

# LDI *Issue Brief*

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## ***Sale of Prescription Drugs Over the Internet***

Editor's Note: Online drugstores represent one of the hottest categories in electronic commerce. The Internet offers great promise in expanding access to prescription drugs for the disabled, the elderly, and people living in rural areas. But with this promise comes the danger of eliminating the safeguards that protect consumers from inappropriate use of medications and adverse drug events. This Issue Brief highlights two studies that investigate the availability of prescription drugs over the Internet, and focuses on the alarming ease with which consumers can obtain drugs without seeing a physician or a pharmacist.

## ***Selling prescription drugs over the Internet can bypass traditional regulations***

Prescription drugs are well-regulated in this country, by a system that includes premarket approval by the federal Food & Drug Administration (FDA), state licensure of health care practitioners who are allowed to prescribe, and state oversight of pharmacists and pharmacies that are allowed to dispense. The sale of prescription drugs over the Internet has challenged this regulatory system because:

- Web sites based outside of the U.S. can easily market non-FDA-approved drugs to consumers in this country.
- Health care practitioners licensed in one state can easily prescribe drugs to patients they have never met in any state through the Internet. However, under existing law in most states, this is considered the unlicensed practice of medicine.
- Web-based pharmacies in one state can dispense prescription drugs to consumers in any state, thereby bypassing each state's regulations.

## ***Study finds Web sites selling prescription drugs without physician visits or prescriptions***

Between February and March 1999, Bloom and Iannacone catalogued Web sites offering physician consultations and selling prescription drugs directly to the public. They determined the requirements for obtaining a prescription, the availability of online physician consultations, the geographic location of the company providing the Web site, and the medications available for sale.

- Using multiple search engines, Bloom found 46 Web sites that provided prescription drugs, including 13 based outside the United States. Of these, all of the U.S. sites and four international sites required a physician consultation or prescription from the site's consulting physician or a personal physician.
- Only five sites would reveal their geographic location (city and country) beyond any information offered on the Internet. No site would reveal the specific address or qualifications of consulting physicians.
- U.S.-based Web sites primarily sold Viagra<sup>®</sup>, used to treat impotence, and Propecia<sup>®</sup>, used to treat hair loss. Other sites also sold popular drugs used to treat allergies, arthritis, herpes, as well as drugs targeting weight-loss.

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## ***Viagra® is readily available over the Internet***

In April 1999, Armstrong and colleagues investigated Web sites that sold Viagra® without a physician visit or prescription from an outside source. They chose Viagra® because of its potential consumer appeal and potential medical risks.

- Using various search engines, Armstrong and colleagues found 86 sites selling Viagra® that did not require a physician visit or a prescription from another source. In the 10-day interval between when they found the site and collected data, nine of the sites ceased operating. Twenty-two of the sites appeared to be based outside of the U.S.
- Of the 77 remaining sites, only 42 sites (55%) provided information about contraindications, 34 (44%) about other potential adverse effects, and 36 (47%) about efficacy.
- Online medical evaluation, consisting of a medical history questionnaire, was required by only 42 sites (55%), offered but not required by 4 sites (5%), and not offered by 31 sites (40%). Only 35 sites (45%) asked about a previous evaluation for impotence.

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## ***Online medical evaluations do not meet reasonable standards of care***

Armstrong and colleagues looked further at the content and design of the medical history questionnaire. Taking a medical history before prescribing Viagra® is essential because of the medical risks to patients taking certain heart medications (nitrates). Taking nitrates and Viagra® together could cause a serious fall in blood pressure.

- Only 27 sites (35%) specified that a physician would review the questionnaire, and no site provided information about the physician's qualifications or specialty.
- Of the 44 sites (60%) that included a questionnaire, only 34 (44%) required information on the use of nitrates. Forty sites (52%) asked about a diagnosis of angina or coronary heart disease; 33 sites (43%) asked about symptoms of coronary heart disease.
- Sites based outside of the U.S. were less likely to ask medical information, or to provide information about risks.
- Consumers were asked to release the companies from liability in 52 sites (68%) and specifically to waive their need for a physical examination in 12 sites (16%).

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## ***Obtaining prescription drugs online is more costly for patients***

Although many sites advertise lower prices to consumers than otherwise available, Bloom and colleagues found that this was not the case. On average, prices for Viagra® and Propecia® were about 10% more expensive when they were obtained from a local Web site than from a local pharmacy. Of course, consumers may be willing to pay more for the convenience of an online pharmacy.

- Based on the same dose, the median price per pill for Viagra® was \$5.49 through the Internet, as compared to \$4.50 in Philadelphia-area pharmacies. The median price per pill for Propecia® was \$1.94 through the Internet, compared with \$1.83 in Philadelphia-area pharmacies. Shipping costs averaged \$18 among U.S.-based Web sites.
  - Physician consultations were also more expensive than in-person visits. Internet physician consultations ranged from \$20 to \$70 (median price, \$70). This fee is 16.7% higher than payment by managed care organizations and Medicare for a primary care visit in the Philadelphia area (\$60).
  - A U.S. patient using a U.S.-based Web site to obtain a physician consultation and a 30-day supply of Propecia® would pay a 40% premium (\$68 more) for this service, not including shipping costs.
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### ***Web sites selling prescription drugs pose regulatory challenges***

Even in cases of clearly illegal activity (such as selling prescription drugs without a prescription), regulating these Web sites is difficult and uncharted. Regulatory challenges include:

- the ease with which Internet sites can appear and disappear, changing names and appearance.
- multiple jurisdictions. FDA regulates marketing of drugs, but not prescribing once a drug is approved. States traditionally have regulated both the prescribing and dispensing of drugs. Several states, however, have found it difficult to identify and locate violators and to bring effective enforcement actions because the seller, prescriber, and purchaser of a drug may reside in different states.
- foreign sites, over which U.S. authorities have limited jurisdiction. It is illegal to ship undeclared drugs into the U.S., but Customs Service and Postal Service personnel cannot inspect all incoming packages.

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### ***Regulatory and professional agencies are taking action to protect the public***

The availability of drugs over the Internet has attracted the attention of various groups. Because the regulation of Internet sites is so difficult, most groups are trying to influence the medical professionals that prescribe or dispense medications.

- In June 1999, the American Medical Association (AMA) issued guidelines for physicians on Internet prescribing. They state that any health care practitioner who offers a prescription to a patient based solely on an online questionnaire, without ever having met the patient, has generally not met the appropriate medical standard of care.
- More than a dozen state licensing boards have taken action against physicians who prescribe over the Internet to patients not known to them. These actions have ranged from fines to license suspensions.
- A number of state attorneys general have filed lawsuits against Web site owners for violating state laws (for example, providing drugs without a pharmacy license in that state, or mailing drugs to minors).
- Pfizer, the manufacturer of Viagra<sup>®</sup>, filed a complaint asking the Federal Trade Commission (FTC) to assert authority over Internet prescribing of Viagra<sup>®</sup>. The company believes that Internet sale of the drug based on an online questionnaire does not adequately convey the risks of the product. In general, the FTC can act when an online pharmacy makes false or misleading claims about the products it provides.

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### ***POLICY IMPLICATIONS***

These studies document some of the dangers posed by Internet drug prescribing. Clearly, policies are needed to protect the public's health while allowing the benefits of electronic pharmacy commerce to continue.

- Consumers need to be able to distinguish between sites with questionable practices and legitimate sites. Toward that end, the National Association of Boards of Pharmacy (NABP) has started a new program to verify the licensure of Internet pharmacy sites and inform the public about whether those sites are in good standing with the appropriate state board(s) of pharmacy. The program will provide a NABP "seal of approval" to sites meeting the organization's standards. Over time, this seal of approval may assure consumers that the designated sites are offering FDA-approved drugs and meet medical practice standards.

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## **POLICY IMPLICATIONS**

*Continued*

- State licensing boards should move quickly to establish and enforce guidelines for health professional involvement in Internet prescribing. States should also consider developing new regulations for Web-based pharmacy sites, if existing regulations do not address the documented problems.
- The federal government can support state enforcement efforts through inter-agency cooperation among the FDA, the FTC, and other regulatory bodies. New legislation may be necessary to ensure that Web site owners are traceable and accountable. In August, Rep. Ron Klink of Pennsylvania introduced the "Internet Pharmacy Consumer Protection Act." The bill would require Web-based pharmacies to list the name of principal practitioner, the address and telephone number of the principal place of business, and in what states the pharmacy and the pharmacists are licensed to do business. It would give the FDA the power to enforce these provisions.
- Effective strategies to address non-U.S. sites will require cooperative efforts of customs authorities, the pharmaceutical industry, and national and international regulatory agencies.

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*This Issue Brief is based on the following two articles: K. Armstrong, J.S. Schwartz, D.A. Asch. Direct sale of Viagra to consumers over the Internet. New England Journal of Medicine, October 28, 1999, vol. 341, pp. 1389-1392; B.S. Bloom, R.C. Iannacone. Internet availability of prescription pharmaceuticals to the public. Annals of Internal Medicine, vol. 141, Advance Web publication, September 1999.*

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## ***Wishing you a happy and healthy holiday season!***

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