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Prescription Drug Importation and Internet Sales: A Legal Overview

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Summary

High prescription drug prices have increased consumer interest in purchasing less costly medications abroad. Policymakers opposed to allowing prescription drugs to be imported from foreign countries argue that the Food and Drug Administration (FDA) cannot guarantee the safety of such drugs. Importation proponents, who claim that importation would result in significantly lower prices for U.S. consumers, say that safety concerns are overblown and would recede if additional precautions were implemented. The debate about drug importation continues.

Just as the FDA has expressed concerns about the safety of imported drugs, federal regulators have become increasingly worried about the risks posed by some online pharmacies and Internet drug sales. The regulation of prescription drug importation and the oversight of online pharmacies often overlap because many consumers use online pharmacies to purchase imported drugs. Regardless of whether or not drugs purchased online are imported, the FDA is worried about the safety of such medications because of its concern that a small number of online doctors and pharmacies are exploiting regulatory gaps to prescribe and dispense illegal, addictive, or unsafe drugs.

In response to concerns about prescription drug imports and Internet sales, lawmakers introduced multiple bills in previous Congresses. The 109th Congress approved a provision in the appropriations bill for the Department of Homeland Security which prohibited the U.S. Customs and Border Protection (CBP) from using funds to prevent individuals from transporting on their person a 90-day supply of Canadian prescription drugs that comply with the Federal Food, Drug, and Cosmetics Act (FDCA). Bills introduced in the 110th Congress include H.R. 194, H.R. 380, S. 242, and S. 251.

The following federal and state agencies are involved in regulating aspects of prescription drug importation and Internet sales: the FDA, CBP, the Drug Enforcement Agency (DEA), state boards of pharmacy, and state medical boards. This report focuses on legal aspects of prescription drug importation and Internet sales, including antitrust law, international trade law, and patent law issues. However, policy issues are also addressed because they are closely linked. For a more complete analysis of policy issues, see CRS Report RL32511, *Importing Prescription Drugs: Objectives, Options, and Outlook*, by Susan Thaul.

Contents

I. Introduction 1

II. Prescription Drug Importation: Legal Regulation 4
- Importation of U.S.-Manufactured Prescription Drugs 5
- Importation of Foreign Versions of Prescription Drugs 7
- Canadian Prescription Drug Importation After the FY2007 Homeland Security Appropriations Bill 8
- Penalties Under the FDCA and Other Federal Laws 11
- The FDA's Personal Importation Procedures 13
- State and Local Importation of Prescription Drugs: Violation of Federal Law? 15
- Businesses That Facilitate Importation of Prescription Drugs 20
- Antitrust Laws 23
  - Federal Antitrust Law 24
  - State Antitrust Law 29
- International Trade Law 31
  - General Agreement on Tariffs and Trade 31
  - WTO Agreement on Technical Barriers to Trade 34
  - General Agreement on Trade in Services 36
- Patent Law 38

III. Internet Pharmacies 39
- Federal Oversight 40
- State Oversight 43

IV. Conclusion 45

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Prescription Drug Importation and Internet Sales: A Legal Overview

This report explores the legal issues raised by prescription drug importation and Internet sales. Although this report is intended to focus on legal analysis, policy issues are also addressed because they are closely linked. For a more complete analysis of policy issues, see CRS Report RL32511, *Importing Prescription Drugs: Objectives, Options, and Outlook*, by Susan Thaul.

I. Introduction

In general, there are two types of prescription drug imports: commercial imports by wholesalers and pharmacists, and personal imports by consumers. High prescription drug prices have increased consumer interest in purchasing less costly medications abroad by means of either commercial or personal imports.[1] Meanwhile, congressional legislators have been exploring a variety of legislative solutions to the problems posed by rising drug costs. The 109th Congress approved a provision in the appropriations bill for the Department of Homeland Security which prohibited the U.S. Customs and Border Protection (CBP) from using funds to prevent individuals from transporting on their person a 90-day supply of Canadian prescription drugs that comply with the Federal Food, Drug, and Cosmetics Act (FDCA).[2] However, few, if any, prescription drugs from Canada will comply with the requirements of the FDCA because such drugs are likely to be unapproved, mislabeled, or improperly dispensed. During the 108th Congress, the Medicare prescription drug benefits bill, H.R. 1, modified a provision of existing law that authorizes the Food and Drug Administration (FDA) to allow the importation of prescription drugs if the Secretary of Health and Human Services (HHS) certifies that implementing such a program is safe and reduces costs, a determination that no

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[1] A recent study by the senior citizens' lobby AARP noted that prices rose 6.3 percent from June 2005 to June 2006 for 193 brand-name prescription drugs commonly prescribed for senior citizens. Prices of generic drugs rose 0.4 percent. Inside Washington Publishers, *AARP Cites Rx Drug Price Hikes to Lobby for Reimportation Legislation*, FDA WEEK, Sept. 22, 2006. However, others note that particular drugs may not necessarily cost more than before, as clinicians may have substituted more expensive drugs, though these drugs are not necessarily more effective. Spending on prescription drugs may have increased because clinicians are writing more prescriptions as well.

[2] P.L. 109-295, § 535. The provision excludes narcotics, biologics, internet sales, and importations of Canadian prescription drugs by mail order. Inside Washington Publishers, *Conferees Strike Deal to Allow Personal Rx Importation*, FDA WEEK, Sept. 29, 2006.

Secretary has made in the years since a similar certification requirement was established in 2000.[3]

Despite the fact that the provision in the Department of Homeland Security appropriations bill and the final Medicare bill did not change the law with respect to the prohibition against importing prescription drugs from Canada and other foreign countries, the debate about drug importation continues. On the one hand, some policymakers remain opposed to allowing prescription drugs to be imported from foreign countries. Worried about the risk to consumers, these critics argue that, with its current resources and authority, the FDA cannot guarantee the safety of such drugs,[4] which they contend are more susceptible to being mishandled, mislabeled, unapproved, or counterfeited than drugs sold domestically. In addition, drug manufacturers and other opponents argue that allowing the importation of prescription drugs would stifle investment in the research and development of new drugs.[5] On the other hand, importation proponents, who claim that importation would result in an increased supply of prescription drugs that could result in significantly lower prices for U.S. consumers, say that safety concerns are overblown and would recede if additional precautions were implemented. Arguing that drug manufacturers are concerned only about their profits, proponents of importation contend that U.S. consumers should not subsidize the cost of research and development and that consumers in other countries should share the burden.[6]

Linked to the issue of prescription drug importation is a debate about drug costs.[7] While some comparisons of U.S. and Canadian drug prices conclude that U.S. prices are higher than their Canadian counterparts, other studies do not find such discrepancies. In part, studies may vary depending on which drugs are selected for

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[3] Medicare Modernization Act (MMA), P.L. 108-173 [hereinafter Medicare Act]. The original certification provision was contained in the Medicine Equity and Drug Safety (MEDS) Act. P.L. 106-387. The new Medicare Act also requires HHS to conduct a study and issue a report on importing prescription drugs.

[4] The Canadian government has also stated that it cannot guarantee the safety of drugs exported to the U.S. from Canada. Marc Kaufman, *Canadian Drug Position Misinterpreted*, WASH. POST, May 26, 2003, at A11.

[5] Marc Kaufman, *FDA's Authority Tested Over Drug Imports*, WASH. POST, Nov. 9, 2003, at A11.

[6] *Id.*

[7] For a discussion of the debate about drug costs and prices, see CRS Report RL32511, *Importing Prescription Drugs: Objectives, Options, and Outlook*, by Susan Thaul; CRS Report RL33782, Federal Drug Price Negotiation: Implications for Medicare Part D, by Jim Hahn; CRS Report RL33781, *Pharmaceutical Costs: An International Comparison of Government Policies*, by Gretchen A. Jacobson; CRS Report RL33802, *Pharmaceutical Costs: A Comparison of Department of Veterans Affairs (VA), Medicaid, and Medicare Policies*, by Gretchen A. Jacobson, Sidath Viranga Panangala, and Jean Hearne. *See also* Congressional Budget Office, Prescription Drug Pricing in the Private Sector, Jan. 2007 [http://www.cbo.gov/ftpdocs/77xx/doc7715/01-03-PrescriptionDrug.pdf].

comparison and whether or not U.S. generic drugs, which tend to be cheaper than Canadian brand-name and generic drugs, are considered.[8]

In addition, there is an unresolved debate about whether allowing drug imports would affect drug prices. Supporters argue that drug prices would drop due to competition if imports were allowed, while opponents argue that increased demand for imported drugs and moves by manufacturers to limit supplies of cheaper drugs would cause prices to rise both in the U.S. and abroad and would increase the risk of counterfeit drugs being introduced into the system.[9] Indeed, according to a study by the Congressional Budget Office (CBO), "the reduction in drug spending from importation would be small," in part because of new costs associated with ensuring the safety of imported drugs and because of the likelihood that manufacturers would alter drug formulations or reduce foreign supplies.[10] Furthermore, there are questions about how much it would cost to implement a safe drug importation program. The FDA estimates that such a program would cost at least $100 million but that the figure could rise as high as several hundred million dollars, especially if there is an increase in the volume of imported drugs.[11]

Just as the FDA has expressed concerns about the safety of imported drugs, federal regulators have become increasingly worried about the risks posed by some online pharmacies and prescription drug sales over the Internet.[12] Indeed, the regulation of prescription drug importation and the oversight of online pharmacies often overlap because many consumers use online pharmacies to purchase imported drugs. Regardless of whether or not drugs purchased online are imported, the FDA is worried about the safety and quality of such medications because of its concern about the lack of adequate physician supervision, the prospects for tampering with or counterfeiting such drugs, and the possibility that such drugs may be handled, dispensed, packaged, or shipped incorrectly.[13]

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[8] HHS Task Force on Drug Importation, Health and Human Services, *Report on Prescription Drug Importation*, Dec. 2004, at 65 [http://www.hhs.gov/importtaskforce/Report1220.pdf].

[9] Gardiner Harris, *The Nation: Prescriptions Filled; If Americans Want to Pay Less for Drugs, They Will*, N.Y. TIMES, Nov. 16, 2003, § 4, at 4.

[10] Congressional Budget Office, *Would Prescription Drug Importation Reduce U.S. Drug Spending?*, Economic and Budget Issue Brief, April 29, 2004. The HHS Task Force on Drug Importation found that "total savings to consumers from legalized importation under a commercial system would be a small percentage relative to total drug spending the U.S. (about one to two percent." HHS Task Force on Drug Importation, *supra* note 8, at 65.

[11] Inside Washington Publishers, *$58 Million for Canadian Rx Importation Based on Outdated Estimate*, FDA WEEK, March 19, 2004.

[12] Some of these concerns are reflected in a report by the Government Accountability Office (GAO; formerly the General Accounting Office). GAO Report GAO-04-820, *Internet Pharmacies: Some Pose Safety Risks for Consumers*.

[13] FOOD AND DRUG ADMINISTRATION, *Buying Medicines and Medical Products Online*, [http://www.fda.gov/oc/buyonline/default.htm].

In response to concerns about prescription drug imports and Internet sales, a number of congressional legislators have introduced bills that would make changes to existing law in these areas. Bills introduced in the 110th Congress include H.R. 194, H.R. 380, S. 242, and S. 251.

Current regulation of prescription drug importation and Internet sales consists of a patchwork of federal and state laws in an array of areas.[14] At the federal level, the FDA regulates prescription drugs under the FDCA, which governs, among other things, the safety and efficacy of prescription medications, including the approval, manufacturing, and distribution of such drugs.[15] It is the FDCA that prohibits the importation — sometimes referred to as "reimportation"[16] — of certain prescription drugs by anyone other than the manufacturer and that requires that prescription drugs may be dispensed only with a valid prescription.[17] After a recent change in enforcement policy by CBP, the FDA assumed the primary responsibility for determining whether foreign drug imports may legally enter the country.[18] In addition, the Drug Enforcement Agency (DEA) administers the Controlled Substances Act, which is a federal statute that establishes criminal and civil sanctions for the unlawful possession, manufacturing, or distribution of certain addictive or dangerous substances, including certain prescription drugs that share these properties, such as narcotics and opiates.[19] At the state level, state boards of pharmacy regulate pharmacy practice, and state medical boards oversee the practice of medicine. Thus, some of the laws that govern online pharmacies and doctors vary from state to state.

Finally, although foreign laws are beyond the scope of this report, it is important to note that such laws may also affect the importation of drugs from those countries.

II. Prescription Drug Importation: Legal Regulation

At the federal level, the FDA regulates prescription drugs under the Federal Food, Drug, and Cosmetic Act (FDCA), which governs, among other things, the safety and efficacy of prescription medications, including the approval,

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[14] For other information on prescription drug importation and Internet sales, *see* CRS Report RL32511, *Importing Prescription Drugs: Objectives, Options, and Outlook*, by Susan Thaul; 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 GAO Report GAO-01-69, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight*.

[15] 21 U.S.C. § 301 et seq.

[16] "Reimportation" is a term that is commonly used to describe importation. The term "importation" is used throughout this report.

[17] 21 U.S.C. § 353(b).

[18] *See* Canadian Prescription Drug Importation After the FY2007 Homeland Security Appropriations Bill, *infra* at 8.

[19] *Id*. at § 801 et seq. For more information on the Controlled Substances Act, see CRS Report 97-141A, *Drug Smuggling, Drug Dealing and Drug Abuse: Background and Overview of the Sanctions Under the Federal Controlled Substances Act and Related Statutes*, by Charles Doyle.

manufacturing, and distribution of such drugs.[20] Although many states also have their own laws that regulate drug safety, the FDA maintains primary responsibility for the premarket approval of prescription drugs, while the DEA and CBP have somewhat more limited regulatory authority over such drugs.

The FDCA contains several provisions that apply to prescription drug imports. First, the statute contains an outright prohibition that forbids anyone other than the U.S. manufacturer from importing prescription drugs. This prohibition affects only drugs that originally are made in the U.S. Second, the FDCA contains a number of other provisions relating to drug approvals and labeling that make it nearly impossible for prescription drugs made for foreign markets to comply with the extensive statutory requirements, in part because the FDA considers any drugs not made on an FDA-inspected production line to be unapproved and therefore illegal. These provisions generally affect foreign versions of drugs that are approved for domestic sale.

Importation of both U.S.-manufactured prescription drugs and unapproved foreign versions of U.S.-approved prescription drugs are discussed in this next section, as are the recent change in CBP policy with regard to seizure of mail order prescription drugs, the penalties under the FDCA, the FDA's personal importation procedures, state plans to import prescription drugs, and businesses that facilitate the importation of prescription drugs. In addition, this section contains a discussion of other legal areas that may affect prescription drug importation, including antitrust law, trade law, and patent law.

Importation of U.S.-Manufactured Prescription Drugs

Currently, the FDCA prohibits anyone other than the U.S. manufacturer of a prescription drug from importing that drug into the United States.[21] Thus, it is technically a violation of the statute for individual consumers or online pharmacies to import a prescription drug back into the country, even though the drug was, prior to export, originally manufactured in the U.S. and even if the drug otherwise complies with the FDCA.[22] Although critics of this law argue that there is no rational justification for forbidding the importation of a drug that is theoretically identical to

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[20] 21 U.S.C. § 301 et seq.

[21] *Id.* at § 381(d)(1). The Secretary, however, is authorized to allow the importation of any drugs that are required for emergency medical care. *Id.* at § 381(d)(2).

[22] Under the FDA's personal importation procedures, however, the FDA currently allows border staff to exercise discretion in implementing the prohibition against individuals who import a limited supply of prescription drugs for personal use. *See infra* notes 74-84 and accompanying text. The CBP previously enforced importation laws in the same general manner as the FDA's personal importation procedures, then increased enforcement for an almost eleven-month period. *See infra* notes 45-62 and accompanying text. However, due to a recent change in enforcement policy after the passage of a provision in the FY2007 Department of Homeland Security appropriations act, the CBP will now "focus on intercepting only counterfeit medicines, narcotics, and illegal drugs." Christopher Lee, *U.S. to Stop Seizing Prescription Drugs Imported for Personal Use*, WASH. POST, Oct. 5, 2006, A16.

its counterpart sold in the U.S., the FDA contends that the agency can no longer guarantee the safety of a prescription drug once it has left the country and the agency's regulatory control. According to the agency, the FDA "cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by the FDA."[23]

In response to concerns about the rising costs of prescription drugs, however, Congress adopted importation amendments to the FDCA in 2000. Under the Medicine Equity and Drug Safety (MEDS) Act,[24] the FDA was authorized to allow pharmacists and wholesalers to import prescription drugs from foreign countries if certain safety precautions were followed.[25] The act, however, stipulated that the importation provision would not become effective until and unless the Secretary of HHS determined that the implementation of the provision would "pose no additional risk to the public's health and safety; and [would] result in a significant reduction in the cost of covered products to the American consumer."[26] Citing safety concerns, both the current and the former Secretaries declined to implement this provision.

In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (hereinafter referred to as the Medicare Act),[27] Congress revisited the issue of prescription drug importation. Like the MEDS Act it superseded, the Medicare legislation directs the FDA to allow pharmacists and wholesalers to import prescription drugs if certain safety precautions are followed.[28] Unlike the MEDS Act, which covered prescription drugs from a specified group of foreign countries, the Medicare Act allows imports from Canada only.[29] In addition, the Medicare Act, unlike the MEDS Act, also authorizes the FDA to allow, by regulatory waiver, individuals to import prescription drugs for personal use under certain circumstances.[30] Despite these new importation provisions, the Medicare Act, like the MEDS Act, stipulates that the importation provisions will not become effective until and unless the Secretary certifies that the implementation of the provision would

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[23] Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, Food and Drug Administration, to Robert P. Lombardi, Esq., The Kullman Firm 1 (Feb. 12, 2003), [http://www.fda.gov/ora/import/kullman.pdf] [hereinafter Lombardi Letter].

[24] P.L. 106-387.

[25] 21 U.S.C. § 384.

[26] *Id.* at § 384(l).

[27] Medicare Act, *supra* note 3.

[28] The Medicare Act also required the Secretary to conduct a study on the importation of drugs. This study, which was released in December 2004, concluded that legalizing drug importation would be likely to result in increased risk to consumers and would not significantly reduce retail drug prices. Department of Health and Human Services, Report on Prescription Drug Importation (December 2004), [http://www.hhs.gov/importtaskforce/Report1220.pdf].

[29] Medicare Act, *supra* note 3.

[30] *Id.* This legislation, which is similar to the FDA's personal importation procedures, is discussed in more detail in a separate section below.

"pose no additional risk to the public's health and safety; and [would] result in a significant reduction in the cost of covered products to the American consumer."[31] As noted above, the Secretary of HHS has thus far declined to provide such certification. Absent such certification, the ban on the importation of prescription drugs remains in effect.

Importation of Foreign Versions of Prescription Drugs

Even if the FDCA did not contain an explicit prohibition against drug importation, the FDA maintains that consumer imports of prescription drugs from foreign countries would almost certainly violate other provisions of the act.[32] For example, such drugs are likely to be unapproved,[33] mislabeled,[34] or improperly dispensed.[35] According to the FDA:

> The reason that Canadian or other foreign versions of U.S.-approved drugs are generally considered unapproved in the U.S. is that FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance... . Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the U.S. approval, and thus it is considered to be unapproved. Virtually all shipments of prescription drugs imported from a Canadian pharmacy will run afoul of the Act, although it is a theoretical possibility that an occasional shipment will not do so. Put differently, in order to ensure compliance with the Act when they are involved in shipping prescription drugs to consumers in the U.S., businesses and individuals must ensure, among other things, that they only sell FDA-approved drugs that are made outside of the U.S. and that comply with the FDA approval in all respects.[36]

The difficulty in determining whether a drug is FDA-approved is demonstrated by the agency's response to a letter from Representative Edward Markey. On October 11, 2006, he asked the agency how a consumer would know if a product is FDA-approved or unapproved.[37] The agency responded with a recommendation that consumers

> access the FDA site to search for the active ingredient or name of drug. The names of approved companies for a drug will be listed... . If the manufacturer of a consumer drug is not listed, the drug may be unapproved or there may be data

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[31] *Id.*

[32] Lombardi Letter, *supra* note 23, at 2.

[33] 21 U.S.C. § 355.

[34] *Id.* at §§ 352, 353(b)(2).

[35] *Id.* at § 353(b)(1).

[36] Lombardi Letter, *supra* note 23, at 3.

[37] Inside Washington Publishers, *Markey Eyes Bill on Stronger Unapproved Drugs Enforcement*, FDA WEEK, Jan. 5, 2007.

> errors. The drug may also be an approved drug, but distributed under the name of another company. Consumers are also advised to check with the drug manufacturer.[38]

In addition to complying with the requirements regarding FDA approvals, imported drugs must also meet FDA requirements regarding labeling and dispensing. For example, mislabeling a drug is a violation of the FDCA, as is the act of introducing or receiving a mislabeled drug in interstate commerce.[39] In order to be properly labeled, prescription drugs must be labeled in accordance with the FDA's extensive labeling requirements.[40] Furthermore, the FDCA requires that prescription drugs may be dispensed only with a valid prescription.[41] Therefore, it is a violation of the act to import prescription drugs without a legitimate U.S. prescription.

According to the FDA, an inspection of prescription drug shipments by CBP found that 1,728 of 1,982 drug shipments from foreign countries violated the FDCA because they contained "unapproved drugs" that could pose safety problems.[42] Although the reason for the violation varied depending on the shipment, the FDA and CBP found shipments of drugs that, among other things, had never been approved by the FDA, were inadequately labeled (e.g., lacked instructions or were labeled in a foreign language), had been withdrawn from the U.S. market due to safety concerns, could cause dangerous interactions, required monitoring by a doctor, or were controlled substances.[43] An FDA investigation found that approximately 43 percent of the imported drugs that the agency intercepted from four countries — India, Israel, Costa Rica, and Vanuatu — were shipped to fill orders that consumers believed that they were placing with Canadian pharmacies. Of the products believed to be Canadian, only 15 percent actually originated in Canada, while the remaining 85 percent were manufactured in 27 different countries.[44]

Canadian Prescription Drug Importation After the FY2007 Homeland Security Appropriations Bill

Until recently, the Department of Homeland Security, via the U.S. Customs and Border Protection agency (CBP), was responsible for examining imported prescription drugs at the nation's international mail centers and borders and for detaining and destroying any FDA-regulated prescription drugs that did not meet

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[38] *Id.*

[39] 21 U.S.C. §§ 331 (a)-(c), 353(b)(2).

[40] 21 C.F.R. §201.100(c)(2).

[41] 21 U.S.C. § 353(b)(1).

[42] Press Release, Food and Drug Administration, Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments (Jan. 27, 2004), [http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html].

[43] *Id.*

[44] Press Release, Food and Drug Administration, FDA Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate From Other Countries (Dec. 16, 2005), [http://www.fda.gov/bbs/topics/NEWS/2005/NEW01277.html].

statutory or regulatory requirements.[45] Prior to November 17, 2005, CBP officials tolerated prescription drug mail orders from Canada of up to 90 days worth of medication, "generally interpreting U.S. laws against the importation of drugs as applying to wholesalers and distributors."[46] However, the CBP began strictly enforcing importation laws on November 17, 2005, two days after the beginning of open enrollment for the Medicare prescription drug program. This policy change lead consumer groups and Canadian pharmacies to complain that CBP's policy was intended to encourage seniors to enroll in the Medicare plan and decrease competition for often costly prescription drugs. CBP officials denied this charge, noting that the new enforcement policy was designed "to protect consumers from potentially dangerous drugs manufactured abroad."[47] For the next eleven months, CBP agents confiscated mail packages with foreign prescription drugs and often destroyed the drugs, then mailed letters about the violation to consumers attempting to import the drugs.[48] An estimated 37,000 to 40,000 packages were detained by CBP during this period.[49]

In past years, the House of Representatives Committee on Appropriations had added provisions to appropriations bills that would have prohibited the FDA from using monies to prevent drug importation from foreign countries. Such provisions were always removed during conferences between the House and the Senate. Last year, Representative Emerson added a similar provision to the FY2007 Homeland Security appropriations bill prohibiting CBP from using funds to prevent importation of "FDA-approved" drugs.[50] Opponents labeled the provision "an inappropriate way to address the issue of drug affordability" and expressed concerns that the U.S. would be more exposed to harmful counterfeit drugs or that terrorists would take advantage of the provision.[51] Additionally, some Canadian pharmacist associations and other importation opponents worried that their country would encounter shortages as a result of the provision.[52] Supporters noted that the provision was "aimed at forcing

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[45] Lee, *supra* note 22.

[46] *Id.*; Lisa Girion, *U.S. to Allow Canadian Drug Imports*, L.A. TIMES, Oct. 4, 2006.

[47] Lisa Girion, *Seized Drugs Being Released*, L.A. TIMES, Mar. 1, 2006, at C1; Susan Heavey, *FDA Role Restored Over Mail-Order Drug Imports*, WASH. POST, Oct. 4, 2006; Girion, *supra* note 46.

[48] Heavey, *supra* note 47.

[49] Inside Washington Publishers, *Senators' Effort to Force Reimportation Floor Debate Blocked*, FDA WEEK, Aug. 4, 2006; Lee, *supra* note 22.

[50] Inside Washington Publishers, *Homeland Security Approps Bill Allows Drug Reimportation*, FDA WEEK, June 2, 2006.

[51] Executive Office of the President, OMB, *Statement of Administration Policy: H.R. 5441 – Department of Homeland Security Appropriations Bill, FY 2007*, May 25, 2006, at 3; Inside Washington Publishers, *FDA to Resume Rx Drug Import Oversight as Customs Backs Off*, FDA WEEK, Oct. 6, 2006; Inside Washington Publishers, *Reimportation Debate Rages on with Little Movement in Congress*, FDA WEEK, July 28 2006.

[52] Inside Washington Publishers, *Lawmakers' Solution to High-Cost Drugs Makes Waves in Canada*, FDA WEEK, Oct. 27, 2006.

FDA to assess prescriptions from foreign countries for safety instead of simply blocking all reimported drugs."[53]

The Senate Committee on Appropriations subsequently stripped the Homeland Security appropriations bill of the importation provision, but Senators Vitter and Nelson introduced the CBP funding prohibition for certain seizures of Canadian drug imports in an amendment that passed 68-32.[54] As passed on September 25, 2006, Section 535 reads as follows:

> None of the funds made available in this Act for United States Customs and Border Protection may be used to prevent an individual not in the business of importing a prescription drug (within the meaning of section 801(g) of the Federal Food, Drug, and Cosmetic Act) from importing a prescription drug from Canada that complies with the Federal Food, Drug, and Cosmetic Act: Provided, That this section shall apply only to individuals transporting on their person a personal-use quantity of the prescription drug, not to exceed a 90-day supply: Provided further, That the prescription drug may not be-- (1) a controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802); or (2) a biological product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262).[55]

The provision excludes narcotics, biologics, internet sales, and importations of Canadian prescription drugs by mail order.[56] Most importantly, the bill appears to allow individuals to transport a 90-day supply of prescription drugs from Canada across the border by foot or vehicle. However, the provision ultimately appears to have limited effect because it states that individuals may personally import Canadian prescription drugs that comply with the FDCA. By definition, most prescription drugs from Canada do not comply with the FDCA. As the previous section explained, drugs that comply with the FDCA must be approved by the FDA, be dispensed with a valid prescription by a U.S. doctor, and meet, among other possible requirements, mandates that are manufacturer and product specific, manufacturing controls and processing methods, extensive labeling requirements, and source and active ingredient specifications.[57] While it is possible that a prescription drug could meet FDA requirements and therefore obtain FDA approval, in almost all cases, imported prescription drugs will not comply with the FDCA. Thus, the provision does not change the current illegal status of most drugs imported from Canada, and it appears that CBP may still legally use funds to detain Canadian drug imports that do not comply with the FDCA.

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[53] Inside Washington Publishers, *Following House Lead, Senate Votes to Allow Drug Reimportation*, FDA WEEK, July 14, 2006.

[54] *Id.*

[55] P.L. 109-295.

[56] Inside Washington Publishers, *Conferees Strike Deal to Allow Personal Rx Importation*, FDA WEEK, Sept. 29, 2006.

[57] Lombardi letter, *supra* note 23. *See* 21 C.F.R. § 314.50; notes 33-37, 40-42 and accompanying text.

Despite the limited effect of the importation provision, CBP announced a change in its enforcement policy, effective October 9, 2006. CBP agents now "focus on intercepting only counterfeit medicines, narcotics, and illegal drugs."[58] As a result, the FDA assumed the primary responsibility for determining whether Canadian and other international drug imports may legally enter the U.S. In most cases, prescription drugs are illegal to import into the U.S.[59] The FDA has the authority to seize "[a]ny article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce ... ."[60] However, the FDA's ability to "thoroughly inspect and handle confiscated imports" is questioned by some, given the agency's shortage of resources and staff.[61]

In December 2006, Senators Grassley and Baucus attempted to alter the Homeland Security importation provision. Their modification would have only allowed importation from Canada of prescription drugs "with at least two generic competitors" and would have excluded certain drugs and biologics from the those that the Homeland Security appropriations bill intended to allow individuals to personally carry across the Canadian border in a 90-day supply.[62]

Penalties Under the FDCA and Other Federal Laws

If a business or consumer violates the FDCA by importing unapproved or misbranded prescription drugs, there are a number of criminal and civil penalties that may apply. As set forth in the act, penalties vary depending on the offense. Violations of the act's general prohibitions are a misdemeanor offense punishable by up to a year in prison or a fine of up to $1,000, or both.[63] A violation of a general FDCA prohibition that occurs after a prior conviction for violating the act or that is committed with the intent to defraud or mislead is a felony offense punishable by up to three years of imprisonment or up to a $10,000 fine, or both.[64] Penalties for violations of the FDCA's importation provisions are stricter. If a business or consumer knowingly imports a drug in violation of these provisions, then the

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[58] Lee, *supra* note 22.

[59] *Id.*; *U.S. Steps Back on Drug Confiscations*, N.Y. TIMES, Oct. 4, 2006.

[60] 21 U.S.C. § 334(a)(1).

[61] Heavey, *supra* note 47; Lee, *supra* note 22.

[62] Inside Washington Publishers, *Grassley, Baucus Tried Banning Drug Imports When Generics Available*, FDA WEEK, Dec. 8, 2006. The provision would have excluded "therapeutic DNA plasmid products, therapeutic synthetic peptide products, monoclonal antibody products used in vivo, therapeutic recombinant DNA-derived products, infused drugs, injected drugs, drugs inhaled during surgery, drugs with at least two generic competitors, and sterile ophthalmic drugs intended for use on the skin or in the eye." *Id.*

[63] 21 U.S.C. § 333(a)(1). In addition, misdemeanor violations of the act are strict liability offenses. United States v. Dotterweich, 320 U.S. 277, 284 (1943).

[64] 21 U.S.C. § 333(a)(2).

violation is a felony offense punishable by up to 10 years in prison or up to $250,000 in fines, or both.[65]

Despite these designated penalties, individuals and corporations that violate the act may face monetary fines far greater than those specified in the FDCA because those sanctions are superceded by general fines set forth in the Sentencing Reform Act of 1984, which applies across the board to all federal crimes. That statute raised the limit on the maximum penalties that apply to federal crimes. As a result, misdemeanor violations of the FDCA are actually punishable by a fine of up to $100,000 for individuals and up to $200,000 for organizations, and felony violations of the act are punishable by up to $250,000 for individuals and up to $500,000 for corporations.[66] In addition, federal courts are authorized to issue injunctions in order to enjoin violations of the act,[67] and any drug that is adulterated or misbranded is subject to seizure under the act.[68]

It is important to note that "[t]hose who aid and abet a criminal violation of the act, or conspire to violate the act, can also be found criminally liable."[69] Federal criminal law generally makes it a separate crime to aid or abet any criminal offense against the United States or to conspire to commit a criminal offense against the United States,[70] so illegal importers could potentially be charged with these offenses as well as other general federal crimes, such as mail or wire fraud or making false statements. In addition, the FDCA explicitly forbids certain acts, as well as the causing of such prohibited acts.[71] Thus, businesses that facilitate the importation of unapproved prescription drugs or U.S.-manufactured prescription drugs may be liable if they are deemed to be "causing" violations of the act. In addition to penalties under the FDCA and other federal criminal statutes, individuals or businesses that illegally import prescription drugs that are also controlled substances may be subject to penalties under the Controlled Substances Act.[72]

Despite the range of penalties that FDA has available to punish those who import prescription drugs in violation of the act, the agency has clarified that its "highest enforcement priority would not be actions against consumers."[73] Indeed, the FDA exercises its enforcement discretion leniently in this regard by allowing consumers to import certain otherwise illegal prescription drugs under certain

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[65] *Id.* at §§ 333(b)(1), 381(d)(1). The act provides exceptions to the penalties in certain cases of good faith. *Id.* at § 333(c).

[66] 18 U.S.C. §§ 3559, 3571.

[67] 21 U.S.C. § 332.

[68] *Id.* at § 334.

[69] Lombardi Letter, *supra* note 23, at 1.

[70] 18 U.S.C. §§ 2, 371.

[71] 21 U.S.C. § 331.

[72] *See infra* notes 226-228 and accompanying text.

[73] Lombardi Letter, *supra* note 23, at 4.

circumstances. These enforcement procedures, known as the FDA's personal importation procedures, are described in detail below.

The FDA's Personal Importation Procedures

Because importing unapproved prescription drugs is a violation of the FDCA, the FDA is responsible for determining whether pharmaceuticals should be admitted into the U.S.[74] To determine whether to allow or refuse entry to imported drugs, the FDA developed its personal importation procedures. Under the procedures, the FDA exercises its enforcement discretion to permit consumers to import otherwise illegal prescription drugs for purposes of personal use. Recognizing that the agency's limited enforcement resources are best directed at commercial shipments of imported drugs rather than personal imports, the FDA may, at its discretion, refrain from taking legal action against illegally imported drugs under the following circumstances:

> a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means;
> b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue;
> c) the product is considered not to represent an unreasonable risk; and
> d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than three month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.[75]

Ultimately, the personal importation procedures detail the FDA's enforcement priorities for imported drugs, but are not intended to grant a license to consumers to import unapproved prescription drugs into the United States.[76] Indeed, the FDA

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[74] CBP, Medication/Drugs, [http://www.cbp.gov/xp/cgov/travel/clearing_goods/restricted/medication_drugs.xml]. According to the FDA, CBP has the initial responsibility for examining imported goods at the nation's borders. Accordingly CBP is supposed to notify the FDA if it has detected a mail or baggage shipment of "an FDA-regulated article intended for commercial distribution, an article that FDA has specifically requested be detained, or an FDA-regulated article that appears to represent a health fraud or an unknown risk to health." OFFICE OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, *Coverage of Personal Importations*, REGULATORY PROCEDURES MANUAL, [http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html]. In light of the CBP's policy change in October 2006, it is unclear whether the CBP is continuing to alert the FDA if it detects shipments of the above-mentioned items.

[75] *Id. See also*, OFFICE OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, *Importation of Prescription Medicines/Drugs*, [http://www.fda.gov/ora/import/traveler_alert.htm]; OFFICE OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, *Information on Importation of Drugs* (April 3, 1998), [http://www.fda.gov/ora/import/pipinfo.htm].

[76] OFFICE OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, *Coverage of Personal Importations*, REGULATORY PROCEDURES MANUAL, [http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html].

emphasizes that even if all of the factors above are met, "the drugs remain illegal and FDA may decide that such drugs should be refused entry or seized."[77] Furthermore, these procedures do not apply to commercial shipments of unapproved prescription drugs, nor are they intended to permit the importation of foreign versions of drugs that are already approved in the United States. Thus, it appears that personal importations of cheaper versions of prescription drugs that are already available in the U.S. do not conform to the FDA's personal importation procedures.[78] Nevertheless, U.S. consumers continue to import drugs from abroad, and one Canadian group claims that Canadian pharmacies supply two million people in the U.S., or roughly one percent of the U.S. market for prescription drugs.[79]

Meanwhile, in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress authorized the FDA to allow individuals to import prescription drugs for personal use under certain circumstances, provided that the Secretary has certified that importation is safe and cost-effective.[80] Specifically, the act, subject to certification, requires the Secretary of HHS to allow individuals to import prescription drugs from Canada if the drug:

> (A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;
> (B) is accompanied by a copy of a valid prescription;
> (C) is imported from Canada, from a seller registered with the Secretary;
> (D) is a prescription drug approved by the Secretary ...
> (E) is in the form of a final finished dosage that was manufactured in [a registered] establishment ...
> (F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.[81]

Although the new individual importation provisions in the Medicare Act appear similar to the FDA's personal importation procedures, the legislation differs significantly because it contains the certification requirement. The current Secretary of HHS, however, has declined to provide such certification in the past, and it is unclear what direction the agency will take in the future. Thus, the new individual importation provisions do not appear to represent a codification of the FDA's personal importation procedures.

Although the FDA exercises its enforcement discretion to permit personal importation, such importation remains illegal. However, an elderly couple from Chicago challenged the FDCA's prohibition on personal importation. In *Andrews v.*

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[77] OFFICE OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, *Importation of Prescription Medicines/Drugs*, [http://www.fda.gov/ora/import/traveler_alert.htm].

[78] OFFICE OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, *Information on Importation of Drugs* (April 3, 1998), [http://www.fda.gov/ora/import/pipinfo.htm].

[79] Inside Washington Publishers, *Canadian Pharmacist to Drug Firms: Support Limited Rx Imports,* FDA WEEK, May 7, 2004.

[80] Medicare Act, *supra* note 3, at § 1121.

[81] *Id.*

United States Department of Health and Human Services,[82] the court rejected the plaintiffs' claim that the statutory prohibition on personal drug importation violated their substantive due process rights under the Fifth Amendment of the Constitution. The standard of review that courts use when reviewing substantive due process claims depends on whether or not the statute in question affects a fundamental right. If a statute affects a fundamental right, then strict judicial scrutiny is required; if the statute does not affect a fundamental right, then a court applies rational basis review. In the *Andrews* case, the court determined that there is no fundamental right "to purchase drugs from a preferred source at a preferred price."[83] As a result, the court, applying the rational basis test, upheld the ban on personal importation because it is rationally related to a legitimate governmental interest in ensuring the safety of prescription medications.[84]

State and Local Importation of Prescription Drugs: Violation of Federal Law?

Just as individual consumers have sought to buy cheaper prescription drugs from foreign sources, several state and local governments have in place or have considered plans to import or facilitate the importation of prescription drugs in order to save themselves or their residents money on medicines. Contending that carefully structured state programs will provide a sufficient degree of safety, states and cities continue to argue that they have a duty to explore innovative methods for providing more affordable prescription drugs to their residents, even at the risk of violating federal law. Currently, eleven states have online prescription drug importation programs, and several localities, including Boston, Massachusetts, are importing prescription drugs from Canada.[85] Interest in importing Canadian prescription drugs may be beginning to wane due to factors including the Medicare Part D prescription drug program, a temporary increase in seizures by the CBP, declining currency-exchange rates, and a greater use of generic drugs.[86] For example, the first city to import Canadian prescription drugs, Springfield, Massachusetts, reported no problems with its Canadian prescription drug importation program; however, it recently switched to a state health benefits program which does not import Canadian prescription drugs.[87]

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[82] 2005 U.S. Dist. LEXIS 5710 (D.D.C. 2005).

[83] *Id*. at *7.

[84] *Id*. at *8-9.

[85] City of Boston, Affordable Prescription Drugs, [http://www.cityofboston.gov/publichealth/prescription.asp]. The states are: Illinois, Kansas, Minnesota, Missouri, Nevada, New Hampshire, North Dakota, Rhode Island, Vermont, Washington, and Wisconsin. Kelley M. Butler, *Local Rx Import Programs Find Fewer Takers*, Employee Benefit News, Jan. 1, 2007.

[86] *Id.*; *Kelley* M. Butler, *Local Rx Import Programs Find Fewer Takers*, Employee Benefit News, Jan. 1, 2007. Last fall, several retail pharmacies said they would sell certain prescription drugs for as low as $4. *Id.*

[87] Christopher Rowland, *Mass. City Ends Drug Plan that Defied U.S.*, Boston Globe, Aug.

(continued...)

Each state and local importation plan varies somewhat in the details. Illinois, for example, has implemented a drug importation program known as I-SaveRx. Under the program, the state has established website that offers information regarding pharmacies in Canada, Ireland, and Great Britain that the state has inspected and determined to be reliable sources for prescription drugs. The state, however, does not import drugs directly, but rather provides users with information on available drugs, prices, and order forms. Currently, Kansas, Missouri, Vermont, and Wisconsin also participate in I-SaveRx.[88] In addition, Rhode Island legislators passed a law that allows the state to license Canadian pharmacies.[89] Many other states and localities have considered and/or implemented importation plans of their own.[90]

In addition, several states, including Vermont, have petitioned the FDA in hope that the agency would, as it has done with regard to personal drug importation, exercise its enforcement discretion and allow states to establish prescription drug importation pilot plans.[91] The Medicare Act authorized the FDA to provide waivers for individual importation, and some lawmakers have argued that the individual importation waiver authority extends to state importation plans because such plans are intended to provide prescription drugs to individual state residents. The FDA, however, responded that the waiver provisions in the Medicare Act become effective only upon certification by the Secretary that drug importation is safe and reduces costs.[92]

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[87] (...continued)
26, 2006.

[88] See [http://www.i-saverx.net/] for more information on drug importation programs for Illinois, Wisconsin, Kansas, Vermont, and Missouri.

[89] Inside Washington Publishers, *Rhode Island is First State to Pass Canadian Drug Import Law,* FDA WEEK, July 9, 2004. The FDA has warned Rhode Island that the legislation may be preempted by federal law. Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, Food and Drug Administration, to Governor Donald L. Carcieri (July 1, 2004), [http://www.fda.gov/oc/opacom/hottopics/importdrugs/carcieri.pdf]. For a discussion of the preemption doctrine, *see infra* notes 108-109 and accompanying text.

[90] For example, California, Kansas, Illinois, Iowa, Minnesota, Missouri, New Hampshire, North Dakota, Rhode Island, Vermont, and Wisconsin are among the states that have considered and/or implemented importation programs. For current information on state activities with regard to prescription drug importation, see National Conference of State Legislators, *2006 Prescription Drug State Legislation* (Jan. 3, 2007), [http://www.ncsl.org/programs/health/drugbill06.htm]. According to the National Conference of State Legislators, 29 states considered the issue of prescription drug importation during the first seven months of 2006. *Id.*

[91] Inside Washington Publishers, *Vermont Wants FDA to Allow Drug Reimportation for State Employees,* FDA WEEK, Dec. 19, 2003; *see also* Inside Washington Publishers, *Sen. Dorgan Pushes for Drug Import Pilot Program in North Dakota*, FDA WEEK, April 2, 2004; Letter from Lester M. Crawford, Acting Commissioner of Food and Drugs, Food and Drug Administration, to Governor Rod R. Blagojevich, State of Illinois (June 3, 2004), [http://www.fda.gov/oc/opacom/hottopics/importdrugs/GovB63.pdf].

[92] Kelly Field, *Battle Brewing Between Administration, Local Officials Over Drug* (continued...)

Ultimately, Vermont, whose petition for a pilot program was rejected by the FDA, sued the agency, claiming that the FDA's failure to implement regulations that authorize waivers and subsequent denial of Vermont's petition violated the Administrative Procedure Act (APA). The Vermont lawsuit also claimed that the importation provisions in the Medicare Act constitute an unconstitutional delegation of legislative authority to the Secretary of HHS.[93] Vermont's claims, however, were rejected by a federal district court. In the case, *Vermont v. Leavitt*,[94] the court held that the FDA did not act arbitrarily and capriciously in violation of the APA because Vermont's petition asked the agency to approve a program that was illegal. The court based its ruling, in part, on its determination that, as the FDA had argued, the FDCA provision authorizing waivers for personal importation becomes effective only upon certification by the Secretary that drug importation is safe and reduces costs.[95] Likewise, the court rejected Vermont's claim that the certification provision constitutes an unconstitutional delegation of legislative authority, holding that the provision "provides clear guidance to the Secretary of HHS by directing the Secretary to consider safety and cost-effectiveness."[96] Vermont did not appeal the decision.[97]

Montgomery County in Maryland petitioned the FDA for a waiver to allow its residents and employees to import prescription drugs from Canada. The FDA rejected the petition, citing the *Leavitt* case.[98] In response, Montgomery County filed a lawsuit alleging that the FDA's denial of its petition was arbitrary and capricious and violated the APA.[99] Specifically, the County argued that the FDA's action was arbitrary because the agency has tacitly allowed numerous other states and localities to import prescription drugs in violation of the FDCA but nonetheless refuses to assist jurisdictions that attempt to import drugs legally under a waiver program. Furthermore, the County contended that the FDA's failure to act with respect to illegal importation programs indicates that the agency does not believe that importation poses a safety risk, despite the agency's statements to the contrary.[100] The federal district court granted the FDA's motion to dismiss the case. The court

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[92] (...continued)
Importation Issue, CQ TODAY, Dec. 19, 2003.

[93] Vermont v. Thompson (D. Vt. filed Aug. 19, 2004). In January 2005, Mike Leavitt succeeded Tommy Thompson as Secretary of the Department of Health and Human Services, resulting in a different case name.

[94] 405 F. Supp. 2d 466 (D. Vt. 2005).

[95] *Id*. at 473-75.

[96] *Id*. at 476.

[97] Tim Craig, *Duncan Sues FDA Over Canadian Drugs*, WASH. POST, Feb. 23, 2006, at B05.

[98] Letter from Randall W. Lutter, Ph.D., Acting Associate Commissioner for Policy and Planning, Food and Drug Administration, to Douglas M. Duncan, County Executive, Office of the County Executive (Nov. 8, 2005), [http://www.fda.gov/oc/opacom/hottopics/importdrugs/duncan110805.html].

[99] Montgomery County v. Leavitt, 445 F. Supp. 2d 505 (D. Md. 2006).

[100] Press Release, Montgomery County, Maryland, Duncan Sues Bush Administration Over Canadian Drug Import (Feb. 23, 2006), [http://www.montgomerycountymd.gov/apps/News/press/DisplayInfo.cfm?ItemID=1755].

held that the FDA complied with the FDCA and the Medicare Act when it denied the County's waiver request and found the FDA's denial did not violate the APA because it was not arbitrary or capricious.[101] In response to the County's argument that the FDA failed to act with respect to importation programs, the court held that "the FDA's failure to enforce the FDCA in some situations does not constitute *de facto* certification by the Secretary" of HHS, because the statute gives the Secretary discretion to issue such certification that Canadian prescription drug importation programs are safe and cost-effective.[102] The court could not review the Secretary's failure to certify importation programs, nor could the court grant the County any relief, because certification is discretionary.[103]

Despite the efforts of such state and local governments, the FDA continues to maintain that importing unapproved prescription drugs is unsafe and illegal. Indeed, FDA representatives have met with and sought to convince state officials to change their minds about importing drugs in apparent violation of federal law. At the same time, the agency has notified certain states of its legal position regarding drug imports.[104] For example, according to the FDA's response to an inquiry from California officials, "if an entity or person within the State of California (including any state, county, or city program, any public pension, or any Indian Reservation) were to import prescription drugs into the State of California from Canada [or any other foreign country], it would violate FDCA in virtually every instance."[105]

The FDA provides several legal arguments for reaching its conclusion that state and local drug importation is a violation of the FDCA. First, the statute prohibits anyone other than the manufacturer from importing drugs that were originally manufactured in the United States. Second, even if an FDA-approved drug is manufactured outside the U.S., the imported version of the drug will likely violate statutory requirements regarding drug approvals, labeling, and dispensing.[106] These first two arguments are identical to the arguments that FDA has made when explaining why the agency views business and consumer imports of prescription drugs to be statutory violations.[107] Therefore, the FDA considers virtually any imports of prescription drugs, as well as virtually any act that causes such imports, to be illegal, regardless of whether such imports are conducted by businesses, consumers, or governmental entities.

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[101] *Montgomery County*, 445 F. Supp. 2d at 508-10.

[102] *Id.* at 512.

[103] *Id.* at 513-14.

[104] Indeed, the FDA has issued a series of warning letters to states that have considered or that have implemented prescription drug importation plans. These letters are posted on the FDA's website at [http://www.fda.gov/importeddrugs/].

[105] Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, Food and Drug Administration, to Gregory Gonot, Deputy Attorney General, State of California 2 (Aug. 25, 2003), [http://www.fda.gov/opacom/gonot.html] [hereinafter California Letter].

[106] *Id.* at 3.

[107] See *supra* notes 21-44 and accompanying text.

In addition, the FDA contends that any effort by states to enact legislation authorizing prescription drug imports would be preempted by federal law.[108] Although the FDA sets forth several legal arguments for its position, preemption of the act's importation provisions does not appear to have been tested in court, and there are several instances in which other prescription drug provisions in the FDCA have been held not to preempt state law.[109] Finally, the agency has warned some states that they could be subject to lawsuits for injuries to consumers who relied on the state's endorsement when purchasing prescription drugs from Canada. For example, in a letter to Minnesota state officials, the FDA warned of "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."[110]

Despite the FDA's position regarding state and local imports of prescription drugs, it appears that the agency is currently refraining from taking legal action against state and local governments that have established drug importation programs. Indeed, in a warning letter to Minnesota, which established a website that provides information about accessing less costly prescription drugs from Canada, the agency notably refrained from asserting that the state's program violated the FDCA and did

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[108] California Letter, *supra* note 105, at 5-7. In a warning letter to Rhode Island, the FDA elaborated on its preemption argument in greater detail. Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, Food and Drug Administration, to Patrick C. Lynch, Attorney General of Rhode Island (Jan. 28, 2005), [http://www.fda.gov/oc/opacom/hottopics/importdrugs/lynch012805.html]. The preemption doctrine derives from the Supremacy Clause of the Constitution, which establishes that the laws of the United States "shall be the supreme law of the land; and the judges in every state shall be bound thereby, any thing in the Constitution or laws of any State to the contrary notwithstanding." U.S. CONST. art. VI, cl. 2. In applying this constitutional mandate, courts have recognized both express and implied forms of preemption, which are "compelled whether Congress' command is explicitly stated in the statute's language, or implicitly contained in its structure and purpose." Gade v. National Solid Wastes Management Association, 505 U.S. 88, 97 (1992) (quoting Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977)).

[109] Many of these cases, however, deal with prescription drug labeling, not importation, and state common law claims, not state statutory law. David R. Geiger and Mark D. Rosen, *Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards*, 45 DEPAUL L. REV. 395, 408 (1996). It is also important to note that the FDCA expressly preempts state law with regard to over-the-counter drugs and medical devices but not with regard to prescription drugs. As a result, it is more difficult to predict the outcome of a preemption challenge to state laws on prescription drugs. A detailed examination of the preemption issue, however, is beyond the scope of this report.

[110] Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, Food and Drug Administration to the Honorable Tim Pawlenty, Governor of Minnesota 3 (Feb. 23, 2004), [http://www.fda.gov/oc/opacom/hottopics/importdrugs/pawlenty022304.html]. In the Minnesota warning letter, the FDA explicitly noted that Minnesota's own inspection of some of the recommended Canadian pharmacies had revealed potential safety violations. *Id.* at 1-3.

not describe any potential enforcement action that the FDA might take.[111] Likewise, the FDA has indicated that it is unlikely to sue the state of Illinois, which has implemented a plan to import drugs from Canada and certain European countries, despite the agency's earlier pronouncement that it would refrain from suing states and localities as long as those entities imported drugs from Canada and not from other countries.[112] One possibility is that the agency is "simply waiting for a state to actually buy foreign drugs for their residents, which would constitute direct commercial importation, before taking legal action."[113] Although several localities are importing drugs directly, "the FDA has not gone after these cities because they are too small."[114] Previously, the FDA had indicated that it had not yet sued states or localities because "the agency wants to first win its case against Rx Depot, giving FDA bargaining power for the more difficult task of taking formal action against states and local governments."[115] However, in the Rx Depot case, which involved a private company that helped individual consumers import prescription drugs, the FDA successfully concluded its lawsuit when Rx Depot agreed to enter into a consent decree that permanently enjoins the company from the importation of unapproved prescription drugs.[116] The Rx Depot case is discussed in detail in the following section.

Businesses That Facilitate Importation of Prescription Drugs

Although the FDA has refrained thus far from taking legal action against both states and individual consumers who import prescription drugs in violation of the FDCA, the agency has pursued legal action against businesses that facilitate the

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[111] *Id.* One possible explanation for the FDA's silence with respect to the legality of Minnesota's actions could be that it is unclear whether the state is "causing" the prohibited importation activity in violation of the statute, in part because the state neither imports drugs from Canada nor allows consumers to order directly through its website. On the other hand, the Minnesota website does provide order forms, pricing information, and instructions on how to submit an order to the recommended pharmacies, and such actions may be enough to establish that Minnesota is facilitating illegal importation. See [http://www.state.mn.us/portal/mn/jsp/home.do?agency=Rx] to view Minnesota's website.

[112] Inside Washington Publishers, *FDA Signals Reluctance to Sue Illinois for Importing Drugs,* FDA WEEK, Aug. 20, 2004.

[113] Inside Washington Publishers, *CMS Could Refuse Medicaid Approvals for Rx-Importing States,* FDA WEEK, Dec. 10, 2005. Even if a state were to import drugs directly, however, the Centers for Medicare and Medicaid Services (CMS) may be better positioned to halt such state activities than the FDA would be, since the FDA would have to engage in potentially lengthy litigation over the issue, while CMS could deny approval for any state Medicaid plan that contained a drug importation program, thereby eliminating what would otherwise be a significant source of state funding for importation activities.

[114] *Id.*

[115] Inside Washington Publishers, *FDA To Resolve Rx Depot Suit Before Taking on States,* FDA WEEK, Oct. 31, 2003.

[116] Press Release, Food and Drug Administration, Rx Depot Agrees in Consent Decree to Cease Importing Unapproved Drugs from Canada (Aug. 20, 2004), [http://www.fda.gov/bbs/topics/news/2004/NEW01105.html].

importation of such drugs. Unlike pharmacies, which receive orders from consumers and dispense drugs directly, some businesses facilitate drug sales without dispensing drugs directly. Rather, these companies, many of which are online, act as middlemen between consumers, who provide medical and payment information, and foreign (typically Canadian) pharmacies, which then ship drugs directly to consumers. The FDA has pursued legal action against at least one such business. That case is discussed in detail in this section, while separate but related issues involving online pharmacies are discussed in a different section below.

In *United States v. Rx Depot*,[117] the Department of Justice (DOJ), acting on behalf of the FDA, filed suit against Rx Depot, a storefront operation that helped U.S. consumers obtain prescription drugs from Canada.[118] In the suit, DOJ contended that Rx Depot was violating two provisions of the FDCA, namely the provision prohibiting importation and the provision prohibiting the introduction into interstate commerce of any drug that violates the act's approval requirements.[119] Although Rx Depot was not directly importing drugs, the company admitted that it was "engaged in the business of causing the shipment of U.S.-manufactured and unapproved, foreign-manufactured prescription drugs from Canadian pharmacies to U.S. citizens."[120]

Rx Depot countered that the FDA was not actually concerned about the safety of imported drugs because the agency had never tested the drugs it bought from Rx Depot as part of a sting operation against the company.[121] Similar complaints have been voiced by other businesses that facilitate the importation of prescription drugs. Critics of FDA's importation stance also argue that it "fails to protect the public health because it allows individuals to import drugs, while prohibiting 'commercial' operations that are in the best position to develop safeguards,"[122] and allege that the FDA's importation procedures may violate international trade agreements.[123]

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[117] 290 F. Supp. 2d 1238 (D. Okla. 2003) (order granting preliminary injunction).

[118] DOJ initiated this lawsuit after Rx Depot failed to respond to the agency's warning letter and continued to facilitate the importation of prescription drugs and the importation of unapproved drugs. *See* Letter from David J. Horowitz, Esq., Director, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, to Harry Lee Jones, Store Manager, Rx Depot, Inc., (March 21, 2003), [http://www.fda.gov/foi/warning_letters/g3888d.htm]. The FDA has sent similar warning letters to other businesses that facilitate the importation of prescription drugs. *See, e.g.*, Letter from David J. Horowitz, Esq., Director, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, to G. Anthony Howard, President, CanaRx Services, Inc., (Sept. 16, 2003), [http://www.fda.gov/cder/warn/2003/RHoward.pdf].

[119] United States v. Rx Depot, 290 F. Supp. 2d 1238 (D. Okla. 2003) (order granting preliminary injunction); *see also* 21 U.S.C. §§ 331(d), 331(t), and 355.

[120] *Rx Depot*, 290 F. Supp. 2d at 1241.

[121] Inside Washington Publishers, *Rx Depot: FDA Alleged Safety Concerns With Reimportation Are Bogus*, FDA WEEK, Nov. 7, 2003.

[122] *Id.*.

[123] Inside Washington Publishers, *CanaRx Says FDA's Reimportation Policy Violates Trade*
(continued...)

Ultimately, critics argue that the FDA's procedures protect the profits of drug manufacturers at the expense of consumer pocketbooks.[124]

Despite these arguments, the district court held against Rx Depot during a preliminary ruling in the case. Concluding that "Rx Depot's importation of prescription drugs clearly violates the law," the district court issued a preliminary injunction enjoining Rx Depot from facilitating the importation of prescription drugs.[125] While the court's order was not actually a final order on the merits of the case, it did indicate that DOJ had a substantial likelihood of prevailing in the lawsuit. Indeed, the court appeared particularly concerned with the safety of imported drugs:

> [U]napproved prescription drugs and drugs imported from foreign countries by someone other than the U.S.-manufacturer do not have the same assurance of safety and efficacy as drugs regulated by the Food and Drug Administration. ... Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States. For instance, the drugs may be contaminated, counterfeit, or contain erratic amounts of the active ingredient or different excipients. Also, the drugs may have been held under uncertain storage conditions, and therefore be outdated or subpotent.[126]

With regard to Rx Depot, the court specifically noted that drugs ordered through the company were often dispensed in quantities greater than prescribed and did not contain the required package inserts. Although the court acknowledged that the cost of prescription drugs in the U.S. is high and that there are no known cases of an individual who has suffered harm from drugs imported through Rx Depot, the court nevertheless concluded that the FDA has legitimate safety concerns and that Congress is in the best position to resolve the tension between prescription drug safety and cost.[127]

Shortly after the court issued the preliminary injunction, Rx Depot agreed to enter into a consent decree with the FDA. Under the terms of the consent decree, Rx Depot "admitted liability for causing the importation of unapproved new drugs and U.S.-manufactured drugs in violation of the act and agreed to permanently cease such activities."[128] In the wake of the consent decree, the legal battle continued, as the

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[123] (...continued)
Agreements, FDA WEEK, Nov. 7, 2003.

[124] Marc Kaufman, *FDA's Authority Tested Over Drug Imports*, WASH. POST, Nov. 9, 2003, at A11.

[125] *Rx Depot*, 290 F. Supp. 2d 1238.

[126] *Id.* at 1241-42.

[127] *Id.* at 1241-42, 1245.

[128] Press Release, Food and Drug Administration, Rx Depot Agrees in Consent Decree to Cease Importing Unapproved Drugs from Canada (Aug. 20, 2004), [http://www.fda.gov/bbs/topics/news/2004/NEW01105.html].

U.S. requested disgorgement of Rx Depot's profits.[129] The federal court of appeals found that disgorgement was an appropriate remedy under the FDCA because disgorgement "furthers the purposes of the FDCA by deterring future violations of the Act which may put the public health and safety at risk."[130] Many companies like Rx Depot remain in business,[131] and a number of states and localities have contemplated or implemented their own importation programs. In response, several drug manufacturers have begun limiting sales of their drugs to Canadian pharmacies in an effort to prevent the drugs from being resold in the U.S. at cheaper prices. These actions have raised questions about whether such behavior violates federal antitrust laws, a topic that is discussed in the following section.

Antitrust Laws[132]

As noted above, several major prescription drug manufacturers have responded to the rise in the number of businesses and consumers that are importing cheaper drugs into the U.S. by reducing the supply of such drugs to distributors and pharmacies in Canada, where most of the imported drugs originate.[133] Although some manufacturers argue that restrictions on sales are designed to prevent drug shortages in Canada, such moves may instead be intended to limit Canadian distributors and pharmacies to selling prescription drugs to Canadian consumers only, rather than selling excess supplies of prescription drugs to U.S. consumers at cheaper prices than such consumers would pay for similar drugs in the U.S. As a result, several members of Congress have questioned whether these drug manufacturers are violating federal antitrust laws.[134] Several bills introduced in the 109th Congress would have prohibited such sales tactics,[135] and similar legislation has been introduced in the 110th Congress.[136] Furthermore, a federal district court decided what appears to be the first ruling regarding antitrust allegations against several drug

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[129] United States v. Rx Depot, 438 F.3d 1052, 1053 (2006), *cert. denied* 127 S. Ct. 80 (2006).

[130] *Id.* at 1058, 1061.

[131] For example, in a case against a business similar to Rx Depot, the FDA won a permanent injunction that enjoins a company known as Canada Care from importing unapproved prescription drugs. Press Release, Food and Drug Administration, Court Halts Illegal Importation of Prescription Drugs (Dec. 27, 2004), [http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01337.html].

[132] This section was written by Janice E. Rubin, Legislative Attorney in the American Law Division of CRS.

[133] Following the example set by GlaxoSmithKline, Pfizer Inc., the world's biggest drug manufacturer, also announced that the company was limiting sales of prescription drugs to Canadian pharmacies that resold such drugs to U.S. consumers. Ceci Connolly, *Pfizer Cuts Supplies to Canadian Drugstores*, WASH. POST, Feb. 19, 2004, at A10.

[134] Inside Washington Publishers, *Lawmakers Seek DOJ Anti-Trust Probe of Firms Limiting Sales to Canada*, FDA WEEK, Nov. 7, 2003.

[135] *See, e.g.*, H.R. 328; S. 334.

[136] *See, e.g.*, H.R. 380; S. 242.

manufacturers and the decision was affirmed on appeal.[137] In addition, at least one state has launched an investigation into whether or not the drug manufacturer GlaxoSmithKline (GSK) has violated state antitrust laws.[138] This section discusses the potential federal and state antitrust issues raised by the decision of certain drug manufacturers to limit the supply of drugs to Canadian distributors and pharmacies.

Federal Antitrust Law.

Federal antitrust law is concerned with the competitiveness of markets (competition), and not with the competitors — unless they have suffered an injury as a result of an actionable wrong under the antitrust laws. Similarly, the achievement or implementation of specific programs or goals is not a concern of the federal antitrust laws. It is not a given, therefore, that existing federal antitrust laws could be successfully employed to challenge pharmaceutical manufacturers whose actions appear either to reduce the U.S. supply of imported prescription drugs or to make it more difficult for Americans to purchase prescription drugs from other countries such as Canada.

First, neither current antitrust statutes nor doctrine make unlawful the market-oriented activities of individual entities, unless, under certain circumstances, the entity is a monopolist.[139] Section 1 of the Sherman Act[140] makes illegal "[e]very contract, combination ... or conspiracy, in restraint of trade or commerce ... ." That provision, by its terms, may only be violated by multiple parties engaged in concerted, or joint action. Thus, it would not currently be applicable to, for example, a drug manufacturer who, on his own, and not in agreement with another drug manufacturer or other person, refuses to supply, or reduces supplies to, a Canadian or other non-U.S. pharmacy.[141]

> The Sherman Act [15 U.S.C. §§ 1-7] contains a 'basic distinction between concerted and independent action.' *The conduct of a single firm is governed by § 2 [of the Sherman Act, 15 U.S.C. § 2] alone and is unlawful only when it threatens actual monopolization*. It is not enough that a single firm appears to 'restrain trade' unreasonably, for even a vigorous competitor may leave that impression... . Section 1 of the Sherman Act [15 U.S.C. § 1], in contrast, reaches unreasonable restraints of trade effected by a 'contract, combination . . . or

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[137] In Re: Canadian Import Antitrust Litig., 385 F. Supp. 2d 930 (D. Minn. 2005) *aff'd*, 470 F.3d 785 (8th Cir. 2006).

[138] Inside Washington Publishers, *Judge Wants More Info Before Deciding Motion to Compel Against GSK*, FDA WEEK, Nov. 21, 2003.

[139] For a more detailed discussion of this issue, see CRS Report RS20241, *Monopoly and Monopolization — Fundamental But Related Concepts in U.S. Antitrust Law*, and CRS Report RL33708, *The Distinction Between Monopoly and Monopolization in Antitrust Law*, by Janice E. Rubin and Congressional Distribution Memorandum, *Duty of a Monopolist to Deal*, by Janice E. Rubin.

[140] 15 U.S.C. §§ 1-7.

[141] See *infra* the section of this report on "State Antitrust Law" regarding the existence at the state level of some unilateral restraint of trade provisions.

> conspiracy' between *separate* entities. It does not reach conduct that is 'wholly unilateral.'"[142]

Moreover, the Court long ago noted that

> the [Sherman] act does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal; and, of course, he may announce in advance the circumstances under which he will refuse to sell.[143]

The U.S. Court of Appeals for the Federal Circuit added that the fundamental *Colgate* precept of seller choice set out above is not altered by the applicability of either the patent or copyright law to the item(s) in question, unless it is judicially determined that the patent or copyright in question was fraudulently procured.[144]

Second, whether certain joint activity is unlawful and therefore violates the antitrust statutes is not always susceptible of proof. Although the Supreme Court has indicated several times that a formal contract may not be necessary to establish the collective action required by section 1, an antitrust violation may be found if the unlawful agreement[145] can be inferred from the totality of surrounding circumstances.[146]

In 1984, in *Monsanto Co. v. Spray-Rite Service Corp.*, the Court said:

> The correct standard is that there must be evidence that tends to exclude the possibility of independent action by the [parties]. That is, there must be direct or circumstantial evidence that reasonably tends to prove that the [parties] had

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[142] Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 767-68 (1984) (ruling that a parent corporation was not legally capable of conspiring with its own wholly owned subsidiary, and so could not guilty of conspiracy) (citations and footnote omitted) (emphasis added).

[143] United States v. Colgate & Co., 250 U.S. 300, 307 (1919).

[144] In re Independent Service Organizations Antitrust Litigation, 203 F.3d 1322, 1326 (Fed. Cir. 2000).

[145] There are a small number of actions (e.g., price fixing, market allocation, boycotts or concerted refusals to deal) that the courts have designated as *per se* violations of section 1; other actions are analyzed pursuant to the Rule of Reason (anticompetitive consequences weighed against any procompetitive result), and only those found to unreasonably restrain trade are considered unlawful violations of section 1.

[146] "No formal agreement is necessary to constitute an unlawful conspiracy. . . . The essential combination or conspiracy in violation of the Sherman Act may be found in a course of dealings or other circumstances as well as in any exchange of words. [A conspiracy, or unlawful agreement may be found where] the conspirators had a unity of purpose or a common design and understanding, or a meeting of minds in an unlawful arrangement . . . ." American Tobacco Co. v. United States, 328 U.S. 781, 809-810 (1946) (citation omitted).

> a conscious commitment to a common scheme designed to achieve an unlawful objective.[147]

"Conscious parallelism" is the term often given to uniform or synchronous business behavior, which, while prima face *evidence* of concerted behavior, is not *proof* of unlawful agreement.[148] In an early case, for example, the Court held that the circumstances surrounding imposition by eight motions picture distributors of nearly identical restraints concerning the licensing of first-run "feature" films were sufficient to create a valid inference that the distributors had acted in concert, in violation of section 1 of the Sherman Act.

> It is elementary that an unlawful conspiracy may be and often is formed without simultaneous action or agreement on the part of the conspirators. Acceptance by competitors, without previous agreement, of an invitation to participate in a plan, the necessary consequence of which, if carried out, is restraint of interstate commerce, is sufficient to establish an unlawful conspiracy under the Sherman Act.[149]

In *Theatre Enterprises v. Paramount Film Distributing Corp.*, the Court continued to state that parallel behavior by itself is not necessarily proof of a conspiracy:

> The crucial question is whether respondents' conduct toward petitioner stemmed from independent decision or from an agreement, tacit or express. To be sure, business behavior is admissible circumstantial evidence from which the fact finder may find agreement. But this Court has never held that proof of parallel business behavior conclusively establishes agreement or, phrased differently, that such behavior itself constitutes a Sherman Act offense. Circumstantial evidence of consciously parallel behavior may have made heavy inroads into the traditional judicial attitude toward conspiracy; but "conscious parallelism" has not yet read conspiracy out of the Sherman Act entirely.[150]

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[147] 465 U.S. 752, 768 (1984), refusing to find that concerted action may be inferred from the fact that a seller terminated a dealer after the seller had received complaints from a competing dealer about the terminated dealer's pricing policies.

[148] "Tacit collusion, sometimes called oligopolistic price coordination or conscious parallelism, describes the process, not in itself unlawful, by which firms in a concentrated market might in effect share monopoly power, setting their prices at a profit-maximizing, supracompetitive level by recognizing their shared economic interests and their interdependence with respect to price and output decisions. ... Firms that seek to recoup predatory losses through the conscious parallelism of oligopoly must rely on uncertain and ambiguous signals to achieve concerted action. The signals are subject to misinterpretation and are a blunt and imprecise means of ensuring smooth cooperation, especially in the context of changing or unprecedented market circumstances. This anticompetitive minuet is most difficult to compose and to perform ... ." Brooke Group, Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 227, 228 (1993) (citations omitted); .

[149] Interstate Circuit, Inc. v. United States, 306 U.S. 208, 227 (1939) (citations omitted).

[150] 346 U.S. 537, 540-44 (1954) (citations omitted).

Although the Supreme Court has stated, and lower court decisions have continued to illustrate, that an unlawful agreement or conspiracy in restraint of trade may be proved by consciously parallel behavior that is accompanied by any of several "plus" factors — "the additional facts or factors required to be proved as a prerequisite to finding that parallel action amounts to a conspiracy"[151] — there has not been much agreement or standardization concerning exactly which "plus" factors are to be given what, if any, evidentiary weight.[152] The "plus" factors courts have considered favorably include artificial standardization of products[153] and raising prices in time of surplus.[154] Less persuasive is evidence that indicates merely that the parties had an opportunity to collude.[155] That the parties communicated with one another is, at best, ambiguous evidence of conspiracy.[156] The bottom line appears to be whether the parties acted in their own self-interest: where there is no direct evidence of a conspiracy, behavior as consistent with a desire to maintain profitability or to remain in business at all as with any participation in injurious or unlawful conduct does not constitute sufficient indirect evidence of an alleged

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[151] *See, e.g.*, In re Baby Food Antitrust Litigation, 166 F.3d 112, 122 (3d Cir. 1999) (citing Areeda, ANTITRUST LAW § 1433(e)).

[152] For example, the *Baby Food* court, *id.* at 122, quoted Balaklaw v. Lovell, 822 F.Supp. 892, 903 (N.D.N.Y. 1993) and cited Todorov v. DCH Healthcare Authority, 921 F.2d 1438, 1456 note 30 (11th Cir.1991): "[T]he mere presence of one or more of these 'plus factors' does not necessarily mandate the conclusion that there was an illegal conspiracy between the parties, for the court may still conclude, based upon the evidence before it, that the defendants acted independently of one another, and not in violation of antitrust laws"; "If an inference of ... an agreement may be drawn from highly ambiguous evidence, there is a considerable danger that the doctrines enunciated in [Continental T.V., Inc. v. GTE] *Sylvania* [, Inc., 433 U.S. 36 (1977), non-price restraints evaluated under the antitrust rule of reason] and *Colgate* [*supra* note 143, freedom of seller to deal with whom he wishes] will be seriously eroded," Monsanto Co. v. Spray-Rite Service Corp., 465 U.S. 752, 763 (1984).

[153] C-O-Two Fire Equip. Co. v. United States, 197 F.2d 489 (9th Cir. 1952), *cert. denied*, 344 U.S. 892 (1952).

[154] American Tobacco Co. v. United States, 328 U.S. 781 (1946).

[155] *See, e.g.*, Greater Rockford Energy & Tech. Corp. v. Shell Oil Co., 998 F.2d 391 (7th Cir. 1993); Carpet Group International v. Oriental Rug Importers Ass'n, 256 F.Supp.2d 249 (D.N.J. 2003) both standing for the proposition that mere membership in a trade association, even with the knowledge that the association is engaging in unlawful activity, is insufficient to prove that a party participated in such activity.

[156] *See, e.g.*, *Monsanto, supra* note 152, at 764: "Permitting an agreement to be inferred merely from the existence of complaints . . . could deter or penalize perfectly legitimate conduct." *See also* In re Baby Food Antitrust Litigation, *supra* note 151; Intervest, Inc. v. Bloomberg, L.P., 340 F.3d 144 (3d Cir. 2003). *But see e.g.* Toys "R" Us v. Federal Trade Commission, 221 F.3d 928, 934-935 (7th Cir. 2000: "When circumstantial evidence is used, there must be some evidence that 'tends to exclude the possibility' that the alleged conspirators acted independently. . . . The test states only that there must be some evidence which, if believed, would support a finding of concerted behavior. In the context of an appeal from the Commission, the question is whether substantial evidence supports its conclusion that it is more likely than not that the manufacturers acted collusively." (Citations omitted).

conspiracy;[157] similarly, where a defendant would have little or no motive to enter a conspiracy, his actions will be considered unilateral and independent.[158]

Based upon these cases and assuming that there is no evidence that the drug manufacturers in question conspired or colluded when reducing drug supplies to Canadian distributors and pharmacies, it would appear difficult to sustain a charge that the drug companies that limit sales to Canada have violated the Sherman Act. Indeed, there may be lawful reasons for their actions. For example, the manufacturers may be capable of supplying only the United States market and to a lesser extent foreign markets because of limited production capacity. They may also need to recoup research and development costs by obtaining a profit margin through sales primarily in the U.S. However, if one were able to show that the drug companies did in fact conspire or collude or that they engaged in parallel behavior accompanied by other factors, a case might be made for a Sherman Act violation.

In the first federal court case on the question, *In Re: Canadian Import Antitrust Litigation*, a group of consumers and organizations from Minnesota who purchased prescription drugs in the U.S. from American drug companies challenged the defendant drug companies.[159] The plaintiffs claimed that the defendants violated federal antitrust laws "by engaging in a course of conduct designed to suppress the importation of prescription drugs purchased from Canadian pharmacies for personal use in the United States."[160] The district court held that prescription drugs imported from Canada are misbranded and that "the transport of drugs for personal use into the United States constitutes an 'introduction into interstate commerce.' "[161] The introduction of misbranded drugs into interstate commerce violates the FDCA.[162] Noting that the plaintiffs lacked standing "to challenge Defendants' allegedly anti-competitive behavior because the importation of these drugs is unlawful and, therefore, not the type of activity which federal antitrust laws were designed to protect," the district court dismissed the case.[163] The district court also dismissed the

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[157] Intervest, *supra* note 156; Twombly v. Bell Atlantic Corp., 313 F.Supp.2d 174 (S.D.N.Y. 2003).

[158] Matsushita Electric Industries Co. v. Zenith Radio Corp., 475 U.S. 574 (1986); *Todorov, supra* note 152; Hall v. United Air Lines, 296 F.Supp.2d 652, 600 (E.D.N.C. 2003) (quoting *Matsushita* at 588: "[C]onduct as consistent with permissible competition as with illegal conspiracy does not, standing alone, support an inference of antitrust conspiracy. ... a plaintiff seeking damages for a violation of § 1 [of the Sherman Act] must present evidence 'that tends to exclude the possibility' that the alleged conspirators acted independently.")

[159] In Re: Canadian Import Antitrust Litig., 385 F. Supp. 2d 930 (D. Minn. 2005) *aff'd*, 470 F.3d 785 (8th Cir. 2006).

[160] *Id.* at 932.

[161] *Id.* at 934.

[162] 21 U.S.C. §331(a).

[163] 385 F. Supp. 2d at 932.

state and common law claims, which were ancillary to the federal antitrust claim, after deciding not to exercise supplemental jurisdiction over them.[164]

On appeal, the United States Court of Appeals for the Eighth Circuit affirmed the district court judgment, finding that the importation of prescription drugs from Canada is illegal and that the plaintiffs did not have standing under antitrust laws to maintain the suit. Even if importation were legal, according to the court, the antitrust injury that the plaintiffs encountered — "an absence of competition from Canadian sources in the domestic prescription drug market" — was not a result of the defendants' behavior and was not an injury that the antitrust laws were designed to prevent. Rather, the injury to the plaintiffs was "caused by the federal statutory and regulatory scheme adopted by the United States government."[165] Although this decision is not binding on courts in other jurisdictions, it provides an initial glimpse of how the antitrust issue may play out in the courts.

Despite the apparent lack of violation of federal antitrust law, drug manufacturers that limit sales of prescription drugs to Canadian distributors and pharmacies may still violate state antitrust laws. Because antitrust laws vary from state to state, this section does not provide an exhaustive analysis of state antitrust laws, but rather describes the legal dispute between GlaxoSmithKline (GSK) and the state of Minnesota as an example of potential liability under state antitrust statutes.

State Antitrust Law.

Even if drug manufacturers that limit sales of prescription drugs to certain Canadian distributors and pharmacies are found not to have violated federal antitrust laws, they may still be in violation of state antitrust law. Antitrust laws exist in all fifty states and the District of Columbia, but their scope and enforcement differ from state to state.[166] Most state antitrust laws mirror the federal statutes or are interpreted to reflect case law interpreting these federal statutes,[167] although there are a small number of states in which a restraint of trade violation includes a unilateral act.[168] This section describes the recent legal dispute between the state of Minnesota and GlaxoSmithKline (GSK) over state antitrust law and its effect on prescription drug importation.

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[164] *Id.* at 934.

[165] In Re: Canadian Import Antitrust Litig., 470 F.3d 785, 791 (8th Cir. 2006).

[166] *See generally*, Section of Antitrust Law, American Bar Association, STATE ANTITRUST ENFORCEMENT HANDBOOK, 2003.

[167] *Id.*; *see, e.g.*, Minnesota Twins Partnership v. State ex rel. Hatch, 592 N.W.2d 847, 851 (Minn. Ct. App. 1999), *cert. den.,* Hatch v. Minnesota Twins Partnership*,* 528 U.S. 1013 (1999): "Minnesota's antitrust laws are generally interpreted consistently with federal courts' construction of federal antitrust laws," *citing,* State by Humphrey v. Alpine Air Products, Inc., 490 N.W.2d 888, 894 (Minn. Ct. App.1992), *aff'd*, 500 N.W.2d 788 (Minn. S.Ct. 1993).

[168] E.g., § 203(A) of the *Oklahoma Antitrust Reform Act* (OKLA. STAT. tit. 79, §§ 201 *et seq.*) makes illegal and "against public policy" not only agreements, contracts, or combinations in restraint of trade, but also "acts" in restraint of trade.

In late 2003, the Minnesota Attorney General (AG), who is investigating whether GSK violated Minnesota antitrust laws,[169] filed a court motion seeking to compel GSK to release information located in Canada and the United Kingdom about the company's decision to stop selling drugs to Canadian pharmacies that then sell the drugs to U.S. consumers. According to the AG, GSK conspired to limit drug sales to Canada, and "GSK's refusal to supply prescription drugs to Canadian pharmacies that sell drugs to Minnesota buyers violates state laws."[170] In return, GSK argued that "importing drugs from Canada is illegal and a drug company can take steps to stop illegal sales of its products;"[171] and also that federal law preempts Minnesota's antitrust laws. Ultimately, the district court of Hennepin County, Minnesota, ordered GSK to produce the records and information sought by the AG.[172] The court ruled that even if GSK's position that "the importation of non-approved drugs from Canada is illegal under the FDCA, and there cannot be a conspiracy in violation of the antitrust laws to restrain trade in illegal goods"[173] were correct, which the court questioned, "[e]nforcement of federal law is the responsibility of the FDA, not of GSK," especially since "the FDA has never even reviewed GSK's boycott," much less specifically approved it.[174] The district court judge obliquely addressed the preemption argument, finding sufficient authority for the Minnesota AG's investigation and the document request in pursuit of that investigation under the Minnesota statute that mandates that the Attorney General "investigate violations of the business and trade laws of this state ... ."[175]

Based on information revealed in the GSK documents that were turned over, the Minnesota AG filed a lawsuit against GSK in 2004, alleging that the company had violated state antitrust laws.[176] The case has yet to go to trial as GSK and the Minnesota AG have been mired in fighting over the public release of documents turned over by GSK.[177] Minnesota's case against GSK may have been harmed by a

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[169] Minn. Stat. §§ 325D.49 et seq.

[170] Inside Washington Publishers, *Judge Wants More Info Before Deciding Motion to Compel Against GSK*, FDA WEEK, Nov. 21, 2003.

[171] *Id.*

[172] In the Matter of GlaxoSmithKline plc, File No. MC 03-15992 (Minn. District Ct., May 7, 2004) (Slip opinion).

[173] *Id.* at 11.

[174] *Id.*

[175] *Id.* at 6, citing Minn. Stat. § 8.31(2002).

[176] Inside Washington Publishers, *Minnesota Tries to Publicize GSK Documents to Bolster Antitrust Suit*, FDA WEEK, Dec. 17, 2004.

[177] The Minnesota Court of Appeals reversed a decision by the Hennepin County district court that denied a motion by the Minnesota AG to declare that 44 documents designated "confidential" by GSK were not confidential. In the Matter of GlaxoSmithKline plc, 713 N.W. 2d 48, 52 (2006). The Minnesota Court of Appeals held: (1) that the state of Minnesota could challenge GSK's confidential designations, (2) that the state could disclose GSK's "confidential" documents because the court found that they were not "protected nonpublic data," and (3) that the documents were not protected by the First Amendment.

(continued...)

federal court decision in *In re: Canadian Import Antitrust Litigation*, which determined that drug manufacturers had not violated federal antitrust law by attempting to halt the importation of prescription drugs.[178]

International Trade Law[179]

As with antitrust law, international trade obligations may also impact the feasibility of prescription drug importation. On the one hand, permitting some importation of prescription drugs may be seen as removing an existing barrier to trade or trade liberalizing; on the other hand, the United States' international trade obligations may present obstacles to prescription drug importation. Furthermore, legislative and/or regulatory proposals regarding importation may be inconsistent with provisions of various international trade agreements including, but not limited to, the General Agreement on Tariffs and Trade 1994 (GATT 1994), the Agreement on Technical Barriers to Trade (TBT) and the General Agreement on Trade in Services (GATS), all of which are a part of the World Trade Organization (WTO) Agreement to which the United States is a signatory member.[180] At the same time, however, these agreements contain exceptions that may be used to justify some of the potential inconsistencies that may arise.

General Agreement on Tariffs and Trade.

Under the GATT 1994, Articles III:4, I:1 and XI:1 contain provisions that may affect prescription drug imports. Generally, Article III governs the application of domestic regulatory measures requiring that "laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products ... should not be applied to domestic products so as to afford protection to domestic production." Article III:4 specifically obligates Member countries, with respect to all such domestic measures, to provide national treatment to imported products from other WTO Member countries. Simply put, national treatment requires that Member countries not discriminate against imported goods relative to like domestic products. In addition to the national treatment obligation, internal regulatory measures are also required to comply with Article I:1, the most-favored-nation (MFN) clause. MFN requires that "any advantage, favor, privilege

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[177] (...continued)
Id. at 55, 57-58. The Minnesota Supreme Court recently granted GSK's petition for review of the Court of Appeals decision. In the Matter of GlaxoSmithKline plc, No. A04-2150, 2006 Minn. LEXIS 405 (June 28, 2006).

[178] See *supra* notes 159-162 and accompanying text.

[179] This section was written by Todd B. Tatelman, Legislative Attorney in the American Law Division of CRS.

[180] It should be noted that many of the same issues raised in the WTO context may also arise with respect to the North American Free Trade Agreement (NAFTA), to which the United States, Canada, and Mexico are signatories. While it appears that under NAFTA similar defenses are potentially available, the rationales and analysis may be quite different. Furthermore, issues have been raised with respect to other Free Trade Agreements (FTA) to which the United States is a party; however, since each agreement contains different provisions, they should be analyzed independently and are beyond the scope of this report.

or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties." The inclusion of Article III measures within the Article I:1 MFN obligation was intended to extend the obligation to them "regardless of whether national treatment is provided with respect to these matters."[181]

To the extent that any legislative or regulatory proposal contains requirements affecting the internal sale, offering for sale, purchase, transportation, distribution, or use of prescription drugs in the United States, it could be viewed as falling within the purview of Article III. The provisions of Article III have been interpreted broadly, with the use of the word "affecting" having been interpreted as implying that the drafters of the Article intended it to apply to "not only the laws and regulations which directly govern[] the conditions of sale or purchase, but also in any law or regulations which might adversely modify the conditions of competition between the domestic and imported products in the international market."[182] Given this broad interpretation, it appears that any proposals containing provisions affecting the labeling of imported drugs,[183] or requiring that prescription drugs produced in foreign countries for importation be destined only for the United States may be interpreted by the WTO as inconsistent with our national treatment and MFN obligations.

In addition to potential conflicts with Articles III:4 and I:1, GATT Article XI:1 prohibits a Member country from instituting or maintaining quantitative prohibitions or restrictions "on the importation of any product of the territory of any other contracting party."[184] The language of Article XI has been interpreted to be comprehensive, applying to "all measures instituted or maintained by a contracting party prohibiting or restricting the importation, exportation ... of the products other than measures that take the form of taxes duties and charges."[185] Measures may fall

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[181] World Trade Organization, *Analytical Index: Guide to GATT Law and Practice* 30 (6th ed. 1995) (quoting the proposal offered by the United States during the Second Session of the Preparatory Committee of the United Nations Conference on Trade in Employment, Geneva, April-October 1947).

[182] Panel Report on *Italian Discrimination Against Imported Agricultural Machinery*, GATT, Basic Instruments and Selected Documents (BISD), 7th Supp. 60, 64 ¶ 12 (1959).

[183] It should be noted that not all labeling provisions would be inconsistent with GATT obligations. Article IX of the GATT 1994 permits contracting parties to require marks of origin, and the WTO Agreement on Rules of Origin contains additional obligations. Only to the extent that a labeling requirement goes beyond what is permitted in either of these provisions could it be considered inconsistent with Article III:4.

[184] Article XI:1 states that "no prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licenses or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party."

[185] Panel Report *Japan — Trade in Semi-Conductors*, GATT, BISD, 35th Supp. 116, 153, ¶ 104 (1988).

within the scope of Article XI:1 if they "prevent the importation of goods as such,"[186] or "affect the right of importation as such."[187] Furthermore, Article XI:1 requires that any quantitative restrictions that are imposed be instituted on a non-discriminatory basis, in other words, that all exports of like products to and imports of like products of, third countries be similarly restricted or prohibited. Therefore, to the extent that any legislative or regulatory proposal appears to prohibit, or authorize prohibitions, on the importation of prescription drugs under specific circumstances, there is a possibility that the proposals may constitute or result in a measure affecting importation "as such," and thus, may be challenged under Article XI:1.

Article XX contains the general exceptions to the GATT. These general exceptions permit Members to impose otherwise GATT-inconsistent measures to fulfill certain enumerated public policy objectives, provided that the measures are not "applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade."[188] Specifically relevant to legislation involving prescription drugs is Article XX(b), which exempts measures "necessary to protect human, animal or plant life and health."[189]

To determine whether a measure is eligible for the Article XX(b) exception a three-part test, as established by the WTO Appellate Body (AB) must be applied. First, the policy must fall within the range of policies designed to protect life or health. Second, the country invoking the exception must show that any GATT/WTO inconsistent measures are "necessary" to fulfill the policy objective. Third, the measures must be applied in conformity with the introductory clause, or "chapeau," of Article XX.[190] Finally, should the United States invoke Article XX(b) in defense of the import restrictions, the United States would bear the burden of demonstrating that the measures satisfy all three parts of the test.[191]

In addition to Article XX(b), another possibly relevant GATT exception is Article XX(d), which may be invoked where an allegedly GATT-inconsistent measure can be shown to be "necessary to secure compliance with laws or regulations that are not inconsistent with the provisions of the Agreement, including

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[186] Panel Report on *Canada — Administration of Foreign Investment Review Act*, GATT, BISD, 30th Supp. 140, 162-63, ¶ 5.14 (1985).

[187] Panel Report on *Untied States — Measures Affecting Alcoholic and Malt Beverages*, GATT, BISD, 39th Supp. 206, 292, ¶ 5.63 (1993).

[188] GATT Art. XX, chapeau.

[189] *Id.* at Art. XX(b).

[190] *See* Appellate Report on *United States — Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R (Apr. 29, 1996), p. 25 [hereinafter cited as *U.S. - Gasoline (AB Report)*]. The chapeau states that measures are not prohibited so long as they are not "applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade." GATT 1994, Art. XX.

[191] *See generally* World Trade Organization, *WTO Analytical Index; Guide to WTO Law and Practice* 341-42 (1st ed. 2003)[hereinafter cited as *WTO Analytical Index*].

those related to customs enforcement, ... the protection of patents, trade marks and copyrights, and the prevention of deceptive practices."

WTO Agreement on Technical Barriers to Trade.

According to its preamble, the WTO Agreement on Technical Barriers to Trade (TBT Agreement) expands upon the GATT Article III obligations with respect to internal regulations and is intended to promote the general aims of the GATT.[192] The TBT Agreement applies to all products, including industrial and agricultural products, but does not apply to measures covered by the WTO Agreement on Sanitary and Phytosanitary Measures, nor to government purchasing specifications for production or consumption of governmental bodies.[193]

The three categories of measures covered by the TBT Agreement are: (1) technical regulations; (2) standards; and (3) conformity assessment procedures. Of particular relevance to prescription drug importation are technical regulations and conformity assessment procedures.

A "technical regulation" is defined as a "[d]ocument which lays down product characteristics or their related processing and production methods, including their administrative provisions, with which compliance is mandatory."[194] A technical regulation may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method."[195] To qualify as a "technical regulation," a measure must fulfill three criteria, derived from the above-cited definition:

> *First*, the document must apply to an identifiable product or group of products. The identifiable product or group of products need not, however, be expressly *identified* in the document. *Second*, the document must lay down one or more characteristics of the product. These product characteristics may be intrinsic, or they may be related to the product. They may be prescribed or imposed in either a positive or negative form. *Third*, compliance with the product characteristic must be mandatory.[196]

The TBT Agreement's primary obligations require that the central governments of WTO Members provide national treatment with respect to technical regulations.[197]

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[192] TBT Agreement, Preamble.

[193] *See* Appellate Body Report on *European Communities — Measures Affecting Asbestos and Asbestos Containing Products*, WT/DS135/AB/R (Mar. 12, 2001) ¶ 80 [hereinafter *EC — Asbestos (AB Report)*].

[194] TBT Agreement, Annex 1, ¶ 1.

[195] *Id.* at Annex I, ¶ 3.

[196] Appellate Body Report on *European Communities — Trade Description of Sardines*, WT/DS231/AB/R (September 26, 2002), ¶ 176.

[197] *See* TBT Agreement, Art. 2.1 (requiring Member countries to "ensure that . . . products imported from the territory of any Member shall be accorded treatment no less favourable

(continued...)

In addition, WTO Members must also "ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade."[198] This means that "technical regulations shall be no more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfillment would create. Such legitimate objectives [include] ... the prevention of deceptive practices; [and] protection of human health or safety ... ." Moreover, Members are obligated not to maintain technical regulations "if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner."[199]

A conformity assessment procedure is "[a]ny procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled."[200] Such procedures may include, among other things, "procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations."

Obligations concerning conformity assessment procedures are primarily contained in Article 5 of the TBT Agreement, which requires WTO Members to ensure that a number of specific requirements are met "where a positive assurance of conformity with technical regulations is required."[201] These include a requirement that the procedures be prepared, adopted and applied in accordance with the principles of national treatment.[202] The TBT Agreement further provides that "access entails suppliers' right to an assessment of conformity under the rules of the procedure."[203] In addition, conformity assessment procedures may not be "prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade,"[204] meaning, among other things, that "conformity assessment procedures shall not be more strict or be applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the

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[197] (...continued)
than that accorded to like products of national origin and to like products originating in any other country.").

[198] *Id.* at Art. 2.2.

[199] *Id.* at Art. 2.3.

[200] *Id.* at Annex 1, ¶ 3.

[201] *Id.* at Art. 5.1.

[202] *Id.* at Art. 5.1.1 (stating that suppliers are to be granted access to "like products originating in the territories of other Members under conditions no less favourable than those accorded to suppliers of like products of national origin or originating in any other country, in a comparable situation").

[203] *Id.*

[204] *Id.* at Art. 5.1.2.

applicable technical regulations ... , taking account of the risks non-conformity would create."[205]

Application of the TBT Agreement will depend on the details of any prescription drug importation program that might be enacted. The AB has speculated that a measure consisting "*only* of a prohibition on ... [a product] ... might not constitute a 'technical regulation,'" thereby placing it outside the scope of the TBT Agreement.[206] On the other hand, a measure that has both "prohibitive and permissive elements" may potentially be covered by the Agreement.[207] If a legislative or regulatory proposal were to be considered solely in light of provisions that would allow importation of drugs from a limited set of approved countries, the proposal could potentially be viewed as constituting solely a prohibition (albeit implied) on importing prescription drugs from countries other than those named or designated as such. One might thus be able to argue, based on the above-quoted AB statement, that there are no issues under the TBT Agreement. On the other hand, were any such proposal to be viewed more broadly — that is, as having both prohibitive and permissive elements — TBT obligations may come into play.

While the TBT Agreement does not contain a separate Article with general exceptions, there is language within the Agreement that appears to provide for something similar to an Article XX(b) exception. Specifically, the Preamble to the TBT Agreement states that "no country should be prevented from taking measures necessary ... for the protection of human, animal or plant life or health ... ."[208] Given that there has been no WTO panel or AB ruling to date with respect to this language, it remains unclear as to what, if any, weight or interpretation this language would be given, especially considering it appears only in the Preamble and is not within the body of the agreement.

General Agreement on Trade in Services.

The General Agreement on Trade in Services (GATS)[209] applies to "measures by Members affecting trade in services."[210] The Agreement defines trade in services as the supply of a service through four modes, two of which would appear to be most relevant to the issue of prescription drug importation: cross-border supply, or supply "from the territory of one Member into the territory of any other Member" (Mode 1)

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[205] *Id.*

[206] *EC — Asbestos (AB Report)*, *supra* note 190, at ¶ 71.

[207] *Id.* at ¶ 64.

[208] TBT Agreement, Preamble.

[209] General Agreement on Trade in Services (GATS), entered into force January 1, 1995, H.Doc.103-316, v.1, at 1586-1653, and v. 2, at 3748 [http://www.wto.org/English/docs_e/legal_e/26-gats.pdf].

[210] GATS, Art. I:1.

and consumption abroad, or supply "in the territory of one Member to the service consumer of any other Member" (Mode 2).[211]

For purposes of the GATS, the phrase "measures by Members affecting trade in services" has been interpreted broadly, encompassing "any measure of a Member to the extent it affects the supply of a service regardless of whether such measure directly governs the supply of a service or whether it regulates other matters but nevertheless affects trade in services."[212]

A basic obligation of the GATS is the unconditional most-favored-nation (MFN) obligation set forth at Article II:1. The obligation applies to "any" GATS-covered measure, though Members are allowed to exempt specific national measures pursuant to Article II:1 and the Annex on Article II Exemptions and may accord preferential treatment to countries that are members of regional trade agreements (*see* GATS, Arts. V and V *bis*). The other fundamental GATS obligations are the market access and national treatment obligations made with respect to a Member's specific scheduled sectoral commitments.[213] These are set forth, with any limitations, in the Member's Schedule of Specific Commitments by mode of service supply. As with the TBT Agreement, application of the GATS will depend on the details of any specific prescription drug importation that might be enacted. For example, in the event that a legislative or regulatory proposal affects the wholesale distribution of prescription drugs, the measure may be subject to a WTO challenge as inconsistent with our specific GATS commitments.

GATS obligations are also subject to various general exceptions at Article XIV, including one for measures "necessary to protect human, animal, or plant life or health." General exceptions are subject to a requirement that such measures "are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where like conditions prevail, or a disguised restriction on trade in services." While there does not appear to be any WTO jurisprudence on this exception to date, it would seem that the same or similar test as the GATT Article XX(b) exception would also be applicable with respect to the GATS Article XIV. It should be noted, however, that the GATS contains the phrase "like conditions" as opposed to the phrase "same conditions" found in the GATT.

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[211] GATS, Art. I:2. The other two modes of service supply — commercial presence of one Member in the territory of any other Member, and presence of natural persons, or supply "by a service supplier of one Member, through presence of natural persons of a Member, in the territory of any other Member — would not seem to be directly at issue here.

[212] Panel Report on *EC — Regime for the Importation, Sale and Distribution of Bananas,* WT/DS27/R/USA (May 22, 1997) ¶ 7.285. *See generally WTO Analytical Index, supra* note 188, at 1089-91.

[213] GATS, Arts. XVI, XVII. Article XXI of the GATS allows a WTO Member to modify or withdraw any of its scheduled commitments, once three years have elapsed from the date the commitment entered into force, subject to certain conditions, including possible compensation to Members affected by the change.

In the absence of any WTO jurisprudence, it remains unclear whether this change in language would have any effect on the application of the exception.[214]

Patent Law

In addition to raising questions about antitrust law and trade law, the issue of prescription drug imports has also prompted inquiries regarding whether or not a drug importation program would violate patent rights. In particular, a federal court case, *Jazz Photo Corp. v. ITC*,[215] has raised the prospect that a drug manufacturer could, under certain circumstances, sue a drug importer for patent infringement and block U.S. imports of drugs the company sells abroad. Under patent law, the first sale of a patented product in a given market extinguishes, or "exhausts," the patent holder's rights in the product. Prior to the *Jazz Photo* decision, some legal commentators believed that this exhaustion doctrine extended internationally, meaning that the sale of a patented product abroad would exhaust the patent rights in the U.S. and elsewhere, thereby allowing the purchaser of the product to use, sell, or otherwise do as he pleases with the product without regard to the patent holder, unless the purchaser is contractually restricted from importing into the U.S.

In *Jazz Photo*, however, the court, which addressed the exhaustion doctrine question only briefly, stated: "United States patent rights are not exhausted by products of foreign provenance. To invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent."[216] Under this ruling, because the U.S. patent is not exhausted by the foreign sale, the patent holder retains its patent rights. Thus, a drug manufacturer could exercise these rights to block imports of its patented drug products into the U.S. It is important to note, however, that some legal commentators have questioned the validity of the ruling in the *Jazz Photo* case, and at least one bill proposed in the 109th Congress would have overturned the ruling with respect to patent exhaustion for pharmaceutical imports.[217] For further information on the subject, see CRS Report RL32400, *Patents and Drug Importation*, by John R. Thomas.

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[214] Should the United States take any legislative or regulatory action with respect to the importation of prescription drugs, any challenges that are brought on international trade grounds will be required to be adjudicated under the procedures set forth in the specific agreement. For example, if a challenge is brought pursuant to a WTO Agreement, that challenge will be required to be heard according to the procedures contained in the WTO Dispute Settlement Understanding. *See* CRS Report RS20088, *Dispute Settlement in the World Trade Organization: An Overview*, by Jeanne J. Grimmett; *see also* WTO website [http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm].

[215] 264 F.3d 1094 (Fed. Cir. 2001).

[216] *Id.* at 1105

[217] *See* S. 334 (109th Congress). The Federal Circuit has subsequently upheld its *Jazz Photo* ruling in Fuji Photo Film Co. v. Jazz Photo Corp., 394 F.3d 1368 (Fed. Cir. 2005).

III. Internet Pharmacies

Just as the FDA has expressed concerns about the safety of imported drugs, federal regulators have become increasingly worried about the safety of online pharmacies and prescription drug sales over the Internet.[218] Indeed, the regulation of prescription drug importation and the regulation of online pharmacies often overlap because many consumers use online pharmacies to purchase imported drugs. Regardless of whether or not drugs purchased online are imported, the FDA is worried about the safety of such medications because of concerns about the lack of adequate physician supervision for consumers who purchase prescription drugs online, the prospects for tampering with or counterfeiting such drugs, and the possibility that such drugs may be handled, dispensed, packaged, or shipped incorrectly. This section discusses current laws and regulations that govern online pharmacies and physicians who prescribe medications over the Internet. Specifically, this section provides an overview of the various federal and state laws that regulate this field, including laws covering prescription drugs, controlled substances, pharmacies, and the practice of medicine.

With the advent of the Internet, many individuals have turned from traditional neighborhood pharmacies and large chains with a neighborhood presence to online pharmacies to purchase prescription drugs, and an increasing number of physicians have incorporated the Internet and email into their medical practice. Use of this technology has many advantages for both the doctor and the patient, including cost savings, convenience, accessibility, and improved privacy and communication.[219] Although many online pharmacies are legitimate businesses that offer safe and convenient services similar to those provided by traditional neighborhood pharmacies, other online pharmacies — often referred to as "rogue sites" — engage in practices that are illegal, such as selling unapproved or counterfeit drugs or dispensing drugs without a prescription.[220] Some rogue sites operate in a legal gray area in which the online pharmacy, as mandated by federal law, requires a prescription before dispensing prescription drugs, but allows patients to secure a prescription by completing an online questionnaire that is reviewed by a doctor who never examines or speaks to the patient. This practice, though potentially unsafe for patients who may be diagnosed incorrectly, is not necessarily illegal.

Current regulation of online pharmacies and doctors consists of a patchwork of federal and state laws in an array of areas. At the federal level, the FDA regulates prescription drugs under the FDCA, which governs, among other things, the safety and efficacy of prescription medications, including the approval, manufacturing, and

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[218] Some of these concerns are reflected in a report by the Government Accountability Office (GAO; formerly the General Accounting Office). GAO Report GAO-04-820, *Internet Pharmacies: Some Pose Safety Risks for Consumers*.

[219] Food and Drug Administration, *Buying Drugs Online: It's Convenient and Private, But Beware of 'Rogue Sites'* (2001), [http://www.fda.gov/fdac/features/2000/100_online.html].

[220] *Id*.

distribution of such drugs.[221] It is the FDCA that requires that prescription drugs may be dispensed only with a valid prescription.[222] The DEA enforces the Controlled Substances Act (CSA), which is a federal statute that establishes criminal and civil sanctions for the unlawful possession, manufacturing, distribution, or importation of controlled substances.[223] At the state level, state boards of pharmacy regulate pharmacy practice, and state medical boards oversee the practice of medicine.[224] Thus, some of the laws that govern online pharmacies and doctors vary from state to state. The laws that govern each of these areas are described separately below.

Federal Oversight

As noted above, the CSA is a federal statute that establishes criminal and civil sanctions for the unlawful possession, manufacturing, distribution, or importation of controlled substances.[225] The primary purpose of the CSA is to facilitate the legal distribution of controlled substances for legitimate medical purposes while preventing their diversion for illegal uses. Although the CSA is generally known for prohibiting illegal drugs that have a high potential for abuse and no accepted medical use, such as heroin or cocaine, the statute also covers a range of other drugs that have a lesser potential for abuse and an accepted medical use, including certain prescription drugs. Although most prescription drugs are not controlled substances and therefore are not regulated under the CSA, some prescription drugs, such as narcotics and opiates that are often used in the treatment of pain, are regulated under the CSA because they have a greater potential for abuse than other prescription drugs and may lead to physical dependence.

It is the latter category of prescription painkillers that appear to be among the drugs most heavily dispensed by certain Internet pharmacies in accordance with prescriptions that are issued based on online questionnaires.[226] This practice has sometimes been abused by rogue sites that dispense large quantities of addictive substances to customers apparently seeking access to prescription painkillers, and it has lead to instances of addiction, overdose, and death. In response to cases in which online doctors have written thousands of prescriptions for controlled substances without examining their patients, the federal government has begun prosecuting certain doctors under the CSA by charging them with the illegal distribution of

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[221] 21 U.S.C. § 301 et seq.

[222] *Id*. at § 353(b).

[223] *Id*. at § 801 et seq. For more information on the Controlled Substances Act, see CRS Report 97-141A, *Drug Smuggling, Drug Dealing and Drug Abuse: Background and Overview of the Sanctions Under the Federal Controlled Substances Act and Related Statutes*, by Charles Doyle.

[224] The FDCA excludes the practice of medicine from its jurisdiction. 21 U.S.C. § 396.

[225] *Id.* at § 801 et seq.

[226] *See, e.g.*, Gilbert M. Gaul and Mary Pat Flaherty, *Doctors Medicate Strangers on Web*, WASH. POST, Oct. 21, 2003, at A1.

controlled substances.[227] Penalties under the CSA vary depending on the amount and type of substance involved but generally include monetary fines, forfeiture, and imprisonment.[228]

In addition, the CSA regulates imports and exports of controlled substances. Under the statute, it is unlawful to import a controlled substance into the country unless the importer is registered with the DEA and has obtained DEA approval to engage in such importation. Illegal importation of controlled substances is a felony that may result in imprisonment or fines.[229] Because the DEA considers anyone who causes controlled substances to be brought into the country to be an importer of controlled substances, an individual or pharmacy who causes controlled substances to be mailed or shipped into the U.S. may violate the law and be subject to criminal penalties.[230] Specifically, the DEA notes:

> It is illegal for a United States consumer or business to have controlled substances shipped to the United States from a foreign country unless the person receiving the controlled substances is registered with DEA as an importer or researcher and is in compliance with [controlled substances laws and regulations]. ... The acquisition of a controlled substance from a foreign country by any person other than a DEA-registered importer or researcher is a violation of the Controlled Substances Act. Therefore, United States pharmacies which fill prescriptions for controlled substances by obtaining those controlled substances from Canada, or any other foreign country, are in violation of the Controlled Substances Act, regardless of whether the consumer possesses a legitimate prescription issued by a United States practitioner in the usual course of their professional practice. Likewise, consumers are also in violation of the Controlled Substances Act if they have prescriptions for controlled substances filled in foreign countries and shipped to the United States.[231]

As noted above, prescription drugs are also regulated by the FDA under the FDCA.[232] Although state law also governs the prescribing of drugs, the FDCA covers certain aspects of the prescribing process, including the requirement that prescription drugs may not be dispensed without a valid prescription.[233]

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[227] *Id*.

[228] 21 U.S.C. § 841 et seq.

[229] *Id*. at §§ 957, 960.

[230] *See, e.g.*, Importing Controlled Substances From Canada and Other Foreign Countries, 69 FR 38920 (June 29, 2004).

[231] *Id*. at 38921-22. The CSA contains a limited exception for personal medical use, which allows U.S. residents who travel to foreign countries and non-U.S. residents who travel to the United States to carry controlled substances for their legitimate personal medical use, but this exception does not permit the shipment of controlled substances into the country for purposes of an individual's personal medical use. 21 U.S.C. § 956.

[232] *Id* at § 301 et seq.

[233] *Id*. at § 353(b).

Although federal law requires that prescription drugs be dispensed in accordance with a prescription, the FDCA does not define the meaning of "prescription." Rather, each state defines what constitutes a valid prescription under its pharmacy laws. Because such definitions differ from state to state, there is no uniform, national definition of the term "prescription."[234] Thus, certain activities, such as prescribing drugs without performing an in-person examination, may be explicitly illegal in one state but of ambiguous legal status in another.

Concerned about reports of rogue online pharmacies, Congress has considered legislation to establish a federal definition of what constitutes a valid prescription.[235] For example, such legislation has included proposals to establish a single federal standard for prescriptions or to require online pharmacies to disclose information about themselves and about the doctors approving prescriptions on their sites.[236] Congress has also explored the possibility of limiting the means by which allegedly rogue sites do business, namely by restricting their ability to advertise on search engines, make credit card sales, and ship prescription drugs,[237] and some companies have responded with their own proposals. For example, Google, an Internet search engine, no longer accepts advertising from unlicensed pharmacies and prohibits the use of certain controlled substances as keywords for search purposes.[238] Because federal and state regulators face many legal barriers when attempting to exercise jurisdiction over rogue pharmacies based in foreign countries,[239] placing limits on the degree to which search engines, credit card companies, and shipping entities enable rogue sites to sell prescription drug may be one of the only ways to control illicit sales by foreign online pharmacies.

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[234] Inside Washington Publishers, *FDA May Back Changing Law to Define Internet 'Prescription'*, FDA WEEK, March 28, 2003.

[235] *Id*.

[236] *See, e.g., Point, Click, Self-Medicate: A Review of Consumer Safeguards on Internet Pharmacy Sites: Hearing Before the House Comm. On Government Reform*, 108th Cong. (2003). In the 109th Congress, the following bills addressed this issue: H.R. 840, H.R. 1808, H.R. 4769, S. 399, and S. 3834. See also H.R. 616, H.R. 2652, H.R. 2717, H.R. 3870, H.R. 3880, H.R. 4612, H.R. 4790, S. 2464, and S. 2493 in the 108th Congress.

[237] Gilbert M. Gaul and Mary Pat Flaherty, *Google to Limit Some Drug Ads*, WASH. POST, Dec. 1, 2003, at A1. The Bush Administration has also expressed interest in pursuing such a strategy. Press Release, Office of National Drug Control Policy, U.S. Drug Prevention, Treatment, Enforcement Agencies Take on "Doctor Shoppers," "Pill Mills" (Mar. 1, 2004), [http://www.whitehousedrugpolicy.gov/news/press04/030104.html].

[238] Gaul and Flaherty, *supra* note 234.

[239] "The enforcement of a state action or the initiation of a mutual action by a foreign licensing body is virtually unheard of, making it difficult, if not impossible, for state actions to have any effect on foreign pharmacies." National Association of Boards of Pharmacy, *Position Paper on the Importation of Foreign Prescription Drugs* 6 (March 2003), at [http://www.nabp.net/ftpfiles/NABP01/foreigndrug.pdf].

State Oversight

As noted above, state boards of pharmacy are primarily responsible for regulating pharmacy practice,[240] although the FDCA does provide some federal oversight of pharmacies. Because virtually all states require a pharmacy that sells drugs in the state to be licensed with the state, a state board of pharmacy traditionally may exercise regulatory authority over pharmacies and pharmacists located within the state, as well as those that dispense medication across state lines to citizens within the state.[241]

Because each state board of pharmacy sets its own policies with regard to both online and traditional pharmacies, state pharmacy laws regarding Internet pharmacies and doctors differ from state to state. While some state laws specify whether or not prescriptions based on online questionnaires are valid, other state laws fail to address the issue, thus rendering it difficult for some states to prosecute doctors who prescribe drugs without performing an in-person evaluation. For this reason, some critics of the current system have proposed establishing a federal definition of what constitutes a valid prescription.[242]

In addition, some organizations have begun to promote uniform national standards for the industry. For example, the National Association of Boards of Pharmacy (NABP) is an organization that helps state boards of pharmacy by developing uniform standards on pharmacy practice. In response to the proliferation of online pharmacies, NABP established the Verified Internet Pharmacy Practice Sites (VIPPS) program, a certification program that "identifies to the public those online pharmacy practice sites that are appropriately licensed, are legitimately operating via the Internet, and that have successfully completed a rigorous criteria review and inspection."[243] According to NABP, the VIPPS program was developed in order to improve the safety of online pharmacy practices and to "provide a means for the public to distinguish between legitimate and illegitimate online pharmacy

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[240] National Association of Boards of Pharmacy, *Verified Internet Pharmacy Practice Sites (VIPPS): Most Frequently Asked Questions* (2001), at [http://www.nabp.net].

[241] *Id.* "These requirements allow state boards of pharmacy to order non-resident pharmacies to stop shipping product into the state. Within the US, such orders can be enforced by the board of pharmacy where the violation took place, or by mutual action by the board of pharmacy in the state where the pharmacy is located." National Association of Boards of Pharmacy, *Position Paper on the Importation of Foreign Prescription Drugs* 6 (March 2003), at [http://www.nabp.net/ftpfiles/NABP01/foreigndrug.pdf]. Foreign shipments of prescription drugs may also violate state laws if the foreign pharmacy is not licensed in the state, although states often face legal barriers when attempting to exercise jurisdiction over foreign pharmacies.

[242] Inside Washington Publishers, *FDA May Back Changing Law to Define Internet 'Prescription'*, FDA WEEK, March 28, 2003; *see also supra* notes 232-233 and accompanying text.

[243] National Association of Boards of Pharmacy, *Verified Internet Pharmacy Practice Sites (VIPPS): Most Frequently Asked Questions* (2001), at [http://www.nabp.net].

practice sites."[244] Although NABP notes that legitimate online pharmacies outnumber rogue sites and acknowledges that there are many advantages to ordering drugs online, the Association specifically warns consumers against buying prescription drugs online without obtaining an in-person examination and valid prescription from a doctor. Like U.S. pharmacies, Canadian pharmacies may also be certified under the VIPPS program, but only if they do not export drugs to the U.S.[245] However, NABP has indicated that it may extend its VIPPS certification program to Canadian pharmacies that sell to U.S. consumers if Congress approves drug importation or "if HHS does not stop the state and local governments that already are reimporting drugs."[246]

Like pharmacy practice, the practice of medicine has historically been regulated at the state level by state medical boards. According to the Federation of State Medical Boards (FSMB), which coordinates policy among all state medical boards, "[t]he primary responsibility and obligation of a state medical board is to protect consumers of health care through proper licensing and regulation of physicians."[247] Traditionally, states enact laws that regulate the practice of medicine, and state medical boards implement and oversee state policies.[248] If a doctor violates a state law or regulation, state medical boards generally have the authority to discipline the doctor through modification, suspension, or revocation of the doctor's license to practice medicine in that state. In reality, however, laws regarding medical practice vary widely in strength and effectiveness from state to state. While some states have strong laws that explicitly prohibit activities such as prescribing drugs without conducting an in-person examination, other states have weak laws, lax enforcement, or both.

Like NABP, FSMB has developed a specific policy with regard to online pharmacies and doctors that prescribe drugs over the Internet. According to FSMB's model guidelines on the subject, electronic technology "should supplement and enhance, but not replace, crucial interpersonal interactions that create the very basis of the physician-patient relationship."[249] To that end, FSMB guidelines declare that doctors who use the Internet as part of their medical practice should conduct a physical evaluation of the patient before providing treatment. Although FSMB recognizes the benefits of online pharmacies, the organization emphasizes that

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[244] *Id*.

[245] Inside Washington Publishers, *FDA Rebuffs Invitations to Inspect Canadian Pharmacies*, FDA WEEK, May 7, 2004. However, the Canadian International Pharmacy Association (CIPA), which maintains a certification program similar to VIPPS, allows CIPA-certified members to export drugs to the U.S. [http://www.ciparx.ca].

[246] Inside Washington Publishers, *Canadian Internet Pharmacies Ask NABP to Certify Their Operations*, FDA WEEK, Sept. 17, 2004.

[247] Federation of State Medical Boards, *What is a State Medical Board?*, [http://www.fsmb.org/pdf/PUB_WhatIs_StateMedicalBoard_Brochure.pdf].

[248] *Id.*

[249] Federation of State Medical Boards, *Model Guidelines for the Appropriate Use of the Internet in Medical Practice* (2002), at 5 [http://www.fsmb.org/pdf/2002_grpol_Use_of_Internet.pdf].

"[t]reatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care."[250] FSMB further urges that doctors who prescribe drugs on the Internet should be licensed in all states in which their patients reside,[251] a practice that would subject doctors to the oversight of the medical boards in each state in which their patients lived.[252] These professional standards, however, are not legally enforceable in the absence of state laws establishing such requirements.

In addition to establishing policies regarding what constitutes a valid prescription, some states have explored other methods to deter the diversion and abuse of controlled substances. For example, some states have established prescription drug monitoring programs that track data regarding the prescribing and use of controlled substances.[253] Although such programs enable doctors and pharmacies to check whether patients have been seeking controlled substances from other doctors and pharmacies, such programs may be circumvented if patients seek controlled substances from illegal Internet pharmacies.

IV. Conclusion

The current legal framework for regulating online pharmacies and doctors is a patchwork of federal and state laws regarding controlled substances, prescription drugs, pharmacies, and the practice of medicine. Although many doctors and pharmacies who use the Internet prescribe and dispense drugs in a responsible, safe, and legal fashion, others have exploited gaps in the current system to prescribe and dispense potentially dangerous quantities of highly addictive prescription drugs. To combat such abuses, legislators and interest groups have proposed an array of solutions, including establishing a federal definition of what constitutes a valid prescription, requiring doctors to conduct in-person examinations, mandating that online pharmacies disclose identifying information about themselves and the doctors who work for them, establishing state prescription drug monitoring programs to track data regarding the prescription and use of controlled substances, giving state prosecutors the authority to seek nationwide injunctions against rogue sites,

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[250] *Id.* at 8.

[251] *Id.* at 9.

[252] FSMB is not the only medical organization to promulgate standards of professional conduct regarding the prescribing of drugs over the Internet. Several other professional associations, such as the American Medical Association (AMA), have also established policies regarding the safe practice of online medicine. For example, the AMA guidelines, like the FSMB guidelines, state that doctors should perform a physical evaluation of patients before prescribing medication and should be licensed in every state in which their patients reside. The AMA guidelines further advise against prescribing drugs to patients solely on the basis of online communications such as questionnaires. American Medical Association, *Guidance for Physicians on Internet Prescribing (H-120.949)* (2003), [http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-120.949.HTM].

[253] Inside Washington Publishers, *FDA Touts Efforts Against Illegal Diversion of Controlled Substances*, FDA WEEK, March 5, 2004.

educating consumers about the potential dangers of buying drugs online, and establishing certification programs to identify legitimate online pharmacies.

Meanwhile, the debate about importing prescription drugs continues as well. Although the FDA maintains that it cannot guarantee the safety of imported drugs, many U.S. consumers, in search of affordable prices, continue to purchase and import such drugs. As a result, legislators and interest groups have suggested a variety of changes to current law, including encouraging the development of more generic drugs, negotiating lower drug prices through bulk purchase programs, increasing prescription drug insurance coverage, allowing drug imports but restricting ports of entry, establishing state pilot programs, allowing only certain drugs to be imported, educating consumers about the dangers of imported drugs, allowing drug imports from approved Canadian pharmacies only, and regulating credit card companies, search engines, and shipping companies that enable rogue sites to do business.

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