

POLICING ONLINE PHARMACIES: BIOTERRORISM MEETS THE WAR ON DRUGS

In light of the recent terrorists attacks and the increasing threat of bioterrorism, many U.S. citizens have turned to the Internet in an attempt to gather the supplies needed to protect them and their loved ones. Central to the effort is the increased purchasing of prescription drugs over the Internet. This iBrief explores the benefits and risks to consumers from buying drugs online, and examines recent initiatives to police the online pharmacy industry.

Introduction

Can the Internet fight bioterrorism? It may sound far-fetched, but many Americans are turning to the Internet to do what the federal government has yet to accomplish – stop the spread of anthrax. Americans are taking the war on bioterrorism into their own hands, using online pharmacies to stockpile anthrax antibiotic ciprofloxacin (“Cipro”). Capitalizing on this vigilantism, a number of foreign websites are promoting and selling Cipro, a prescription drug, to American consumers. Cipro is the latest example of the growing online accessibility to powerful drugs without a valid prescription. In response, the U.S. Food and Drug Administration (“FDA”) is cracking down on domestic and foreign websites illegally selling prescription drugs. On October 31, 2001, the FDA issued eleven “cyber letters” to websites selling unapproved and non-prescribed doses of Cipro, warning the sites that the sale and distribution in the U.S. may be illegal.¹ This article explores the benefits and risks to consumers from buying drugs online, and examines recent initiatives to police the online pharmacy industry.

Purchasing Drugs Online: Saving Money Can Be Hazardous to Your Health

Consumers who prefer purchasing prescription drugs online point to cost, convenience, and privacy advantages. Since the price of prescription drugs in other countries is often lower than in the U.S., foreign online pharmacies offer American consumers a low-cost alternative. Canadians, for example, pay 20%-50% less than Americans for prescription drugs.² Not surprisingly, The Canadian Drugstore, an online pharmacist, advertises that it “brings Canadian drug prices to the world” and saves consumers up to 50% on all prescription drugs.³ Many elderly patients, a pharmacist’s best customer,

¹ FDA Talk Paper: *FDA Issues Cyber-Letters to Web Sites Selling Unapproved Foreign Ciprofloxacin*, (November 1, 2001), available at <http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01115.html> (last visited November 20, 2001).

² Essif, Mason, *Prescription drugs are crossing the borders to buyers*, CNN (March 12, 2001), available at <http://www.cnn.com/2001/HEALTH/03/12/prescription.drugs/index.html> (last visited November 20, 2001).

³ See <http://www.canadiandrugstore.com/default.asp> (last visited November 20, 2001).

prefer the convenience of ordering drugs without leaving their home. Finally, online pharmacies allow consumers to order products and consult with a pharmacist in the privacy of their homes. Some of the most popular drugs for online purchases are “lifestyle drugs,” such as Viagra for erectile dysfunction, Propecia for hair loss, and Xenical for obesity.⁴ Sometimes, anonymous consultation with a distant pharmacist is easier than a visit to the family doctor.

There are two types of online pharmacies: those that dispense drugs and those that prescribe *and* dispense drugs. At dispensing websites, users create an account by submitting personal information such as a credit card and insurance policy. Then the user must submit a valid doctor’s prescription. Depending on the state, the doctor can either call in or e-mail the prescription. Alternatively, users may fax or mail a written copy of the prescription to the pharmacy.⁵ The online pharmacy then fills and delivers the prescription. Some online pharmacies ship products from a central distribution point, while others partner with local brick-and-mortar pharmacies for customer pick-up. Prescriptions are usually delivered within three days at no shipping charge, and overnight delivery may be available for an extra fee. In the U.S., online pharmacies must be licensed to sell prescription drugs in the state in which they operate and in those states to which they sell.⁶ Thus, legitimate online pharmacies simply dispense drugs based on a physician’s prescription, but add the convenience of home delivery.

While dispensing drugs via the Internet is an accepted practice, prescribing drugs over the Internet creates significant health risks to consumers.⁷ At prescribing websites, consumers obtain prescription drugs merely by answering a questionnaire. The Internet pharmacist is given little information about the patient’s current health status and past medical history. In effect, these sites bypass the traditional physician-patient relationship in favor of self-diagnosis.⁸ Avoiding meaningful interaction with this “learned intermediary” exposes consumers to harmful side effects from inappropriately prescribed medicines and dangerous drug interactions.⁹ Also, self-diagnosis delays a patient’s decision to

⁴ Jane E. Henney, M.D., E-Regulation and Public Health, *Address Before the 2000 Leonard Davis Institute of Health Economics University of Pennsylvania Health Policy Seminar Series* (Sept. 29, 2000), available at <http://www.fda.gov/oc/speeches/2000/ecommerce.html> (last visited November 20, 2001).

⁵ For a discussion of fraud practices associated with counterfeiting doctor prescriptions, see Eric M. Peterson, *Doctoring Prescriptions: Federal Barriers to Combating Prescription Drug Fraud Against Online Pharmacies in Washington*, 75 Wash. L. Rev. 1331, 1335 (2000).

⁶ John Henkel, *Buying Drugs Online: It’s Convenient and Private, but Beware of ‘Rogue Sites’*, available at http://www.fda.gov/fdac/features/2000/100_online.html (last visited November 20, 2001).

⁷ Kara M. Friedman, *Internet Prescribing Limitations and Alternatives*, 10 Ann. Health L. 139, 143 (2001) (describing the distinction between internet dispensing and prescribing).

⁸ Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration, *Statement Before the House Subcommittee on Oversight and Investigations*, Washington, D.C. (July 30, 1999).

⁹ Henkel, *supra* note 6.

seek necessary medical treatment.¹⁰ Worse yet, some foreign sites, like the ones targeted by the FDA most recently, require neither a prescription nor a questionnaire from users.¹¹ Products on these sites may be legal in other countries, but not approved for use in the U.S.¹² Generally, prescription drugs available from a foreign pharmacy are either products for which there are no U.S. counterparts or foreign versions of FDA-approved drugs.¹³ Since foreign websites are not subject to FDA regulation, consumers potentially suffer harm from contaminated, counterfeit, or outdated drugs. Furthermore, these loose standards facilitate supply to the prescription drug black market and ease the way for addicts to import their drugs of choice. Given these health and safety risks, the federal government is giving serious attention to the availability of prescription drugs online, both domestically and abroad.

Policing Online Pharmacies: The War on Drugs Takes a New Twist

Although online sales of Cipro are a recent development, concern over the illegal sale of prescription drugs is not. The rise of domestic and foreign online pharmacies has led to increased surveillance of Internet drug sales, marketing, and distribution. Traditionally, regulation of drug sales is a state role.¹⁴ However, Internet technology makes state regulation of online pharmacies challenging. For instance, a consumer in one state, using an Internet site launched from a computer in a second state, may order a drug dispensed from a third state, under a prescription from a doctor in a fourth state.¹⁵ Because of the interstate (and international) nature of Internet commerce, the federal government plays an active role in regulating online pharmacies. As the former FDA Commissioner said, “Ironically, some of the internet’s strengths – including anonymity, speed, and ability to transcend state and international borders – are also some of the same factors that make enforcement and policymaking in this area extremely challenging.”¹⁶ Through a combined effort of federal agencies, Congressional legislation, and industry regulation, the U.S. is tackling the consumer health risks associated with online pharmacies.

The burden of policing online pharmacies primarily falls on the FDA. Under the Food, Drug, and Cosmetic Act (“FDCA”), the FDA can take action against the importation, sale, or distribution of an adulterated, misbranded, or unapproved drug.¹⁷ Furthermore, the FDA can take action against illegal promotion of a drug, the sale or dispensing of prescription drugs without a valid prescription, and

¹⁰ Friedman, *supra* note 7, at 146.

¹¹ Henkel, *supra* note 6.

¹² Woodcock, *supra* note 8.

¹³ *Id.*

¹⁴ Henney, *supra* note 4.

¹⁵ Woodcock, *supra* note 8.

¹⁶ Henney, *supra* note 4.

¹⁷ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-907 (West 2000) *as cited in* Friedman, *supra* note 7, at 147 and Woodcock, *supra* note 8.

counterfeit drugs.¹⁸ Prescription drugs include any drug that is habit-forming or has a toxicity or method of use that is potentially harmful.¹⁹

When the FDA sent cyber letters to Cipro-selling websites, it was acting under the Internet Drug Sales Action Plan. The plan, launched in 1999 to address the health risks of online pharmacies, focuses FDA enforcement activities on unapproved new drugs, health fraud, and prescription drugs sold without a valid prescription.²⁰ Cyber letters are electronic letters sent by the FDA to offending foreign websites. They warn companies to cease advertising and selling prescription or counterfeit drugs to Americans. Also, cyber letters explain to the offending website the associated civil and criminal penalties. The FDA sent 58 cyber letters in 2000, and has already surpassed that number for 2001.²¹ In dealing with the Cipro websites, the FDA stated that sale and distribution in the U.S. may be illegal, because the FDA was unable to determine whether the imported drugs were made in accordance with U.S. specifications.²² Regardless of their product quality, the Cipro sites were selling a prescription drug without a valid prescription. The FDA can fine offending companies up to \$500,000 for selling a prescription drug to a person without a valid prescription.²³

In addition to the FDA, the Federal Trade Commission (“FTC”) enforces consumer protection laws that prohibit unfair or deceptive acts in the marketplace.²⁴ Applying this power to online pharmacies, the FTC can take action if a website operator makes false or misleading claims about the products or services it provides, including medical consultation in connection with prescribing and dispensing a drug.²⁵ In the past few years, the FTC has used this power to clamp down on unwarranted Viagra prescriptions.

Despite these successes, the FTC recommends new legislation for clear and prominent disclosure of identifying information for the online pharmacist.²⁶ In October 2000, Rep. Tom Bliley introduced the Internet Prescription Drug Consumer Protection Act of 2000, requiring an online pharmacy to post visibly its street address, authorized state of operation, certain prescriber information, and a statement that it will dispense prescription drugs only upon a valid prescription.²⁷ The bill, however, never made it out of

¹⁸ 21 U.S.C. § 331 as cited in Friedman, *supra* note 7, at 148.

¹⁹ *Id.*

²⁰ Woodcock, *supra* note 8.

²¹ Melissa K. Cantrell, *The Taming of E-Health: Asserting U.S. Jurisdiction over Foreign and Domestic Websites*, 103 W. Va. L. Rev. 573, 577 (2001).

²² FDA Talk Paper, *supra* note 2.

²³ Eric M. Peterson, *Doctoring Prescriptions: Federal Barriers to Combating Prescription Drug Fraud Against On-line Pharmacies in Washington*, 75 Wash. L. Rev. 1331, 1335 (2000).

²⁴ Friedman, *supra* note 7, at 149.

²⁵ *Id.* at 150.

²⁶ *Id.* at 152-53.

²⁷ Internet Prescription Drug Consumer Protection Act of 2000, H.R. 5476, 106th Cong. (2000).

committee. In July 2001, Sen. Paul Wellstone introduced the Personal Prescription Drug Import Fairness Act.²⁸ This bill amends the FDCA to allow the importation of prescription drugs by individuals, subject to the use of an Import Form. The Import Form discloses the name, address, and telephone number of the importing consumer, dispensing pharmacy, prescribing licensed physician, and drug manufacturer.²⁹ However, the bill requires evidence that treatment began outside the U.S. and limits the imported dosage to 90 days.³⁰ While both of these bills improve disclosure for consumers and law enforcement officials, neither encourages consumers to bypass local physicians in favor of internet prescriptions.

At the same time, the pharmacy industry established its own program to certify online pharmacies. In 1999, the National Association of Boards of Pharmacy (NABP) started the Verified Internet Pharmacy Practice Sites (VIPPS) program. VIPPS, a voluntary program, certifies an online pharmacy's credentials, including maintenance of state licenses and inspection by NABP-sanctioned teams.³¹ Websites that are awarded VIPPS certification post the VIPPS seal and a link to the VIPPS website. The VIPPS program assures consumers that the online pharmacist is reputable. However, because the program is voluntary, only 12 sites are registered.³² As a result, the program does little to discourage less reputable online pharmacies that prescribe drugs from continuing illicit operations. Furthermore, because it does not apply to foreign pharmacies, where prices are usually cheaper, the program may not stem the tide of non-certified imports.

Conclusion

As fears of bioterrorism spike demand for Cipro, the U.S. is working to eliminate rogue online pharmacies that prescribe unwarranted drugs. Although consumers may benefit from international prices and online anonymity, increased accessibility to prescription drugs online may prove to do more harm than good. As with each commercial domain it enters, the Internet brings new opportunities for businesses and consumers and new challenges for law enforcement.

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²⁸ Personal Prescription Drug Import Fairness Act, S. 1229, 107th Cong. § 2 (2001).

²⁹ *Id.*

³⁰ *Id.*

³¹ Henkel, *supra* note 6.

³² See <http://www.nabp.net/vipps/consumer/listall.asp> (last visited November 20, 2001) for a list of currently certified sites.