

Controversies and Legal Issues of Prescribing and Dispensing Medications Using the Internet

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Online pharmacies fall into 3 major categories: independent Internet-only sites, online branches of “brick-and-mortar” pharmacies, and sites representing partnership among neighborhood pharmacies. Potential benefits of online pharmacies include increased access, lower transaction and product costs, and greater anonymity. However, online pharmacies have generated controversies, including the use of “cyberdoctors” on some sites, the dispensing of drugs without prescriptions from other sites, and the importation of prescription medications. Although some online pharmacies are legitimate and likely provide benefits to patients, other online pharmacies engage in questionable practices. Numerous state and federal regulations

and laws have tried to address controversies surrounding rogue Internet pharmacies. Because online pharmacies are increasingly common, clinicians may encounter patients asking for advice and information about online pharmacies. We review the regulatory framework governing online pharmacies and the potential risks and benefits of using online pharmacies.

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DEA = Drug Enforcement Administration; FDA = Food and Drug Administration; FDCA = Federal Food, Drug, and Cosmetic Act

A 68-year-old man presents to your primary care clinic for a routine follow-up visit. He has multiple medical problems, including hypertension, coronary artery disease, and severe osteoarthritis. During the visit, the patient tells you that he needs refills for all his medications but that he is concerned about his ability to pay for his medications because his medical insurance has no prescription benefits. The patient's friend recommended he purchase medications from an Internet pharmacy because the cost might be less. Also, Internet pharmacies could mail the medications to the patient's home, which would be more convenient because severe knee pain limits his mobility. Finally, the patient has seen commercials for sildenafil, which he thinks might help his “problem.” He has heard that some Internet pharmacies send consumers prescription drugs after they complete a brief questionnaire, and he has considered this option because he does not want people at the clinic or at his local pharmacy to know about his “problem.” He seeks your advice about purchasing prescription medications from Internet pharmacies.

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Online pharmacies provide patients with an appealing alternative to the local pharmacy and are attracting a growing number of patients to their sites (Table 1). They offer some benefits to consumers but have triggered reexamination of the ethical, legal, and safety issues involved in prescribing and dispensing medications.¹ The development of online pharmacies has prompted regulatory and monitoring actions at the federal, state, and professional organization levels. We provide an overview of online pharmacies and their potential benefits, the organizations involved in regulating these sites, and the major controversies surrounding online pharmacies.

METHODS

We searched MEDLINE, LexisNexis, and ISI Web of Science databases to identify pertinent material published between 1997 and 2002. Terms used in the search included *online pharmacies* and *Internet pharmacies*. For the MEDLINE search, we also used the term *Internet prescriptions*. We excluded articles unavailable in English.

Inclusion criteria were discussed and resolved by discussion between 2 investigators, who reviewed the titles and abstracts of articles from the initial search. Articles with titles or abstracts that included the following words or phrases were reviewed: online, Internet, cyber-, dot com, website-based, E-, and virtual pharmacies; online, Internet, cyber-, dot com, website-based, E-, and virtual drugstores; online, Internet, cyber-, dot com, website-based, E-, and virtual prescribing; online drug purchasing; lawsuits, legal actions, legal investigations, and prosecutions related to online prescribing; and consumer fraud and abuse related to online prescribing or Internet sale of medications. We

excluded articles whose titles, abstracts, or text indicated that the article pertained only to electronic or Personal Digital Assistant prescribing, physician or pharmacist electronic order entry, and economic portfolios of online pharmacies. Articles with titles or abstracts that met inclusion criteria were reviewed further. Some articles were primarily used to develop a taxonomy of types of online pharmacies and the framework for online pharmacy regulation.²⁻¹⁵ Investigators independently reviewed the remaining articles to ascertain themes involving the ethical and legal issues surrounding online pharmacies.

RESULTS

The initial search yielded 180 MEDLINE titles, 348 LexisNexis titles, and 85 ISI Web of Science titles. A total of 208 articles met inclusion criteria after reviewing titles and/or abstracts; 3 articles were not available, and 139 articles contained pertinent information, although many of the articles reported about a specific legal case involving an online pharmacy.¹⁶⁻³⁵ Meta-analysis was not possible because of the heterogeneity and qualitative nature of much of the information.

Types of Online Pharmacies

Online pharmacies fall into 3 major categories. First, the online pharmacy may be an independent Internet company that has no physical pharmacy site for a consumer to visit. This first group includes the pharmacy benefits manager arm of health plans, which also may provide selected services for nonmembers.^{36,37}

Second, the online pharmacy may be a “clicks-and-mortar” pharmacy, typically the online branch of a major pharmacy chain that has an actual storefront. Several chains have purchased online companies as a marketing strategy.^{38,39} These partnerships have enabled customers to request refills of prescriptions through Web sites and have given customers the option to pick up the refill at a local branch of a major pharmacy or receive the refill in the mail.⁴⁰

Finally, independent neighborhood pharmacies have formed networks and have built Web sites to represent themselves.⁴¹

Some online pharmacy Web sites have “cyberdoctors,” who evaluate patients via Internet communication and determine whether to prescribe medication based on this communication. The management and services of online pharmacies may be administered entirely in 1 state, may span several states, or may be located offshore.

Potential Benefits of Online Pharmacies

Online pharmacies offer potential advantages over traditional “brick-and-mortar” pharmacies. Some of the reasons consumers have cited for purchasing prescription

Table 1. Select Drug Store Sites Ranked by Unique Audience*

Brand	Unique audience		Growth (%)
	October 2002	August 2003	
Drugstore.com	1,972,000	2,183,000	11
Merck-Medco	1,370,000	1,420,000	4
Walgreens	1,320,000	1,164,000	-12
CVS/pharmacy	715,000	458,000	-36

*Unique audience is the number of individuals who have gone to a site at least once in the defined time period. From Nielsen/NetRatings, with permission.

drugs from online pharmacies are summarized in Table 2.⁴² Online pharmacies can be more accessible to people with limited mobility and to people in remote areas.⁴³ They enable patients to place orders 24 hours a day⁴⁴ and offer mailed delivery of medications.⁴⁵ On some Web sites, patients can compare prices and availability of medications with the click of a mouse.⁴⁶ Also, online pharmacies may leverage economies of scale by using a more efficient centralized order-processing system to reduce transactional costs and the costs of obtaining pharmaceuticals.⁴⁷ These reduced costs potentially may be passed on to consumers in the form of lower prices.

Consumer Reports priced 5 common brand-name drugs at various outlets (drugstore chains, independent pharmacies, supermarkets, mass merchants, and online/mail order pharmacies) and found savings up to 29% with online/mail order pharmacies.⁴⁸ However, Bloom and Iannacone⁴⁹ noted that, on average, online pharmacies included in their study charged higher prices for finasteride and sildenafil than did local pharmacies. Also, shipping and handling charges and online consultation charges may reduce overall savings to the consumer.^{49,50}

Online pharmacies have the potential to promote communication among pharmacists, physicians, and patients; whether this potential has been realized is debatable. For example, the option to send questions at any time of day

Table 2. Motivation for Online Purchase of Prescription Drugs⁴²

Motivating factor	%
Order during off hours	59
Saves time	50
Easier than mail order	50
Cheaper	44
Cuts trips to the drug store	41
Refill reminders	26
Online medication information	23
Customer service	20

From the ePharmacy Opportunity, Forrester Research, Inc, June 2000, with permission.

about the adverse effects of medications may encourage patients to question pharmacists.⁴⁷ In addition, the cloak of anonymity that the Internet offers may encourage patients to ask questions about some medications that they would be too embarrassed to ask in a busy pharmacy.

Legitimate sites appear to have appropriate technology to ensure security.^{51,52} However, visits to some sites may not be anonymous if the sites use “cookies” to collect information about visitors and lack secure Web technology.⁵³

High-volume online pharmacies could provide opportunities to create a central repository of medical information for patients and an increased ability to implement automated systems that will detect drug-drug interactions.⁴⁷ However, this central repository may be incomplete if patients turn to online pharmacies to fill some medications but not others (eg, medications for acute rather than chronic conditions). Online pharmacies have the potential to empower patients by providing information about new medications, adverse effects of medications, and health conditions.⁴⁴ A cross-sectional study of Internet pharmacies and community pharmacies found that, in general, Internet pharmacies provided more comprehensive drug information than community stores on 2 drug information questions used in the study (“Can Eldepryl be taken together with Prozac?” and “Should Sinemet be taken together with food?”), although response times were longer for online pharmacies than for stores.⁵⁴ However, the sample included only 8 pharmacies: 3 Internet pharmacy Web sites associated with retail chain pharmacies and their respective retail store counterparts, 1 independent Internet pharmacy Web site, and 1 independent retail pharmacy store.⁵⁴ Finally, online pharmacies provide another opportunity for patients to report adverse effects and adverse drug reactions⁵⁵ and for pharmacists to improve adherence to medications by sending reminders to patients.^{56,57}

Regulatory Framework

Although online pharmacies offer some benefits, some online pharmacies may engage in practices that pose risks to patients.⁵⁸ Actions aimed at online pharmacies may come from 3 levels: federal, state, and professional organizations. Multiple federal agencies have jurisdiction. The Food and Drug Administration (FDA) is responsible for enforcing the Federal Food, Drug, and Cosmetic Act (FDCA), which mandates a prescription for drugs that cannot be used safely without supervision by a licensed professional. The FDA also regulates “the Internet Drug Sales Action Plan adopted in July 1999, [which]...targets health care fraud, the sale of unapproved, counterfeit, adulterated, or illegal drugs, and prescription drugs sold without a valid prescription.”⁵⁹ The Federal Trade Commission enforces issues related to false or misleading claims that online pharmacies may make

about their products, services, or business practices.⁵⁹ The Drug Enforcement Administration (DEA) enforces regulations about the dispensing and sale of controlled substances, including transactions that take place on the Internet.⁶⁰ The US Customs Service and the US Postal Service also enforce statutes and regulations related to the importation and domestic mailing of drugs.^{40,61}

At the state level, state boards and attorneys general are responsible for regulatory activity related to online pharmacies. State medical and pharmacy boards, empowered by state legislatures, enforce requirements that physicians and pharmacists obtain licenses in the states in which they practice. They ensure that professionals have good moral character and follow statements issued by the boards.⁴⁶ State attorneys general, empowered by state legislatures and state constitutions, enforce the laws of their state and may cooperate with other state attorneys general to produce joint enforcement.⁴⁷

Finally, professional organizations have developed quasi-regulatory programs and have issued statements about online pharmacies. The National Association of Boards of Pharmacy, an organization that represents state pharmacy boards, has formed the Verified Internet Pharmacy Practice Sites (VIPPS) program, which certifies online pharmacies and may suspend certification when sites do not comply with the program.⁶²⁻⁶⁵ Internet pharmacies with the VIPPS seal are listed in Table 3.⁶⁶ In addition, the Federation of State Medical Boards, the National Association of Attorneys General, and the American Medical Association have addressed regulation of online prescribing and dispensing of medications.^{59,67}

Controversies Surrounding Online Pharmacies

Dispensing of Prescription Drugs Without a Valid Physician Order.—The first major concern involves the dispensing of prescription-only medications such as ciprofloxacin and sildenafil without a prescription.⁶⁸ This controversy gained media attention after the anthrax cases in 2001 when officials learned that people had obtained ciprofloxacin without a prescription.^{69,70} In a 1999 cross-sectional study of Internet pharmacies, researchers found that 19.6% (9/46) of Internet pharmacies identified in the study did not require a prescription or physician consultation before dispensing medications.⁴⁹ In a similar study conducted by the General Accounting Office, investigators found that 13% (25/190) of online pharmacies dispensed medications without prescriptions, although most of these pharmacies were offshore.⁷¹ Finally, Armstrong et al⁷² found that sildenafil was readily available without a physician-patient encounter or prescription.

From a legal perspective, dispensing prescription drugs without a valid physician order is a violation of the FDCA

and may result in civil or criminal action against the pharmacist.^{59,73,74} In testimony to Congress, the FDA announced its concern about Web sites that enable patients to obtain prescriptions without the supervision of a licensed health care professional and its plans to target sites that violate the FDCA.⁷⁵ From a patient safety perspective, patients who obtain prescription medications in this manner may expose themselves to drug-drug and drug-disease interactions and to dangerous adverse effects.^{76,77} Officials from the FDA have encouraged health care professionals to provide education to patients about “dangerous on-line practices.”⁷⁸

Importation of Medications.—Senior citizens without a Medicare prescription drug benefit may turn to Internet sites to gain access to more competitively priced prescription drugs sold from foreign pharmacies.⁷⁹⁻⁸¹ A recent Wall Street Journal Online/Harris Interactive Health-Care Poll of the public found that 7% of people sampled stated that they had “bought prescription drugs from a pharmacy in Canada or another foreign country—by going there, on the Internet or by mail—to save money.”⁸² These practices have resulted in a second area of concern: ordering prescription drugs from foreign pharmacies via the Internet.

The importation of unapproved, misbranded, or adulterated drugs is unlawful.^{83,84} Foreign-made versions of US-approved medications are also generally not permitted by the FDA because they typically do not meet all FDA requirements.^{83,85} The FDA has voiced concern that some sites may “dispense expired, subpotent, contaminated or counterfeit product[s].”⁸⁵ However, because of limited resources, the FDA uses enforcement discretion when assessing cases involving unapproved prescription medication for personal use.^{83,86} The factors currently considered under personal importation policy are summarized in Table 4. Of note, William K. Hubbard,⁸³ FDA Senior Associate Commissioner for Policy, Planning and Legislation, testified to Congress that

Due to the inability of FDA to cope with the volume of medications imported for personal use through the mail, and because of the public health risks associated with these products..., FDA has been working to develop a more effective personal importation policy...We are discussing options for revisions to the Agency’s personal importation policy with Secretary Thompson.

Any physician assisting a patient to find non-FDA-approved treatments or supervising a patient who has acquired a non-FDA-approved product should consult legal counsel to review the individual state laws that may govern the extent and type of advice a physician may provide concerning use of unapproved drugs. Issues concerning the risk of being charged with professional negligence should be raised when discussing the case.

Table 3. Web Sites of Internet Pharmacies With the VIPPS Seal of Approval (as of December 2003)

Web business name	Web site address
accuratepharmacy.com	www.accuratepharmacy.com/
AdvanceRx.com	www.AdvanceRx.com
Anthem Prescription	www.anthemprescription.com
Caremark Inc.	www.rxrequest.com
Clickpharmacy.com	www.clickpharmacy.com
CVS Washington, Inc. (CVS.com)	www.cvs.com
drugstore.com	www.drugstore.com
Express Pharmacy Services/ Eckerd.com	www.Eckerd.com
Familymeds.com	www.Familymeds.com
Medco Health Solutions, Inc.	www.medcohealth.com
NCS Healthcare (Care For Life)	www.careforlife.com
RxWEST Pharmacy	www.rxwest.com
Tel-Drug, Inc./CIGNA	www.teldrug.com
walgreens.com, Inc.	www.walgreens.com

From the National Association of Boards of Pharmacy Web site,⁶⁶ with permission. The National Association of Boards of Pharmacy created the Verified Internet Pharmacy Practice Sites (VIPPS) program in 1999 in response to consumers’ and regulators’ complaints about suspiciously operating online pharmacies. VIPPS-certified pharmacies post a digital seal of approval on their home page that notifies consumers that the pharmacy is validly licensed in all applicable jurisdictions, its policies and Web site have been reviewed, and the pharmacy has passed an on-site inspection and criteria review.

When reviewing importation of prescription drugs that have FDA approval for use in the United States, the FDA considers factors such as whether it has certified and approved the manufacturing source or whether it has issued a warning that it cannot ensure the safety of the product.⁷⁹ Again, because the FDA has limited resources for enforcement, many patients have been able to import prescription medications approved for use in the United States that they purchased from Canadian and other foreign pharmacies. However, the FDA has begun raising awareness in Canada about its view on the importation of Canadian prescription drugs and participated in a forum on the international sale

Table 4. Factors Considered by the US Food and Drug Administration When Evaluating Importation of Unapproved Prescription Drugs^{83,86}

Product for personal use (90-day supply or less, and not for resale)
Intended use for serious condition for which effective treatment may not be available domestically (therefore, the policy does not permit inspectors to allow foreign versions of US-approved drugs into the United States)
No known commercialization or promotion to US residents by those involved in the distribution of the product
Product considered not to represent an unreasonable risk
Individual seeking to import the product affirms in writing that it is for the patient’s own use and provides the name and address of the US-licensed doctor 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

of prescription drugs from Canada that was sponsored by the Canadian National Association of Pharmacy Regulatory Authorities.⁸⁵ The FDA has attempted to enforce the FDCA by sending warnings to offshore pharmacies^{87,88} and asking the US Customs Service to seize products at the border.⁸⁹ However, in general, the FDA has had difficulty enforcing the FDCA for online pharmacies administered offshore because the companies are not physically in the United States and therefore are not susceptible to meaningful agency action (eg, an enforceable court-ordered injunction against further conduct or a seizure of assets).

Besides FDA and US Customs Service actions, the DEA may take action when sites dispense controlled substances to US residents.⁹⁰ According to DEA guidelines,⁶⁰

The Controlled Substances Act prohibits any person from importing into the customs territory of the U.S. any controlled substance or List I chemical (21 U.S.C. 971 and 21 CFR part 1313) unless that person maintains a valid, current authorization to import such substances or chemicals (21 U.S.C. 957(a)), [even if the patient has a valid prescription from a US physician.]

Finally, the US Postal Service can enforce regulations and statutes.⁴⁰

Use of Cyberdoctors.—A third area of concern involves the filling of prescriptions generated by online physicians who obtain patient information solely from online questionnaires⁹¹⁻⁹⁴ that may have check boxes that are preselected for the response that helps the patient obtain the medication in question.⁹⁵ This model of care is concerning because patients may use these online physician services to obtain medications for symptoms that they may not have disclosed to their local provider. Alternatively, patients may entirely forego appointments with local physicians if they consult a cyberdoctor and receive a medication via the Internet that addresses their complaint.

Many health care professionals and agencies question the safety of online consultations and the quality of care that cyberdoctors are capable of delivering. Concerned about the risks of online consultations, federal, state, and professional organizations have taken actions and issued statements regarding online consultations. The Federal Trade Commission has cited deceptive claims in cases in which online pharmacies made false statements about their medical staff and has required online pharmacy Web sites to meet certain privacy standards.⁵⁹ The DEA-issued guidelines, directed at dispensing and purchasing controlled substances via the Internet, state “It is illegal to receive a prescription for a controlled substance without the establishment of a legitimate doctor/patient relationship, and it is unlikely for such a relationship to be formed through Internet correspondence alone.”⁶⁰

State attorneys general from numerous states have brought cases against online physicians and pharmacy Web sites that fill prescriptions from online physicians. They have enforced state laws that require pharmacists to be licensed in the state in which they dispense medications. Similarly, they have enforced laws that require physicians to be licensed in the state in which they practice.⁵⁵ Under consumer fraud acts, online pharmacies may be liable if they do not tell consumers that they are not licensed in the state in which they dispense medications.^{55,96,97}

Finally, professional federations and associations have taken steps to curb online prescribing practices of cyberdoctors. In its “Report of the Special Committee on Professional Conduct and Ethics,” the Federation of State Medical Boards released guidelines for the appropriate use of the Internet in medical practice and provided specific guidelines for evaluating the patient:⁹⁸

A documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided, must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise.

State medical boards may fine cyberdoctors; however, enforcement can be difficult because some sites do not reveal the identity or location of the prescribing physician.⁹² Furthermore, medical boards may have the authority to enforce fines imposed on cyberdoctors who practice in other states.⁹⁹ The American Medical Association has a clear position on this matter, stating in its “Guidelines for Medical Practice through the Internet” that “physician[s] should refrain from writing prescriptions for medication resulting only from a sale or consultation over the internet.”¹⁰⁰

Although much of the existing literature about online pharmacies raises concerns about cyberdoctors, some have argued that the current patient-physician paradigm is too paternalistic and that online assessments may be acceptable in some circumstances if certain quality criteria are met such as adequate informed consent, thorough medical history, and appropriate patient confidentiality.¹⁰¹ No studies we reviewed have shown that cyberdoctors thus far have been able to meet these quality criteria.

CONCLUSIONS

Clinicians may encounter patients who may be contemplating use of online pharmacies but may have questions about the legitimacy of online pharmacies. Clinicians may also have patients in their practice who are already using online pharmacy services. Some patients may be filling valid prescriptions from their local provider, but others may be acquiring new prescription medications that they receive

through online consultations. Although some online pharmacies are legitimate and may provide benefits to patients, other online pharmacies engage in questionable practices.

Clinicians should familiarize themselves with a few reputable and legitimate online pharmacies that they feel comfortable recommending so that they are more knowledgeable when patients ask for advice about using online pharmacies. They should also consider advising their patients to avoid online sites that dispense medications without a valid prescription or physician visit.

Reviewing the regulations and laws that govern Internet pharmacy activities also introduces clinicians to the legal issues surrounding the prescribing and dispensing of prescription medications in general.

Finally, consumers' interests in online pharmacies should promote self-reflection in the medical community. Physicians and pharmacists should ask themselves why their patients would rather receive medications without a prescription, a face-to-face consultation, or a visit to their local pharmacy, and what legitimate and legal practices the medical community can adopt from online pharmacies to improve the physician-pharmacist-patient relationship.

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