee would be based on anticipated costs of enforcing this act, would be published in advance, and only after a public meeting was held to provide time for public comment, would the fee be published. FDA would then use the collected fees, without further appropriation, to enforce the act.

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. 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. Already several companies reportedly have begun to manipulate the supply of drugs particularly to Canada to circumvent the purpose of any legislation.[69] In early June 2004, the Minnesota Seniors Foundation filed a class

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[66] U.S. FDA, Office of Budget and Program Analysis, Budget Formulation and Presentation Division, Feb. 2004. FDA's drug center is asking for very small budget increase ($519 thousand or less than 0.2% increase) for FY2005: $294.7 million, up from FY2004 enacted appropriations of $295.2 million.

[67] 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. The Secretary may use these fees only for these costs.

[68] "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].

[69] John E. Calfee, "The High Price of Cheap Drugs: the House Is Tempted by a Terrible (continued...)

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.[70] 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.[71] 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.[72] 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 Dorgan bill restricts 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.[73] To ensure that the Canadian drug supply is not overwhelmed by U.S. consumer demand, the Gregg bill would allow Canadian pharmacies to transship drugs from other permitted EU nations to supply U.S. consumers.[74] However, according to the Canadian International Pharmacy Association, it is illegal for any entity to transship drugs in finished dosage form from a foreign country into Canada even if it is designated for export only.[75] The Gregg bill also permits the Secretary to decide after three years that supplies are the hindering factor for imports, and to permit drug imports from the 15-member European Union three-years after enactment.

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[69] (...continued)
Idea," The Weekly Standard, July 21, 2003; and "Drug Dealing," editorial in The Washington Post, July 24, 2003, p. A20.

[70] "Minnesota Seniors File Suit Against Nine Drugmakers," *FDAnews Drug Daily Bulletin*, June 4, 2004 at [FDAnews@newsletters.fdanews.com].

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

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

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

[74] "Gregg Drug Import Bill Wouldn't Punish Firms That Try to Curb Imports," *InsideHealthPolicy.com*, June 3, 2004.

[75] "Canadian Pharmacy Group Says Transshipment Illegal in Canada," *Inside Washington's FDA Week*, vol. 10, no. 23, June 4, 2004, p. 9. Canadian laws prohibit the export of non-Canadian approved drugs. The exception applies to drugs made in Canada solely for export. Neither pharmacists nor individuals can use the exception to export drugs.

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 pharmacies and that the Gregg bill would not. AARP has, therefore, come out with strong support for the Dorgan bill.[76]

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 Dorgan bill (S. 2328) seeks to minimize that behavior making it unlawful to:

> cause there to be a difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and a prescription drug for distribution in Australia, Canada, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland for the purpose of restricting importation of the drug to the United States. ...

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."[77] The Grassley bill (S. 2307) provides a research and development tax incentive.

Influencing Behavior with Rewards and Penalties. Implementation of the MMA is restricted by the requirement that the Secretary certify safety and cost savings. Some criticisms of the MMA and the Gutknecht bill — despite the latter's elimination of the certification requirement — anticipate manufacturer resistance.

To influence drug industry behavior, the Grassley bill (S. 2307) includes tax incentives to encourage manufacturer compliance and penalties to minimize manufacturer interference. It would allow no tax deduction for advertising

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[76] "AARP Backs Prescription Drug Import Legislation," at [http://www.aarp.org/legislative/prescriptiondrugs/rxprices/watchdog/Articles/a2004-06-29-importlegislation.html].

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

expenses[78] unless the drug manufacturer certified that it would not take any action, direct or indirect, to prevent drug importation, in which case the manufacturer would receive a 20% increase in its research and development tax credit. The Dorgan bill (S. 2328) would prevent the blocking of imports by declaring such actions a restraint of trade under the federal antitrust law. It also would compel manufacturer participation and would amend patent law to remove obstacles to importation. The Gregg bill (S. 2493) has no specific incentives (positive or negative) for industry.

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[79] and international trade agreements[80] are 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.[81]

On July 16, 2004, both houses of Congress passed legislation implementing 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

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[78] In 2000, the drug industry deducted a total of $10.3 billion in advertising expenses on its taxes (Internal Revenue Service, Statistics of Income Division, *2000 Corporation Source Book*, Publication No. 1053, Washington, D.C., 2003, p. 69); this figure indicates the potential impact of this action.

[79] CRS experts in foreign trade and law have produced reports relevant to this discussion. See, for example, CRS Report RL32400, *Patents and Drug Importation*, by John R. Thomas; 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 Issue Brief IB10105, *The Hatch-Waxman Act: Legislative Changes Affecting Pharmaceutical Patents*, by Wendy H. Schacht and John R. Thomas.

[80] 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.

[81] An Aug. 2003 World Trade Organization (WTO) General Council agreement 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 are expected to limit production of these generic drugs to amounts needed for public health dangers such as HIV/AIDS, malaria, and tuberculosis, and not use the opportunity for commercial ventures (*WTO News*, "Decision Removes Final Patent Obstacle to Cheap Drug Imports," press release 350, Aug. 30, 2003 at [http://www.wto.org/english/news_e/pres03_e/pr350_e.htm]). See also CRS Report RS21609, *The WTO, Intellectual Property Rights, and the Access to Medicines Controversy*, by Ian F. Fergusson.

source of supply of drugs and possibly setting a precedent for other international free trade agreements.[82]

Australia is listed as a "permitted country" in three of the four import bills discussed in this paper. 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.[83] If pharmaceutical companies contractually or otherwise 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 Dorgan bill (S. 2328) prohibits such behavior.

Concerns have been raised that such a prohibition would cut off the supply of some prescription drugs just as Congress is about to vote on whether to authorize a drug import program.[84] 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 90-95% of Australian drug purchases).[85] 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.[86]

A recent Congressional Budget Office (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

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[82] CRS Report RL32375, *The Proposed U.S.-Australia Free Trade Agreement: Provisions and Implications*, by William Cooper.

[83] The U.S. free trade agreements with Morocco and Singapore have similar provisions.

[84] 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," Sen. Grassley charged, in Feb. 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*, Feb. 10, 2004).

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

[86] John Wilkerson, "Reimportation Ban in Australia Pact Could Affect Domestic Policy," *Inside Health Policy*, Feb. 10, 2004 at [http://insidehealthpolicy.com].

elsewhere.[87] 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.[88] 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.[89] Consequently, unless legislative proposals to import drugs address this patent issue, implementing them might be difficult.[90]

The Dorgan bill (S. 2328) does 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 bill's 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 the Dorgan bill would deny these companies recourse to the courts if drug imports were made legal.[91] The Gregg bill (S. 2493) would not penalize pharmaceutical companies for discriminating against foreign pharmacies who export drugs to U.S. consumers. The Grassley bill (S. 2307) provides tax incentives for U.S. patent owners to not sue for import infringement.

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 do more than 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

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

[88] 264 F.3d 1094 (Fed. Cir. 2001).

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

[90] See CRS Report RL32400, *Patents and Drug Importation*, by John R. Thomas.

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

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.[92] 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.[93] 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).[94]

Others estimate significant savings to U.S. consumers. Using the CBO estimate that Americans over age 65 will spend $1.8 trillion on prescription drugs over the next 10 years, Representative Gutknecht estimates a 10-year savings of $630 billion (35%) by importing drugs.[95] Other estimates include Americans' saving $59.7 billion if, during 2004, they purchased all brand-name drugs at Canadian prices.[96]

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

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

[93] 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., Feb. 27, 2004 (available from CRS).

[94] CBO, Apr. 29, 2004.

[95] Rep. Gutknecht includes this estimate in material on his website at [http://www.gil.house.gov/newsroom/statements/stateOCT/102803pd.htm].

[96] Alan Sager and Deborah Socolar, "Do Drug Makers Lose Money On Canadian Imports?" *Data Brief No. 6*, Boston University School of Public Health, Apr. 15, 2004 at [http://www.bumc.bu.edu/www/sph/hs/images/health_reform/Canadian_importing_break-even_14_Apr%2004_FINAL.pdf].

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.[97] 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.[98]

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 MMA includes a new outpatient prescription drug benefit for Medicare beneficiaries, effective January 1, 2006. What impact it will have on costs for the elderly is uncertain; for many elderly it will provide coverage they have not had.

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

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[97] Sager and Socolar, 2004.

[98] Danzon and Furukawa, 2003.

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 paper.

Appendix 1. 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.[99] 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.[100]

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.[101] On November 18, 2003, the United States

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[99] 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 Mar. 5, 2004.

[100] 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, Feb. 12, 2004.

[101] 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," Dec. 24, 2003 at [http://www.phycybrd.state.mn.us/canada_memo.pdf], visited Mar. 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, Jan. 6-7, 2004 meeting at [http://www.phcybrd.state.mn.us/minutes/2004/jan.pdf], visited Mar. 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

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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.[102]

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.[103] 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.[104]

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.[105] The co-signing has been denounced by provincial and territorial licensing bodies.[106] It also is illegal, according to Canadian

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[101] (...continued)
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).

[102] "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," Nov. 18, 2003 at [http://www.fda.gov/oia/agreements/HCFDAMOU111803.pdf].

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

[104] 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*, Feb. 21, 2003, p. A1; Bernard Simon, "Pressure on Canada's Online Drug Sellers," *The New York Times*, Dec. 10, 2003, p. W1; and "Health Canada says it cannot ban sale of Rx drugs to U.S. consumers," *InsideHealthPolicy.com*, May 6, 2004..

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

[106] Marc Kaufman and Gilberg Gaul, "Canadian Group Seeks Drug Export Ban," *The Washington Post*, Nov. 15, 2003, p. A6; The Nova Scotia College of Pharmacists, "Council (continued...)

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.[107]

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.[108] 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 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.

Some analysts estimate the Canadian share of the prescription drug market at $15.9 billion, a small amount — 7.3% — relative to the $216.4 billion spent in U.S. retail pharmacies.[109]

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[106] (...continued)
Position Statement [on] Internet/Mail-Order Pharmacy Services: International Prescription Industry," updated Dec. 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 Apr. 19, 2004; "Position Statement on Cross-Border Prescription Drug Trade," Canadian Pharmacists Association, Feb. 2004.

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

[108] Gross, 2003.

[109] John Carey, "A Cheap Fix? Not Really," *Business Week*, May 3, 2004.

Appendix 2. Proposed State Laws or Resolutions in 2004 Regarding Importation of Prescription Drugs

State	Content of Proposal
AZ	• Non-binding resolution to urge the HHS Secretary to certify the safety of Canadian drugs for importation [did not pass].
CA	• To require the state pharmacy board to develop a website with drug prices to include those of certified Canadian pharmacies that provide mail order service [did not pass]; • Non-binding resolution to request HHS Secretary to implement the Medicare Act provisions on imports [in committee]; • To require the Board of Pharmacy to collect and publish information concerning suppliers of dangerous drugs that are located and operating outside of the United States that have violated safe shipment, handling, and processing standards [amended in committee]; • To allow the state General Services Department to purchase Canadian drugs for state hospitals and prisons [in committee]; • To allow reimbursement by Department of Health Services for Medi-Cal and AIDS drug assistance for prescription drugs from Canada [to committee].
CT	• To require the Commissioner of Social Services to establish a procedure so that ConnPACE participants can obtain drugs from Canadian pharmacies and waive copayments [Public Act 04-101 signed by Governor].
DC	• To provide that the Department of Health investigate purchases of prescription drugs from outside the U.S. [Act 15-410 signed by Mayor; requires ratification by the U.S. Congress].
FL	• To allow for purchase of Canadian drugs if federally approved [died in committee].
HI	• Non-binding resolutions to urge support for federal legislation authorizing the importation of prescription drugs [2 of 3 passed and were sent to Congress]; • To direct the Governor and agencies to maintain a website to assist Hawaii residents in purchasing Canadian drugs [died at session end]; • To allow prisons to purchase maintenance prescription drugs from Canada for inmates [died at session end]; • To authorize rebate negotiation and purchase from Canadian pharmacies for non-Medicaid-eligible and government program beneficiaries [died at session end].
ID	• Non-binding resolution to urge Congress to adopt legislation to allow U.S. citizens and state and local government entities to legally purchase drugs from Canada [did not pass by session end].

State	Content of Proposal
IL	• To require the public health department to implement a certification program for the foreign drugs, if the state allows state employees or retirees to buy drugs from a pharmacist or distributor outside the United States [to committee]; • Non-binding resolution to urge Congress to pass legislation allowing purchase of drugs in Canada [to committee]; • To require the Senior Health Assistance Program Clearinghouse to provide information concerning the purchase of prescription drugs from sources outside Illinois [to committee]; • To expand the definition of "mail-order pharmacy" and registration requirements to include pharmacies located outside of the U.S., including Canada [to committee].
LA	• To create a crime of illegal importation of prescription drugs [to committee].
MD	• To require the state to implement a Canadian Mail Order Plan for prescription drugs; to require the Plan to provide prescription drugs to specified participants; to authorize the state to include enrollees and recipients of other state prescription drug programs in the Plan [no agreement between branches, died].
MA	• To provide for a state website and an Office of Pharmaceutical Information to assist residents with purchasing prescription drugs from Canada; and to establish a voluntary program to allow state employees and retirees and MassHealth and RxAdvantage enrollees to purchase prescription drugs from licensed Canadian pharmacies approved by the state [Senate passed].
MN	• To require the commissioner of human services to implement a program to obtain discounted drugs through Canadian pharmacies; to establish a website for ordering drugs; to provide access to drugs through state and local employee health plans, state health care programs, health plan companies, and other Minnesota residents [to committee]; • To allow the state to negotiate with state-approved Canadian pharmacies or wholesalers the prices to be charged to Minnesota residents who purchase their Canadian drugs within the state's drug import program [to committee]; • To authorize purchase of drugs from foreign nations for county jail inmates as part of any state agency purchase initiative [to committee].
MO	• Non-binding resolution to urge the President to lift the ban on Canadian pharmaceuticals [did not pass by session end].
NH	• To authorize the state commissioner of administrative services to establish a program to import drugs from Canada [went to conference committee; did not pass].
NY	• To authorize licensed distributors to purchase and distribute drugs purchased from international drug companies [held in committee].

State	Content of Proposal
PA	• Non-binding resolution to urge governor to request that GlaxoSmithKline end efforts to keep PA residents from purchasing pharmaceuticals from Canadian retailers [carried over from 2003]; • Non-binding resolution to request Congress to enact legislation to lift barriers that prevent drug imports from Canada [in committee].
RI	• To allow certain Canadian pharmacies to obtain a license to dispense prescriptions in the state [did not pass by session end]; • To allow licensed Canadian pharmacies to get a RI Dept. of Health license to do business in RI; to allow RI Board of Pharmacy to exercise its authority in the event of misconduct [became law without Governor's signature].
TN	• To require the governor and state insurance committee to request federal approval for drug imports from Canada with protections to insure the import of only quality drugs [did not pass by session end]; • Non-binding resolution to urge the HHS Secretary to *stop* the sale and importation of prescription drugs over the Internet [did not pass by session end].
VT	• To direct the state to establish a program to provide for and facilitate the purchase of prescription drugs from Canada [did not pass by session end]; • To require that the state establish a program with a website and written information to describe how VT residents are able to purchase prescription drugs from Canada, including information about ordering through the mail or otherwise from a participating Canadian pharmacy [Act 122 (appropriations) signed by governor]; • To direct the Dept. of Prevention, Assistance, Transition, and Health Access to establish a program to publicize and facilitate the purchase of prescription drugs from Canada by providing information to consumers [did not pass by session end]; • To specify that any health insurer shall cover prescription drugs purchased outside this country on the same terms as drugs purchased in this country [did not pass by session end]; • Non-binding resolution to urge governor to establish a drug reimportation program for the state [passed].
VA	• Non-binding resolution to request Congress to remove restrictions on drug purchases from Canada [carried over to 2005]; • To evaluate and implement a process for purchasing reduced cost drugs from Canada for state employees' health benefits program [did not pass committee].
WA	• To authorize certain state agencies to purchase prescription drugs from Canadian wholesalers and pharmacies; to create a website regarding opportunities to purchase prescription drugs from Canada and the best means to ensure that they are safely manufactured. House version added that state agencies should not implement this for bulk purchasing until federal statutory or regulatory action is taken to authorize such purchasing [did not pass by session end].

State	Content of Proposal
WV	• To explore the feasibility of using or referencing Canadian pricing and for the state to serve as wholesale distributor of prescription drugs purchased in Canada [the West Virginia Pharmaceutical Availability Act signed into law by governor].
WI	• Non-binding resolution to urge Congress to enact legislation allowing individuals and pharmacies to import prescription medicines purchased in other countries that have regulatory safeguards for the manufacture and distribution of drugs comparable to the United States [failed]; • Non-binding resolution to urge Congress and the administration to create a safe and legitimate program for prescription drug importation or through negotiated trade agreements with other nations [Senate adopted].

Source: "2004 Prescription Drug State Legislation," Health Program, National Conference of State Legislatures, updated July 9, 2004 at [http://www.ncsl.org/programs/health/drugdisc04.htm].