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Prescription Drug Importation and Internet Sales: A Legal Overview

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Summary

As prescription drug prices have escalated in recent years, so too has consumer interest in purchasing less costly medications abroad. Meanwhile, in July, 2003, the House of Representatives passed H.R. 2427, a bill that would allow wholesalers, pharmacists, and consumers to import certain prescription drugs from 25 different countries, including Canada, where drug prices are often lower than in the United States. Although H.R. 2427 passed the House, the provisions allowing drug importation faced opposition in the Senate and were not included in the conference agreement on Medicare prescription drug benefits. Instead, the final Medicare 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 certifies that implementing such a program is safe and reduces costs, a determination that no Secretary has made in the years since a similar certification requirement was established in 2000.

Despite the compromise reached in the final Medicare bill, the debate about drug importation continues. On the one hand, the FDA and some lawmakers remain opposed to allowing prescription drugs to be imported from foreign countries, arguing that the FDA cannot guarantee the safety of such drugs. On the other hand, 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.

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. 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 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, several congressional lawmakers have introduced the following bills: H.R. 616, H.R. 780, H.R. 847, H.R. 2497, H.R. 2652, H.R. 2717, H.R. 2769, S. 1781, S. 1974, and S. 1992. Currently, the following federal and state agencies are involved in regulating aspects of prescription drug importation and Internet sales: the Food and Drug Administration, the U.S. Customs and Border Protection (CBP), the Drug Enforcement Agency (DEA), state boards of pharmacy, and state medical boards. Although this report is intended to focus on legal aspects of prescription drug importation and Internet sales, both legal and policy issues are addressed because they are closely linked. For a more complete analysis of policy issues, see CRS Report RL31503, *Importing Prescription Drugs* and CRS Report RL32107, *Importing Prescription Drugs – Comparison of the Drug Import Provisions in the Medicare Reform Bills, H.R. 2427, and Current Law*.

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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, both legal and policy issues are addressed because they are closely linked. For a more complete analysis of policy issues, see CRS Report RL31503, *Importing Prescription Drugs* and CRS Report RL32107, *Importing Prescription Drugs – Comparison of the Drug Import Provisions in the Medicare Reform Bills, H.R. 2427, and Current Law*.

I. Introduction

As prescription drug prices have escalated in recent years, so too has consumer interest in purchasing less costly medications abroad. Meanwhile, congressional legislators have been exploring a variety of legislative solutions to the problems posed by rising drug costs. In July, 2003, the House of Representatives passed H.R. 2427, a bill that would allow wholesalers, pharmacists, and consumers to import prescription drugs that are approved by the Food and Drug Administration (FDA) and that are manufactured in FDA-approved plants. Under the bill, drugs could be imported from 25 different countries, including Canada, where drug prices are often lower than in the United States. Despite opposition from the leadership, H.R. 2427 easily passed the House, but the provisions allowing drug importation faced opposition in the Senate and were not included in the conference agreement on Medicare prescription drug benefits. Instead, the final Medicare bill, H.R. 1, modified a provision of existing law that authorizes the 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 Secretary has made in the years since a similar certification requirement was established in 2000.[1]

Despite the fact that the final Medicare bill did not make it easier to import prescription drugs from Canada and other foreign countries, the debate about drug importation continues. On the one hand, the FDA and some lawmakers remain opposed to allowing prescription drugs to be imported from foreign countries. Worried about the risk to consumers, these critics argue that the FDA cannot guarantee the safety of such drugs,[2] which they contend are more susceptible to being mishandled, mislabeled, unapproved, or counterfeited than drugs sold domestically.

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[1] Pub. L. No. 108-173 [hereinafter Medicare Act]. The original certification provision was contained in the Medicine Equity and Drug Safety (MEDS) Act. Pub. L. No. 106-387.

[2] 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.

In addition, drug manufacturers and other opponents argue that allowing the importation or reimportation of prescription drugs would stifle investment in the research and development of new drugs.[3] On the other hand, 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. Arguing that drug manufacturers are actually concerned about their profits and not about consumer safety, 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.[4]

Linked to the issue of prescription drug importation is a debate about drug costs. While some comparisons of U.S. and Canadian drug prices conclude that U.S. prices are up to 70 percent higher than their Canadian counterparts,[5] other studies conclude that Canadian prices are actually slightly higher than U.S. prices when adjusted for per capita income.[6] In addition, there is an unresolved debate about whether allowing drug imports would affect drug prices, with supporters arguing that drug prices would drop due to competition if imports were allowed and opponents arguing 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.[7]

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. 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 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.[8]

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. In addition to H.R. 2427, several other bills – including H.R. 616, H.R. 780, H.R. 847, H.R. 2497, H.R. 2717, H.R. 2769, S. 1781, S. 1974, and S. 1992 – would amend current importation policy, and at least three bills – H.R.

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

[4] *Id.*

[5] *Id.*

[6] Inside Washington Publishers, *Canadians Pay More for Drugs When Per Capita Income Adjusted,* FDA WEEK, Dec. 19, 2003, at 1.

[7] 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.

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

616, H.R. 2652, and H.R. 2717 – would make changes to the law governing how drugs are sold online.

Current regulation of prescription drug importation and Internet sales consists of a patchwork of federal and state laws in an array of areas.[9] At the federal level, the Food and Drug Agency (FDA) regulates prescription drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA), which governs, among other things, the safety and efficacy of prescription medications, including the approval, manufacturing, and distribution of such drugs.[10] It is the FFDCA that prohibits the importation or reimportation of certain prescription drugs by anyone other than the manufacturer and that requires that prescription drugs may be dispensed only with a valid prescription.[11] Meanwhile, U.S. Customs and Border Protection (CBP) has the initial responsibility for examining imported goods at the nation's borders and for detaining any FDA-regulated products that appear to pose a health risk. 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.[12] 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.

II. Prescription Drug Importation: Legal Regulation

At the federal level, the FDA regulates prescription drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA), which governs, among other things, the safety and efficacy of prescription medications, including the approval, manufacturing, and distribution of such drugs.[13] Although many states also have their own laws that regulate drug safety, the FDA maintains primary responsibility for overseeing prescription drugs in the United States, while the DEA and CBP have somewhat more limited regulatory authority over prescription drugs.

The FFDCA contains several provisions that apply to prescription drug imports. First, the statute contains an outright prohibition that forbids anyone other than the

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[9] For other information on prescription drug importation and Internet sales, see CRS Report RL31503, *Importing Prescription Drugs*; CRS Report RL32107, *Importing Prescription Drugs – Comparison of the Drug Import Provisions in the Medicare Reform Bills, H.R. 2427, and Current Law*; and GAO Report GAO-01-69, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight*.

[10] 21 U.S.C. § 301 et seq.

[11] *Id*. at § 353(b).

[12] *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*.

[13] 21 U.S.C. § 301 et seq.

U.S. manufacturer from reimporting prescription drugs. This prohibition therefore affects drugs that originally are made in the U.S. Second, the FFDCA 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. These provisions generally affect foreign versions of drugs that are approved for domestic sale.

Both reimportation of U.S.-manufactured prescription drugs and importation of unapproved foreign versions of U.S.-approved prescription drugs are discussed in this section, as are the penalties under the FFDCA, the FDA's Personal Importation policy, state plans to import prescription drugs, and businesses that facilitate the importation of prescription drugs.

Reimportation

Currently, the FFDCA prohibits anyone other than the U.S. manufacturer of a prescription drug from reimporting that drug into the United States.[14] Thus, it is technically a violation of the statute for individual consumers or online pharmacies to reimport 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 FFDCA.[15] Although critics of this law argue that there is no rational justification for forbidding the reimportation of a drug that is theoretically identical to 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."[16]

In response to concerns about the rising costs of prescription drugs, however, Congress adopted importation amendments to the FFDCA in 2000. Under the Medicine Equity and Drug Safety (MEDS) Act,[17] the FDA was authorized to allow pharmacists and wholesalers to import prescription drugs from foreign countries if certain safety precautions were followed.[18] 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

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[14] *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).

[15] Under the FDA's Personal Importation policy, however, the FDA currently does not enforce this prohibition against individuals who import a limited supply of prescription drugs for personal use. *See infra* notes 42-49 and accompanying text.

[16] 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].

[17] Pub. L. No. 106-387.

[18] 21 U.S.C. § 384.

the cost of covered products to the American consumer."[19] Citing safety concerns, both the current and the former Secretaries declined to implement this provision.

In the recently enacted Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (hereinafter referred to as the Medicare Act),[20] Congress once again 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. Unlike the MEDS Act, which covered prescription drugs from a specified group of foreign countries, the Medicare Act allows imports from Canada only.[21] 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.[22] 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 "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."[23]As noted above, the Secretary of HHS has thus far declined to provide such certification. Absent such certification, the ban on the importation and reimportation of prescription drugs remains in effect.

Importation of Foreign Versions of Prescription Drugs

Even if the FFDCA did not contain an explicit prohibition against drug reimportation, the FDA maintains that consumer imports of prescription drugs from foreign countries would almost certainly violate other provisions of the Act.[24] For example, such drugs are likely to be unapproved,[25] mislabeled,[26] or improperly dispensed.[27] 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

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[19] *Id.* at § 384(l).

[20] Medicare Act, *supra* note 1.

[21] *Id.*

[22] *Id.* This legislation, which is similar to the FDA's Personal Importation policy, is discussed in more detail in a separate section below.

[23] *Id.*

[24] Lombardi Letter, *supra* note 16 at 2.

[25] 21 U.S.C. § 355.

[26] *Id.* at § 353(b)(2).

[27] *Id.* at § 353(b)(1).

> 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.[28]

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 FFDCA, as is the act of introducing or receiving a mislabeled drug in interstate commerce.[29] In order to be properly labeled, prescription drugs must be labeled in accordance with the FDA's extensive labeling requirements.[30] Furthermore, the FFDCA requires that prescription drugs may be dispensed only with a valid prescription.[31] Therefore, it is a violation of the Act to import prescription drugs without a legitimate U.S. prescription.

According to the FDA, a recent inspection of prescription drug shipments by U.S. Customs and Border Patrol found that 1,019 of 1,153 drug shipments from foreign countries violated the FFDCA because they "contained unapproved drugs" that "could pose clear safety problems."[32] 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.[33]

Penalties Under the FFDCA

If a business or consumer violates the FFDCA by importing unapproved or misbranded prescription drugs, there are a number of criminal and civil penalties that may apply. Although the 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.[34] A violation that occurs after a prior

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[28] Lombardi Letter, *supra* note 16 at 3.

[29] 21 U.S.C. §§ 331 (a)-(c), 353(b)(2).

[30] 21 C.F.R. §201.100(c)(2).

[31] 21 U.S.C. § 353(b)(1).

[32] Press Release, Food and Drug Administration, FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments (Sept. 29, 2003), http://www.fda.gov/bbs/topics/NEWS/2003/NEW00948.html.

[33] *Id.*

[34] 21 U.S.C. § 333(a)(1). In addition, misdemeanor violations of the Act are strict liability
(continued...)

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.[35] If a business or consumer knowingly violates the reimportation provision, then the violation is a felony offense punishable by up to 10 years in prison or up to $250,000 in fines.[36] In addition, federal courts are authorized to issue injunctions in order to enjoin violations of the Act.[37]

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."[38] 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,[39] so illegal importers could potentially be charged with these offenses as well. In addition, the FFDCA explicitly forbids certain acts, as well as the causing of such prohibited acts.[40] Thus, businesses that facilitate the importation of unapproved prescription drugs or the reimportation of U.S.-manufactured prescription drugs may be liable if they are deemed to be "causing" violations of the Act.

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."[41] Indeed, the FDA exercises its enforcement discretion leniently in this regard by allowing consumers to import certain otherwise illegal prescription drugs under certain circumstances. This enforcement policy, known as the Personal Importation policy, is described in detail below.

The FDA's Personal Importation Policy

Although importing unapproved prescription drugs is a violation of the FFDCA, it is the U.S. Customs and Border Patrol (CBP), not FDA, that has the initial responsibility for examining imported goods at the nation's borders. Accordingly, CBP notifies 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

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[34] (...continued)
offenses. United States v. Dotterweich, 320 U.S. 277, 284 (1943).

[35] 21 U.S.C. § 333(a)(2).

[36] *Id.* at §§ 333(b)(1), 381(d)(1).

[37] *Id.* at § 332.

[38] Lombardi Letter, *supra* note 16 at 1.

[39] 18 U.S.C. §§ 2, 371.

[40] 21 U.S.C. § 331.

[41] Lombardi Letter, *supra* note 16 at 4.

represent a health fraud or an unknown risk to health."[42] In order to assist agency personnel in determining when to allow or refuse entry to imported drugs, the FDA developed its Personal Importation policy.

Under the FDA's Personal Importation policy, 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 3 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.[43]

Ultimately, the Personal Importation policy is designed to set forth guidance for agency personnel regarding the FDA's enforcement priorities for imported drugs, but it is not intended to grant a license to consumers to import unapproved prescription drugs into the United States.[44] Indeed, the FDA 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."[45] Furthermore, this policy does not apply to commercial shipments of unapproved prescription drugs, nor is it 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

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[42] 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.

[43] *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.

[44] 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.

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

drugs that are already available in the U.S. do not conform to the FDA's Personal Importation policy.[46]

Meanwhile, in the recent 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.[47] Specifically, the Act 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.[48]

Although the new individual importation provisions in the Medicare Act appear similar to the FDA's Personal Importation policy, the legislation contains one important restriction: It stipulates that the new importation provisions will not become effective until and unless the Secretary certifies 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."[49] 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 policy.

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 are currently considering plans to reimport prescription drugs in order to save money on medicines which they reimburse for or provide to their residents and employees. For example, states such as California, Iowa, Illinois, Minnesota, and New Hampshire have begun exploring the prospect of drug importation, and at least one locality, Springfield, Massachusetts, has already begun to import drugs.[50] Contending that carefully

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

[47] Medicare Act, *supra* note 1 at § 1121.

[48] *Id.*

[49] *Id.*

[50] Pam Belluck, *Boldly Crossing the Line for Cheaper Drugs*, N. Y. TIMES, Dec. 11, 2003, (continued...)

structured state programs will provide a sufficient degree of safety, states 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.

Each state and local importation plan varies somewhat in the details. Springfield, for example, has been facilitating the purchase of Canadian drugs as part of a plan to provide cheaper medications to city employees, and the city estimates that it has saved it least $750,000 since beginning the program in the summer of 2003.[51] Meanwhile, officials in New Hampshire plan to import prescription drugs from Canada for state prison inmates and certain Medicaid recipients that receive medications through state drug plans. The state also intends to establish a web site for New Hampshire residents to purchase drugs from Canadian pharmacies that are licensed in Canada and approved by the state.[52] In addition, Vermont has petitioned the FDA in hope that the agency will, as it has done with regard to personal drug importation, exercise its enforcement discretion and allow Vermont to provide imported Canadian drugs to state employees.[53]

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. 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 FFDCA in virtually every instance."[54]

The FDA provides several legal arguments for reaching its conclusion that state and local drug importation is a violation of the FFDCA. First, the statute prohibits anyone other than the manufacturer from reimporting drugs that were originally

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[50] (...continued)
at A38.

[51] *Id.*

[52] *Id.*

[53] Inside Washington Publishers, *Vermont Wants FDA to Allow Drug Reimportation for State Employees,* FDA WEEK, Dec. 19, 2003, at 3. The new Medicare bill authorizes the FDA to provide waivers for individual importation, and some lawmakers are arguing 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, notes that the waiver provisions in the Medicare bill become effective only upon certification by the Secretary that drug importation is safe and reduces costs. Kelly Field, *Battle Brewing Between Administration, Local Officials Over Drug Importation Issue*, CQ TODAY, Dec. 19, 2003.

[54] 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].

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 almost certainly violate statutory requirements regarding drug approvals, labeling, and dispensing.[55] 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.[56] 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.

Finally, the FDA contends that any effort by states to enact legislation authorizing prescription drug imports would be preempted by federal law.[57] 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 FFDCA have been held not to preempt state law.[58]

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 are importing such drugs. Although "FDA and industry officials say the agency has not ruled out possible future legal action," "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."[59] In the Rx Depot case, which is discussed in detail in the following section, the FDA is pursuing legal action against a private company that helps individual consumers import prescription drugs.

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[55] *Id.* at 3.

[56] See *supra* notes 14-33 and accompanying text.

[57] California Letter, *supra* note 54 at 5-7. 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)).

[58] 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 FFDCA 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.

[59] Inside Washington Publishers, *FDA To Resolve Rx Depot Suit Before Taking on States,* FDA WEEK, Oct. 31, 2003, at 1, 1, 8.

Businesses That Facilitate Importation of Prescription Drugs

As noted above, the FDA is currently refraining from taking legal action against both states and individual consumers who import prescription drugs in violation of the FFDCA because the agency has instead chosen to focus its initial enforcement effort on pursuing businesses that facilitate the 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 is currently pursuing legal action against one such business. That case is discussed in detail in this section, while separate but related issues involving online pharmacies are discussed in a separate section below.

In *United States v. Rx Depot*,[60] the Department of Justice (DOJ), acting on behalf of the FDA, filed suit against Rx Depot, a storefront operation that helps U.S. consumers obtain prescription drugs from Canada.[61] According to the suit, DOJ contends that Rx Depot is violating two provisions of the FFDCA, namely the provision prohibiting reimportation and the provision prohibiting the introduction into interstate commerce of any drug that violates the Act's approval requirements.[62] Although Rx Depot is not directly importing drugs, the company admits that it is "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."[63]

Rx Depot has countered that the FDA is not actually concerned about the safety of imported drugs because the agency never tested the drugs it bought from Rx Depot

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[60] No. 03-CV-0616-EA (M), 2003 U.S. Dist. LEXIS 20135 (D. Okla. Nov. 6) (order granting preliminary injunction).

[61] DOJ initiated this lawsuit after Rx Depot failed to respond to the agency's warning letter and continued to facilitate the reimportation 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. 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. CanaRx is the business that currently assists Springfield, Massachusetts in importing prescription drugs. Press Release, Food and Drug Administration, CanaRx Illegally Supplying Prescription Drugs (Nov. 6, 2003), http://www.fda.gov/bbs/topics/NEWS/2003/NEW00973.html.

[62] *United States v. Rx Depot*, 2003 U.S. Dist. LEXIS 20135 (D. Okla. Nov. 6) (order granting preliminary injunction). *See also*, 21 U.S.C. §§ 331(d), 331(t), and 355.

[63] *Id.* at *6-*7.

as part of a sting operation against the company.[64] 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,"[65] and allege that the FDA's importation policy may violate international trade agreements.[66] Ultimately, critics argue that the FDA's policy protects the profits of drug manufacturers at the expense of consumer pocketbooks.[67]

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.[68] While the court's order is not actually a final order on the merits of the case, it does indicate that DOJ has 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.[69]

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.[70]

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[64] Inside Washington Publishers, *Rx Depot: FDA Alleged Safety Concerns With Reimportation Are Bogus*, FDA WEEK, Nov. 7, 2003, at 15.

[65] *Id.* at 16.

[66] Inside Washington Publishers, *CanaRx Says FDA's Reimportation Policy Violates Trade Agreements*, FDA WEEK, Nov. 7, 2003, at 16. An analysis of international trade agreements is beyond the scope of this report.

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

[68] *United States v. Rx Depot*, 2003 U.S. Dist. LEXIS at *23, *36.

[69] *Id.* at *8.

[70] *Id.* at *8-*9, *16-*18.

As noted above, the district court's decision to issue a preliminary injunction against Rx Depot is not a final decision on the merits of the case. Meanwhile, as the legal battle continues, many companies like Rx Depot remain in business, and an increasing number of states and localities have begun to contemplate 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

As noted above, several major prescription drug manufacturers have responded to the rise in the number of businesses and consumers that are reimporting cheaper drugs into the U.S. by reducing the supply of such drugs to distributors and pharmacies in Canada, where most of the reimported drugs originate. Such moves appear to 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,[71] and several bills introduced in the 108th Congress would prohibit such sales tactics.[72] In addition, at least one state has launched an investigation into whether or not the drug manufacturer GlaxoSmithKline (GSK) has violated state antitrust laws.[73] 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.

Under federal law, the Sherman Act,[74] one of the major federal antitrust statutes, makes illegal "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce . . ."[75] The statute does not, however, prohibit independent action by a single entity; the Supreme Court has specifically stated:

> The Sherman Act contains a 'basic distinction between concerted and independent action.' The conduct of a single firm is governed by § 2 alone and is unlawful only when it threatens actual monopolization. . . . Section 1 of the Sherman Act, in contrast, reaches unreasonable restraints of trade effected by a

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[71] Inside Washington Publishers, *Lawmakers Seek DOJ Anti-Trust Probe of Firms Limiting Sales to Canada*, FDA WEEK, Nov. 7, 2003, at 3.

[72] *See, e.g.*, H.R. 2497, H.R. 2769, S. 1992.

[73] Inside Washington Publishers, *Judge Wants More Info Before Deciding Motion to Compel Against GSK*, FDA WEEK, Nov. 21, 2003, at 10.

[74] 15 U.S.C. §§ 1-7.

[75] 15 U.S.C. § 1.

> 'contract, combination . . . or conspiracy between *separate* entities. It does not reach conduct that is wholly unilateral.'[76]

Nevertheless, a formal contract may not be necessary to show collective action that violates section 1 of the Sherman Act.[77] To define how much proof is necessary to find an "inference of agreement"[78] a number of cases have examined the question of what constitutes the establishment of collective action. For example, *American Tobacco Co. v. United States*,[79] an early Supreme Court case in this area, defined agreement as "a unity of purpose or a common design and understanding or a meeting of minds in an unlawful arrangement."[80] Later decisions have reasoned that these agreements may be found even without verbal statements among the parties.[81] In *Monsanto Co. v. Spray-Rite Service Corp.,*[82] the Supreme Court established a standard for determining whether concerted action exists:

> 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 a conscious commitment to a common scheme designed to achieve an unlawful objective.[83]

Courts often use the term "conscious parallelism" or "consciously parallel behavior" to refer to actions by competitors that are based on a pattern of uniform business conduct. In the early case *Interstate Circuit, Inc. v. United States*,[84] the Supreme Court held that the nearly identical restraints imposed by eight motion picture distributors concerning the licensing of first run "feature" pictures was sufficient to infer that the distributors acted in concert and thereby violated the federal antitrust laws.

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[76] *Copperweld Corp. v. Independence Tube Corp*., 467 U.S. 752, 767-68 (1984)(citations and footnote omitted).

[77] *See, e.g.*, *United States v. General Motors Corp*., 384 U.S. 127, 142-43 (1966) (stating "it has long been settled that explicit agreement is not a necessary part of a Sherman Act conspiracy").

[78] ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS 4 (4th ed. 1997).

[79] 328 U.S. 781 (1946).

[80] *Id*. at 810.

[81] *See e.g.*, *United States v. General Motors Corp*., 384 U.S. 127, 142-43 (1966) (stating that "although we regard as clearly erroneous and irreconcilable with its other findings the trial court's conclusory 'finding' that there had been no 'agreement' among the defendants and their alleged co-conspirators, it has long been settled that explicit agreement is not a necessary part of a Sherman Act conspiracy–certainly not where, as here, joint and collaborative action was pervasive in the initiation, execution, and fulfillment of the plan").

[82] 465 U.S. 752 (1984).

[83] *Id.* at 768.

[84] 306 U.S. 208 (1939).

> 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.[85]

However, in *Theatre Enterprises v. Paramount Film Distributing Corp.*,[86] the Supreme Court held that parallel behavior by itself is not necessarily proof of a conspiracy. The Court stated:

> 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.[87]

Lower courts, in following these Supreme Court decisions, have seemed for the most part to hold that conscious parallelism by itself does not show that the parties have violated the Sherman Act.[88] The courts have required that other factors be looked at in conjunction with parallel behavior to find concerted action resulting in a Sherman Act violation. Some of these other factors include artificial standardization of products[89] and raising prices in time of surplus.[90] Less persuasive is evidence that indicates merely that the parties had an opportunity to collude.[91]

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

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[85] *Id.* at 227 (citations omitted).

[86] 346 U.S. 537 (1954).

[87] *Id.* at 540-41 (citations omitted).

[88] *See, e.g.*, *Wallace v. Bank of Bartlett*, 55 F.3d 1166, 1168 (6th Cir. 1995), *cert. denied* 116 S.Ct. 709 1996) (stating that "parallel pricing, without more, does not itself establish a violation. . . . Courts require additional evidence which they have described as 'plus factors'"). *See also*, *Todorov v. DCH Healthcare Auth.*, 921 F.2d 1438, 1456 (11th Cir. 1990) (stating that "we require more than mere evidence of parallel conduct by competitors to support an inference of a conspiracy").

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

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

[91] *See, e.g.*, *Greater Rockford Energy & Tech. Corp. v. Shell Oil Co.*, 998 F.2d 391 (7th Cir. 1993).

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.

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 current legal dispute against GlaxoSmithKline (GSK) in Minnesota as an example of potential liability under state antitrust statutes.

State Antitrust Law.

Although most states have their own antitrust laws, enforcement of these statutes differs from state to state. In October 2003, the Minnesota Attorney General (AG), who is investigating whether GSK violated state antitrust laws, filed a court motion seeking to compel GSK to release information 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."[92] Meanwhile, GSK contends that "importing drugs from Canada is illegal and a drug company can take steps to stop illegal sales of its products."[93] The company further argues that federal law preempts Minnesota's antitrust laws, but the Minnesota AG challenges that assertion. Although no lawsuit has actually been filed against GSK, the Minnesota AG may decide to file such a suit if the court grants its motion to compel GSK's release of documents and if the AG subsequently finds evidence of an antitrust violation.[94]

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. 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

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[92] Inside Washington Publishers, *Judge Wants More Info Before Deciding Motion to Compel Against GSK*, FDA WEEK, Nov. 21, 2003, at 10, 10.

[93] *Id.*

[94] *Id.*

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 to large chains with a neighborhood presence and 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.[95] 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.[96] 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 FFDCA, which governs, among other things, the safety and efficacy of prescription medications, including the approval, manufacturing, and distribution of such drugs.[97] It is the FFDCA that requires that prescription drugs may be dispensed only with a valid prescription.[98] The DEA enforces the Controlled Substances Act (CSA), 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.[99] At the state level, state boards of pharmacy regulate pharmacy practice, and state medical boards oversee the practice

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

[96] *Id.*

[97] 21 U.S.C. § 301 et seq.

[98] *Id.* at § 353(b).

[99] *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*.

of medicine.[100] 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, or distribution of addictive or dangerous substances.[101] Although the CSA is generally known for prohibiting illegal drugs like heroin and cocaine and does not include many drugs legally available by prescription, the statute does cover certain prescription drugs that have addictive properties, such as narcotics and opiates that are often used in the treatment of pain.

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.[102] 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 controlled substances.[103] Penalties under the CSA vary depending on the amount and type of substance involved but generally include monetary fines, forfeiture, and imprisonment.[104]

As noted above, prescription drugs are also regulated by the FDA under the FFDCA.[105] Although state law also governs the prescribing of drugs, the FFDCA covers certain aspects of the prescribing process, including the requirement that prescription drugs may not be dispensed without a valid prescription.[106]

Although federal law requires that prescription drugs be dispensed in accordance with a prescription, the FFDCA 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

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

[101] *Id.* at § 801 et seq.

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

[103] *Id*.

[104] 21 U.S.C. § 841 et seq.

[105] *Id* at § 301 et seq.

[106] *Id*. at § 353(b).

uniform, national definition of the term "prescription."[107] 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.[108] During the Clinton Administration, for example, legislators contemplated requiring online pharmacies to disclose information about themselves and about the doctors approving prescriptions on their sites, but the legislation ultimately faded.[109] In the wake of recent reports of abuses by online pharmacies, however, interest in such legislation has revived, and Congress recently held hearings to discuss legislative solutions, including the establishment of a single federal standard for prescriptions.[110]

Congress is also exploring the possibility of controlling 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 to consumers. For example, Google, an Internet search engine, recently announced that it no longer accepts advertising from unlicenced pharmacies and now prohibits the use of certain controlled substances as keywords for search purposes.[111] Meanwhile, at least three congressional committees are investigating "the roles played by Visa International, MasterCard Inc., FedEx Corp. and United Parcel Service Inc. in the Internet sales,"[112] as well as exploring the prospects for establishing a certification program that would make it easy for such companies to determine when they are doing business with a legitimate site.[113] Because federal and state regulators face many legal barriers when attempting to exercise jurisdiction over rogue pharmacies based in foreign countries,[114] placing limits on the degree to which search engines, credit card companies, and shipping entities facilitate prescription drug purchases from rogue sites may be one of the only ways to control illicit sales by foreign online pharmacies.

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[107] Inside Washington Publishers, *FDA May Back Changing Law to Define Internet 'Prescription'*, FDA WEEK, March 28, 2003, *at* 1, 10.

[108] *Id*. at 1.

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

[110] *Point, Click, Self-Medicate: A Review of Consumer Safeguards on Internet Pharmacy Sites: Hearing Before the House Comm. On Government Reform*, 108th Cong. (2003), http://reform.house.gov/UploadedFiles/Online%20Pharmacies%20Final%20Print.pdf.

[111] Gilbert M. Gaul and Mary Pat Flaherty, *Google to Limit Some Drug Ads*, WASH. POST, Dec. 1, 2003, at A1.

[112] *Id.*

[113] Inside Washington Publishers, *FDA Rep: Internet Pharmacy Certification Could Be Easy Process*, FDA WEEK, Dec. 19, 2003, at 5.

[114] "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.

State Oversight

As noted above, state boards of pharmacy are primarily responsible for regulating pharmacy practice,[115] although the FFDCA 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.[116]

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.[117]

In addition, some organizations have begun to promote uniform national standards for the industry. For example, the National Association of Boards of Pharmacy (NABP), whose members include all 50 state boards, 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."[118]

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

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

[116] *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. 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.

[117] Inside Washington Publishers, *FDA May Back Changing Law to Define Internet 'Prescription'*, FDA WEEK, March 28, 2003, *at* 1, 1. *See also*, *supra* notes 107-10 and accompanying text.

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

distinguish between legitimate and illegitimate online pharmacy practice sites."[119] 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 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 50 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."[120] Traditionally, states enact laws that regulate the practice of medicine, and state medical boards implement and oversee state policies.[121] 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."[122] 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 "[t]reatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care."[123] FSMB further urges that doctors who prescribe drugs on the Internet should be licensed in all states in which their patients reside,[124] a practice that would subject doctors to the oversight of the medical boards in each state in which their patients lived.[125] These professional

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[119] *Id.*

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

[121] *Id.*

[122] *Id.*

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

[124] *Id.*

[125] 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 (continued...)

standards, however, are not legally enforceable in the absence of state laws establishing such requirements.

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, giving state prosecutors the authority to seek nationwide injunctions against rogue sites, 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 such drugs in increasing numbers. 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, educating consumers about the dangers of imported drugs, and allowing drug imports from approved Canadian pharmacies only

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[125] (...continued)
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), *at* http://www.ama-assn.org/.