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Prescription Drug Sales Over the Internet

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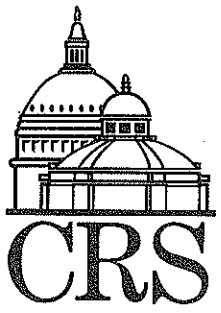

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ABSTRACT

This report provides an overview of prescription drug sales over the Internet and related legislative activities. The report discusses how online pharmacies operate and some of the concerns raised by the sale of drug products in electronic commerce. The report also describes some recent government and private sector actions taken to address these concerns. The report will be updated as needed.

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Prescription Drug Sales Over the Internet

Summary

The sale of prescription drugs is highly regulated in the United States. In recent years, the growth of the Internet and electronic commerce has made it possible for consumers to purchase prescription drugs online. The sale of prescription products over the relatively unregulated Internet has raised several issues and concerns for policymakers, regulators, and medical practitioners. One concern is that some online pharmacies engage in the practice of prescribing and dispensing prescription drugs without a medical examination of the patient by a licensed physician. Another concern is the use of the Internet to obtain prescription drugs from foreign-based online pharmacies. Such purchases may involve drugs that are counterfeit or are not approved by the Food and Drug Administration (FDA) for use in the U.S., or drugs that were manufactured and stored under poor conditions.

There are also concerns associated with the practices of what many view as legitimate and ethical online pharmacies. One such concern is that online pharmacies do not provide the same level of care as traditional pharmacies because the consumer does not have face-to-face contact with a pharmacist. Some observers have suggested that information about a patient is not secure when it is transmitted over the Internet, under any circumstances, and that confidentiality cannot be guaranteed once the information is received by the online pharmacy.

Despite the concerns raised by the sale of prescription drugs via the Internet, there is the view held by many that online pharmacies offer significant advantages to consumers. Online pharmacy purchases can be convenient, allowing consumers to order prescriptions from their home at any time of day. Some online pharmacies arguably offer lower prices than their traditional retail counterparts. Moreover, the Internet provides a convenient and effective means for online pharmacies to provide consumers with more information on their ailments and the proper medications used to treat them, including links to online health information.

Both the government and the private sector have taken actions to address some of the concerns expressed regarding online pharmacies. To date, three bills (S. 881, H.R. 2763, and H.R. 3636) have been introduced and one hearing has been held in the 106th Congress related to the online sale of prescription drugs. The Clinton Administration has developed its own proposal to facilitate enforcement activities by the FDA, including allocating additional funds specifically for investigating and prosecuting illegal online pharmacies. The FDA has introduced a website to educate consumers on purchasing drugs online and has sent letters to operators of foreign-based online pharmacies warning the operators that their practices may be illegal. Some state governments have filed lawsuits against unlicensed online pharmacies. The National Association of Boards of Pharmacy (NABP) has developed its own program, called the Verified Internet Pharmacy Practice Sites (VIPPS), to issue seals of approval to online pharmacies that meet legal and ethical requirements.

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Prescription Drug Sales Over the Internet

Overview and Issues of Concern

Purchasing prescription drugs over the Internet is a relatively new phenomenon that has arisen with the explosive growth in the public use of the Internet and electronic commerce. Unlike the sale of many goods, the sale of prescription drugs through traditional retail channels is highly regulated. Prescription drugs can be obtained only with a physician's consent and only from licensed pharmacies. Both the physician and the pharmacist dispensing the medication must be licensed. Furthermore, the product sold, as well as the methods by which it was produced and marketed, must be approved by the U.S. Food and Drug Administration (FDA). Thus, the sale of prescription drugs (a regulated product in traditional settings) over the relatively unregulated Internet has become a concern for policymakers, regulators, and medical practitioners. Distinctions are often made between "legitimate" online pharmacies and those that engage in unethical or illegal dispensing practices.[1] The concerns associated with online pharmacies tend to be directed more towards the practices that are unethical or illegal and less towards those of legitimate online pharmacies.

Legitimate online pharmacies operate much the same way as mail-order pharmacies. However, rather than placing the order via telephone or mail, patients order their medications via the Internet. Medications purchased online are either sent directly to patients or, in some instances, picked up by them later at a local affiliated pharmacy. To verify that the prescription ordered online is accurate, patients mail or fax their new prescriptions to the online pharmacy. Alternatively, they can ask their physicians to phone the online pharmacy and provide the new prescription information directly.[2] Patients can also order refills of prescription drugs previously dispensed by the online pharmacy and transfer existing prescriptions from other pharmacies (both online and traditional). Some online pharmacies require patients to submit a medical profile, which the online pharmacy maintains along with a record of previous prescriptions. This allows the online pharmacy to determine if there are any potential drug interactions or side effects which may have an adverse effect on the patient. Online pharmacies usually have telephone numbers or email addresses so that their customers can contact a pharmacist should they need to discuss their medications or other problems they may encounter.

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[1] See "Issue Brief: Internet Pharmaceutical Services," National Association of Chain Drug Stores, August 2, 1999. Available at [http://www.nacds.org/news/releases/nr_080299_brief.html].

[2] This method of transmitting prescription information is also acceptable for prescriptions obtained at traditional retail establishments.

Although getting a prescription filled online can be done relatively easily with just a few clicks, receiving the medication may take several days. One online pharmacy, Drugstore.com [www.drugstore.com], instructs consumers to allow 3-5 days for the pharmacy to receive the prescription and another 1-2 days for the pharmacy to process the prescription. The time it takes to deliver the medication from the online pharmacy to the customer can vary depending on the preferences of the customer. Drugstore.com provides free standard delivery via the U.S. Postal Service Priority mail, which requires another 2-3 days. However, customers can opt for UPS 2-Day Shipping for $5.95 or UPS Overnight Shipping for $11.95. Other online pharmacies that deliver prescriptions operate similarly. Some online pharmacies, such as [www.cvs.com], [www.riteaid.com], and [www.walgreens.com], are online extensions of traditional chain pharmacies. The online version of traditional chain pharmacies generally give customers the option of having the medication delivered or picking it up themselves from a local chain outlet.

There is a spectrum of online pharmacies whose activities fall outside what many would consider ethical and legitimate pharmacy practices. One practice that tends to receive criticism is when both the prescribing and the dispensing of the drug are performed online simultaneously. Several websites allow customers to receive a prescription for medication without a physical examination by a physician. In place of a traditional face-to-face consultation, the customer fills out a medical questionnaire. Reportedly, a licensed physician at the online pharmacy evaluates the questionnaire, then, if the prescription is medically justified, authorizes the online pharmacy to send the medication to the patient. This practice tends to be limited more to "lifestyle" prescription drugs, such as those that alleviate allergies, promote hair growth, treat impotence, or control a person's weight. Nevertheless, it is feasible that controlled prescription drugs could be dispensed via the Internet without a medical examination. The American Medical Association (AMA) is critical of prescribing drugs without a physical examination. Such a practice violates AMA's ethical standards, and, in the association's opinion, raises serious quality-of-care issues.[3]

A second practice, and one that is illegal in many circumstances, is the sale of prescription drugs to American consumers via the Internet by foreign-based companies. With some exceptions, it is illegal to import prescription drugs that are not approved by the FDA. FDA approval involves not only assessing a drug's safety and effectiveness, but also inspecting the facility in which it is manufactured.[4] Unless the importing party can prove that the drugs bought from abroad are FDA-approved, and manufactured in an FDA-approved facility, the agency treats the imported drugs as unapproved products.[5] Despite this policy, there are numerous

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[3] Melba Newsome, "Physicians Cry Foul Over Web Drug Sales," *Investor's Business Daily*, March 8, 1999, p. A1.

[4] For more information on FDA procedures, see CRS Report 95-422 SPR, "Food and Drug Administration: Selected Funding and Policy Issues for FY2000" by Donna U. Vogt, updated January 31, 2000.

[5] See "Information on Importation of Drugs," prepared by the Division of Import Operations and Policy, U.S. Food and Drug Administration. Available at

(continued...)

foreign-based pharmacies that sell prescription drugs to American consumers. These products may be drugs not approved for use in the U.S. by the FDA, counterfeit copies of FDA-approved drugs, or FDA-approved drugs that have not been manufactured, stored, and handled in an FDA-approved manner. Moreover, many foreign countries do not require patients to obtain prescriptions for some drugs while patients buying the same drugs in the U.S. may be sold only by prescription. This means that foreign-based online pharmacies may be selling prescription drugs to American customers who do not have a physician's consent to use the drug. Consequently, drugs obtained from foreign online pharmacies could pose serious health and legal problems for American consumers.

Although most criticism is focused on foreign-based online pharmacies and American online pharmacies with questionable practices, so-called legitimate pharmacies are not free from controversy. Questions have been raised regarding the quality of care received by patients when they are not able to consult with pharmacists in person. In order to provide patient access to a pharmacist, some online pharmacies allow customers to submit personalized questions to pharmacists via email. Furthermore, some online pharmacies do not disclose to patients the name or credentials of the pharmacist. Thus, some have expressed concern that patients may be consulting with a pharmacist who is not licensed in the patient's state.

There are other concerns associated with legitimate online pharmacies. Yet these concerns are not constrained only to the sale of prescription drugs; rather, they apply to electronic commerce transactions in general. One issue is whether using the Internet is secure enough to offer customers an appropriate degree of privacy. Some online pharmacies require customers to submit credit card, medical, and insurance information over the Internet. This practice raises concerns that such personal information could be accessed by other people as it is transmitted. In an attempt to protect the transmission of personal information, several online pharmacies use secure servers that encrypt customers' personal information so that it cannot be read as it travels over the Internet.

Another issue involves the confidentiality of consumer information once it is received by the pharmacy. Some legislators are concerned because it is not certain whether online pharmacies are adequately protecting consumers' personal information.[6] A spokesperson for the online pharmacy Soma (now part of [www.cvs.com]) claimed that, compared to the corner drugstore, online pharmacies offer more privacy.[7] However, this is not an issue that solely affects online pharmacies. For example, the traditional retail pharmacy operations of Giant Food and CVS reportedly shared detailed information on customers with Elensys, a data

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[5] (...continued)
[http://www.fda.gov/ora/import/pipinfo.htm].

[6] Letter to General Accounting Office from Reps. John D. Dingell, Ron Klink, Henry A. Waxman, and Sherrod Brown requesting investigation into online pharmacies.

[7] Lesly C. Hallman and Joyce Cutler, "Pharmaceutical Industry Seeks Regulations to Guide Growing Use of Internet," *Daily Report for Executives*, Bureau of National Affairs. March 9, 1999.

management company.[8] According to this report, Elensys arranged for drug manufacturers to pay the pharmacies for this information so that the manufacturers could send "educational" material to consumers. Although the practice was defended as benefitting consumers, both companies announced that it would be discontinued.[9]

Advantages of Online Pharmacies

Despite the concerns raised by legitimate online pharmacies and the existence of some unethical and illegal online pharmacies, purchasing prescription drugs over the Internet can provide consumers many advantages over traditional retail pharmacies. One major advantage is convenience. Online pharmacies deliver the drugs directly to the customer. While the customer may have to wait several days to receive the drugs, he or she does not have to travel to a local traditional pharmacy to order the drug and wait there for the prescription to be filled. Furthermore, for those with easy access to Internet connections, online pharmacies are available 24 hours a day, 7 days a week.

Some online pharmacies advertise that they provide lower prices to consumers than traditional retail pharmacies. Online pharmacies tend to operate similarly to mail-order pharmacies. Because many online pharmacies do not operate retail outlets, they may have lower operating costs. Online pharmacies can also buy in larger volumes than many small, independent pharmacies (but not necessarily more cheaply than large retail chains), possibly leading to greater cost savings. These lower costs could be passed on to consumers in the form of lower prices. However, although consumers may be paying a lower base price for online prescriptions, shipping and handling charges may reduce their savings, or even result in a higher price than the consumer would pay in a retail pharmacy. This is more likely to occur when a consumer chooses overnight delivery over the free standard delivery by the U.S. Postal Service. On the other hand, for relatively high-priced prescription drugs, shipping costs are less likely to mitigate the savings.

Another advantage, often advertised by many online pharmacies, is easier access to health and medical information. Many online pharmacies provide detailed drug information on their websites, such as the availability of a generic substitute, possible food and drug interactions, and other possible side effects. Some online pharmacies provide information about illnesses, allowing customers to learn more about their medical conditions. Online pharmacies also tend to list their prices for commonly prescribed drugs.[10] This could assist consumers in selecting the lowest priced online pharmacy to have their prescriptions filled. While this kind of information may be available from retail pharmacies, some find that computer access provides a more convenient and accessible source of information.

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[8] Robert O'Harrow, Jr., "Prescription Sales, Privacy Fears; CVS, Giant Share Customer Records with Drug Marketing Firm," *Washington Post*, February 15, 1998.

[9] Robert O'Harrow, Jr., "CVS Also Cuts Ties to Marketing Service; Like Giant, Firm Cites Privacy on Prescriptions," *Washington Post*, February 19, 1998.

[10] These prices are for cash-paying customers. Online pharmacies usually indicate that the prices listed may vary for consumers with prescription drug insurance.

Recent Government Actions

The emergence of online pharmacies has prompted actions by Congress, the Clinton Administration, FDA, and several state governments. These actions have taken the form of proposed policy changes, heightened government oversight, and greater enforcement of existing consumer protection regulations.

Congressional Actions

Three bills related to online prescription drug sales have been introduced in the 106th Congress. The Medical Information Protection Act of 1999 (S. 881) was introduced on April 27, 1999 by Senator Robert Bennett and referred to the Committee on Health, Education, Labor, and Pensions. This bill seeks to prevent the unauthorized disclosure of consumers' health information while at the same time allowing health care professionals to access patient data to improve health care and research. The bill's privacy provisions target all health care delivery, not just online pharmacies. However, online medicine is one factor that influenced the proposed legislation.[11]

On August 5, 1999, the Internet Pharmacy Consumer Protection Act (H.R. 2763) was introduced by Representative Ron Klink and referred to the House Committee on Commerce. This bill would establish a set of minimum requirements for online pharmacies. The bill would require online pharmacies to have a webpage on their sites that displays (1) the name, address of the principal place of business, and telephone number of the online seller, (2) each state in which the business is authorized to dispense prescription drugs, (3) the name of each of the online pharmacy's pharmacists and the state in which he or she is licensed to practice, and (4) when the online pharmacy provides medical consultations, the name, type of profession, and state of licensure of each individual providing consultation. Each page on the online pharmacy's site would be required to have a clearly visible link to the page providing the information described above. Furthermore, the bill would make the Secretary of Health and Human Services responsible for enforcement of these provisions. However, for states that have regulations on online pharmacies more stringent than those specified in the bill, and have the means to enforce the regulations, the measure gives them primary enforcement responsibility.

A third bill related to the sale of prescription drugs over the Internet was introduced on February 10, 2000. The bill, entitled the Pharmaceutical Freedom Act of 2000 (H.R. 3636) was introduced by Representative Ron Paul and referred to the Committee on Commerce and the Committee on Ways and Means. Among other things, the bill seeks to make it easier to import prescription drugs. The bill would allow authorized importers to bring prescription drugs into the United States if the importer submits an application to the Secretary of Health and Human Services and the Secretary approves the application. H.R. 3636 also contains a section specifying how the bill is to be enforced with respect to online pharmacies. The bill states that the Secretary may not take any action against online drug sales under the Act as long as (1) the online sale was made in compliance with the Act and applicable state laws,

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[11] See Senator Bennett's website [http://www.senate.gov/~bennett/mipaspeech.html].

and (2) the online pharmacy provides on its website accurate information regarding compliance with the Act and applicable state laws.

On July 30, 1999, the Subcommittee on Oversight and Investigations of the House Commerce Committee held a hearing on the benefits and risks of online pharmacies. Witnesses that testified at the hearing included officials from the FDA, the U.S. Department of Justice, and the Federal Trade Commission. Other witnesses included state officials in charge of enforcing laws pertaining to the practices of online pharmacies as well as the chief executive officers (CEO) of two licensed online pharmacies. Federal enforcement officials testified that they believed no new laws were needed to deal with the practices of online pharmacies. Instead, federal officials stated that what was needed is more assistance for enforcement of existing laws. State officials, on the other hand, favored new legislation. State officials stated that, at a minimum, a law requiring online pharmacies to post information on how to contact the pharmacy operators is needed. State officials also advocated allowing state attorneys general to file suits against illegal online pharmacies in federal courts. This would allow the states to obtain injunctions against the nationwide operations of illegal online pharmacies, as opposed to obtaining injunctions only against operations being conducted within the state filing the lawsuit. The CEOs at the hearing represented the licensed online pharmacies of PlanetRx [www.planetrx.com] and Drugstore.com. These executives advocated enforcement of existing laws for online pharmacies operating illegally and industry self-regulation for those operating within the law.

The Clinton Administration's Proposal

In December 1999, the Clinton Administration introduced a proposal to address problems raised by online pharmacies. The proposal would require online pharmacies to demonstrate to the FDA that their practices comply with state and federal prescription drug laws. Sites operating without demonstrating compliance with agency rules would be subject to sanctions. The Administration proposal would create new civil monetary penalties of $500,000 per violation for the sale of prescription drugs to consumers without valid prescriptions. To facilitate FDA investigations into online pharmacy practices, the Administration's proposal would provide the agency with administrative subpoena authority when investigating potentially illegal drug sales over the Internet. Furthermore, the Administration's proposal would provide $10 million in the FDA's FY 2001 budget for the agency to develop a rapid response team and to upgrade its computer technology so that the agency can more effectively identify, investigate, and prosecute illegal prescription drug sales practices conducted over the Internet. The Administration also announced a new public education campaign, both over the Internet and through traditional media outlets, informing consumers on how to safely purchase prescription drugs online.

FDA Enforcement

In December 1999, the FDA announced the launching of an Internet site aimed at helping consumers choose legitimate and safe online pharmacies. The website, [www.fda.gov/oc/buyonline], provides consumers with tips and precautions for

buying prescription drugs over the Internet. The FDA website warns consumers to avoid buying from online pharmacies that do not require a prescription, do not provide access to a pharmacist, or are located in foreign countries. The website also allows consumers to report suspicious online pharmacies to the FDA.

The FDA has also taken action against foreign online pharmacies selling prescription drugs to American consumers. In February 2000, the agency announced that it had sent letters via the Internet ("cyber" letters) to potentially illegal foreign-based pharmacy websites. The "cyber" letters warned the foreign operators that their businesses may be operating illegally and informed the websites of U.S. prescription drug laws and regulations. The "cyber" letters also warned the websites that future shipments of their products into the U.S. may be detained and subject to refusal of entry. Hard copies of the "cyber" letters were sent to the website operator, U.S. Customs officials, and officials in the home country of the website operator. As of February 2, 2000, one targeted website had responded to the FDA and had indicated that it will cease its illegal activities.[12]

Actions at the State Level

Some states have taken their own action against online pharmacies. In June 1999, the State of Kansas filed lawsuits against five online pharmacies. Illinois and Missouri filed separate but similar lawsuits in October 1999. Online pharmacies must be licensed in each state to which the pharmacy sends its products. The state lawsuits are targeting online prescription drug sales by companies and individuals who allegedly are not licensed to practice medicine or dispense prescription drugs in the states to which drugs have been delivered. The parties charged in the lawsuits also allegedly engaged in prescribing medication over the Internet without any physical contact with customers or without verifying the validity of the medical information the customers provided.

Private Sector Actions

The private sector has also taken its own actions to address problems raised by the sale of prescription drugs over the Internet. On February 9, 1999, the National Association of Boards of Pharmacy (NABP) announced the development of an online pharmacy verification program. This program, known as the Verified Internet Pharmacy Practice Sites (VIPPS) program, developed a set of criteria that online pharmacies should meet. An online pharmacy meeting the criteria can display the VIPPS seal of approval which indicates to consumers that the online pharmacy engages in ethical and legitimate practices. NABP also provides a list of online pharmacies meeting the VIPPS criteria on its website.[13] As of March 1, 2000, four online pharmacies (CVS, Drugstore.com, Merck-Medco Managed Care, and PlanetRx.com) were approved under the VIPPS program. The VIPPS criteria cover

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[12] To view copies of the "cyber" letters, see [http://www.fda.gov/cder/warn/cyber/cyber2000.htm].

[13] To view a list of VIPPS-approved pharmacies, see [http://www.nabp.org/vipps/consumer/listall.asp].

licensure by state agencies, compliance with state and federal laws, protection of patient confidentiality, communication with a pharmacist, storage and shipment of medication, and various other issue areas.[14]

[14] For a complete list of the VIPPS criteria, see [http://www.nabp.org/vipps/consumer/criteria.asp].