

Psychotropics Without Borders: Ethics and Legal Implications of Internet-Based Access to Psychiatric Medications

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Medical practitioners are revisiting many of the ethics and the legal implications surrounding the clinical frameworks within which we operate. In today's world, distinguishing between virtual and physical reality continues to be increasingly difficult. The physician may be found grappling with the decision of whether to continue to treat a patient who may be obtaining psychotropic medications through the Internet. This article approaches some of the clinical and legal implications and the ethics regarding the availability of prescription psychotropics over the Internet.

J Am Acad Psychiatry Law 39:104–11, 2011

The boundaries between our virtual and physical realities are becoming more and more blurred. The cyber world is increasingly permeating every aspect of the real world. The futuristic worlds depicted in the films *Avatar* and *Gamer*, in which it is difficult to distinguish virtual reality from actuality, are starting to resemble day-to-day life. Although the distinctions between physical and virtual reality are increasingly questioned, the impact of one on the other is undeniable. It is, therefore, not surprising that medical practitioners are finding themselves revisiting many of the ethics and the legal implications surrounding the clinical frameworks within which we operate.^{1,2} In these ever-increasing scenarios, the physician may be found grappling with the decision of whether to continue to treat a patient who may be living through and treating his illness in a virtual world. In the game *Second Life*, a player can create an online character who has a home, job, and relationships and can even seek treatment from a doctor played by another person.

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Disclosures of financial or other potential conflicts of interest: None.

This article focuses only on the purchase of prescription medication over the Internet on websites that do not require verification of a prescription or that issue one on the basis of a brief online questionnaire. It addresses background and statistical data pertaining to medications bought without a prescription over the Internet, clinical considerations regarding the physicians' required pharmacological fund of knowledge, and the effects on the doctor-patient relationship, as well as the legal implications surrounding these concerns. Finally, hypothetical scenarios are presented to promote ongoing commentary on these concerns.

Unfortunately, the literature in this area is minimal. Several authors have demonstrated the availability of prescription-only medications without a prescription via the Internet. These articles have reviewed availability of medical pharmacotherapies for the treatment of psoriasis,³ antibiotic treatments (with the associated risk of inappropriate treatment and development of bacterial resistance),⁴ thyroid replacement therapies,⁵ medications for the treatment of sexually transmitted diseases,⁶ and oral contraceptives.⁷ The largest market comes from online sales of phosphodiesterase type 5 (PDE-5) inhibitors and analgesics. All of the above medications have the potential to be lethal in combination with other

drugs, or in the case of other pathologic medical conditions. With respect to psychotropic medications or treatments of psychiatric illnesses outside the realm of narcotic or stimulant abuse,⁸ the literature is limited to anecdotal case reports of lithium toxicity derived from a dietary supplement that did not disclose proper information,⁹ and a case of niacin overdose and intoxication due to misleading information regarding treating schizophrenia with high-dose niacin.¹⁰

Internet Availability of Medications

Online pharmacy sales have skyrocketed since the first online pharmacy was launched in the United Kingdom in 1999. Currently, it is estimated that sales through online pharmacies generate billions of dollars each year,¹¹ although a definite estimate cannot be established. Approximately 10 to 15 million Americans buy their prescription medications in pharmacies outside the United States,¹² and the number increases dramatically if American-based online pharmacies are included. According to the Drug Enforcement Agency (DEA), 85 percent of Internet drug sales are controlled drugs, while only 11 percent of those same drugs are being sold at traditional pharmacies.¹³

The motivations driving this increase in online pharmaceutical sales appear fairly clear. First, medications bought from pharmacies abroad can have a dramatically lower price than the same medications in the United States, sometimes as much as 80 percent less.¹⁴ The concept of reimportation¹⁵ of medications as a means of purchasing them in the United States has been formally suggested to lower medication costs and improve access to therapies, especially for the large population of uninsured Americans. In July 2003, a legislative movement was initiated to enable the legal importation of medications from Canada and Europe. The savings are estimated to be from about 20 percent to more than 80 percent for some medications.¹⁴ Notably, among the medications offering the largest mean yearly savings is olanzapine, marketed as Zyprexa, a psychotropic drug for which no generic equivalent is currently available.¹⁶ These cost-saving estimates do not take into account the added expenditures of the patient seeking to have office-based prescriptions filled at a neighborhood pharmacy, such as the cost of the doctor visit and transportation.

Second, online prescription purchases offer conveniences in terms of time management and efficiency. The process of placing a medication order online is often completed within minutes, compared with the hours or days usually required for traditional methods. Medications are delivered to the patient's door, which is particularly convenient for homebound or disabled patients. Refills can be scheduled automatically, if the person has established a membership and registered a credit card.

A recent study indicated that most online prescription consumers are of middle to high socioeconomic status, as inferred by the fact that they are literate and have access to Internet and credit cards.¹⁷ Stigma against psychiatric illness is still prominent,^{18–20} and buying psychotropics online offers a level of discretion that allows for mental illness to remain off the record for those who do not want to create documentation of treatment for insurance, employment, and licensure reasons. Thus, professionals such as high-profile attorneys, airline pilots, businessmen, and psychiatrists in a patient role, may be motivated to seek out this modality of access to medications.

Other potential advantages of online pharmacies include access to the range of medications not available in the U.S. market and the inexhaustible availability of medications at all times. Finally, Internet-based consumers have access to extensive medication information through websites such as erowid.com, crazymeds.com, and drugs.com, among many others. Online, one can find a peer-based system of monitoring medication effects and associated side effects. Also available are quick comparisons of medication prices and alternative treatments and descriptions of drug interactions.

The practice of purchasing medications, particularly psychotropic medications, online without physician monitoring has some obvious disadvantages and dangers.²¹ Often, buyers have not had a proper medical or psychiatric evaluation, including a review of medical history or a personal examination. The use of brief online questionnaires creates an exceedingly high risk of misdiagnosis. Proper diagnosis and treatment could be delayed, with life-threatening consequences. The absence of regularly scheduled opportunities to monitor for side effects that may not be evident to the consumer creates additional risks. The patient who is self-treating is also at increased risk of drug abuse, which is facilitated by a narcotics

market that literally delivers to the consumer's doorstep.²² Moreover, online pharmacies often dispense medications to minors (knowingly or not), who are at high risk of falling into a pattern of drug abuse.²³

Other serious problems associated with online pharmaceutical use, for those who have physician-issued prescriptions and self-treaters alike, is that online medications often do not carry a guarantee that the products are genuine, are as potent as the U.S.-based alternative, are within their expiration date, or are produced under even basic sanitary standards.¹¹ Furthermore, pharmacy websites are often scam portals that illegitimately charge credit cards without subsequent product delivery or attempt identity theft or violate privacy-assurance standards. Finally, although consumer medication information may be suboptimal in physical pharmacies, it is completely unregulated in web-based pharmacies. Online pharmacy websites often do not comply with the information disclosure required for sales of medications in the United States²⁴ or may convey misleading information regarding a medication's risks and benefits. True informed consent is thus jeopardized.

How psychiatrists approach this paradigm shift into the digital world is extremely important, as remaining uneducated about Internet-associated implications for practice and risk management is not safe for proper patient care.²⁵ A recent study compared the efficacy and safety of e-medicine versus traditional medicine as it pertained to prescription of PDE-5 inhibitors. When closely monitored, the e-system was equally safe or even safer than the traditional system.²⁶ Thus, as the medical profession moves closer to adopting alternative e-practice models, a review of the ethics and of the risk management and legal implications is warranted. This review is particularly relevant, because a significant number of the adversely affected subgroup of this population may in fact require psychiatric care.

Regulation of Medication

The U.S. Food and Drug Administration (FDA) is responsible for regulating and supervising the safety of dietary supplements, prescription and non-prescription medications, and biopharmaceuticals, among other duties. It is also in charge of overseeing regulatory programs regarding sanitation, drug marketing, and safety monitoring; research guidelines for the use of living organisms; and regulation of devices for medical use or research. Established by President

Theodore Roosevelt in 1906, it has undergone several reforms throughout history, with an increased scope of responsibilities as the result of legislation.²⁷

Most relevant to the subject at hand, however, are the FDA's primary roles in regulating approval, advertising, transit, and monitoring of new drug applications (NDAs), generic drugs or abbreviated new drug application (ANDAs), and over-the-counter (OTC) drugs. The FDA oversees approximately \$275 billion per year in drug sales. The agency is within the U.S. Department of Health and Human Services and works in conjunction with the Department of Agriculture, DEA, Customs and Border Protection, and Consumer Product Safety Commission. It is monitored by governmental and nongovernmental agencies. It is currently under intense scrutiny for allegations of undue influence of the pharmaceutical industry on its Center for Drug Evaluation and Research (CDER).²⁸

A similar entity in Europe, the European Medicines Agency (EMA), was created with funding from the European Union and the pharmaceutical industry, as well as indirect subsidy from member states, in an attempt to harmonize (but not replace) the work of existing national medicine regulatory bodies. In comparison to the FDA, it is decentralized and operates as a scientific, not a regulatory, agency. New drugs are also sent to the EMA for approval, but the agency is obliged to reach a decision within 210 days, as opposed to more than twice that time for the FDA. Overall, the EMA is the agency that most closely resembles U.S. regulatory parameters. Other countries worldwide, however, may not be as stringent in their medication-handling parameters, and thus, make it possible to dispense medications without a prescription or more detailed control.

Before prescribing any medication, physicians are required to obtain informed consent from their patients for treatment. The standards for informed consent have shifted due to case law, ethics-related considerations, and evolving standards of clinical practice. Nevertheless, informed consent involves the fundamental requirements of disclosure of information (including potential benefits, risks, and alternative treatments), freedom from coercion, and competency to consent or refuse. Of these, only disclosure of information is addressed when considering online pharmacies. The FDA establishes regulations pertaining to the labeling of medications and their dosages, the listing of the diagnoses or syn-

dromes for which they are approved as treatments, and the availability of information pertaining to potential side effects. However, online pharmacies that are based abroad are not subject to the same regulations, and monitoring U.S.-based online pharmacies to ensure proper disclosure is difficult.

As psychiatrists, we may be aware that patients are obtaining drugs from sources other than medical prescriptions, including herbal remedies, medications facilitated by family members based on their own indication or response, or illicit drugs sold on the street. However, doctors may not be aware that their patients are receiving medications from other sources and because they assume that their patients are not engaging in such activities, they may not ask them, or may ask but receive less than truthful responses.

Along this continuum, worldwide communications through the Internet bring about a similar paradigm. Patients have access to medications that may not be available in the United States. Examples of some of these psychotropics include reboxetine, pemoline, calcium carbimide, maprotiline, mesoridazine, methotrimeprazine, pipotiazine, trimipramine, sulpiride and amisulpride, sertindole, rimobabant, and bifeprunox.

The legality and risks of purchasing drugs online depend on the specific kind and amount of drug being purchased. With regard to controlled substances, 21 USC, § 952 dictates that purchasing such substances from an overseas pharmacy is illegal, under penalty of up to five years of imprisonment and a \$250,000 fine. Possession of a controlled substance without a valid prescription (the FDA does not recognize online-issued prescriptions as valid, as it requires a face-to-face relationship with a physician) could be sanctioned under 21 USC, § 844 for up to one year and a one thousand dollar fine.

If the medication being ordered online is not a controlled substance, 21 USC, § 301(aa) requires that certain conditions be met to ensure its legality:

The drug is imported from Canada, from a seller registered with the Secretary (i.e., with the FDA).

The drug 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.

The drug is accompanied by a copy of a valid prescription.

The drug is a prescription drug approved by the Secretary.

The drug is in the form of a final finished dosage that was manufactured in an establishment registered under § 510.

The drug is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

The law further specifies that enforcement be focused on cases in which importation of a drug by an individual poses a significant threat to public health, and discretion should be exercised to permit individuals to make such importations in circumstances in which the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

The Department of Homeland Security Appropriations Act, § 535, Customs and Border Patrol, has similar guidelines for the importation of medications. Nonapproved drugs are also banned from legal importation by mail under 21 USC §§ 331(d) and 355(a). Furthermore, laws regulating importation, possession, and trafficking in prescription drugs and/or controlled substances can vary by individual jurisdiction.

Enforcement of these laws is difficult. The FDA and Customs Enforcement are more focused on pursuing the online distributors than the individual customers, and many of these web-based pharmacies are located overseas, requiring the support of the host government. Furthermore, there are at least hundreds of identified online pharmacy websites, rendering prosecution of all of them unlikely. Likewise, the amount of incoming packages containing prescription drugs exceeds Customs' capacity to inspect and seize them. Scrutiny is therefore focused on those containing large amounts of narcotics or amphetamines (where intent to distribute is suspected). From a different perspective, the largest population of web-based prescription consumers are the elderly, the uninsured, and the disabled; thus prosecution of this means of access to needed medications would leave them in a dire situation without a feasible alternative.

Nevertheless, several cases exemplify the government's approach to enforcing these laws. Operation Cure.All was started in 1999 as a joint effort between the FDA and Health Canada (Canada's regulatory agency) to track down websites with fraudulent

claims of medication effects. In 1999, Kansas filed consumer protection lawsuits and restraining orders against seven online pharmacies. In 2000, President Clinton put forward a proposal that would have allowed for increased budgets for the FDA and DEA to tighten web-based medication sales monitoring, administrative privileges to subpoena records for federal certification, and up to \$500,000 in civil penalties for failing to comply with regulations. In 2005, the DEA's Operation Cyber-Chase made 20 arrests in eight U.S. cities (in Pennsylvania, Florida, Texas, New York, and South Carolina) and four foreign countries, targeting major Internet pharmacies that were trafficking in controlled substances.²⁹ In Europe in 2008, the matter of Internet pharmacies was raised in a case pertaining to violation of advertisement regulations.³⁰

Physicians have been implicated in litigation due to their issuing of prescriptions for online pharmacies, as opposed to treating physicians of patients who are filling their prescriptions online. A case in point occurred in Chicago in 2006,³¹ when a medical malpractice suit was filed against two doctors who were charged with deviating from the standard of care for prescribing alprazolam and tramadol in excessive dosages to a patient they had never seen or examined and practicing without a license in the state of Illinois (the patient was located in Illinois, whereas the doctors were in New Jersey and Pennsylvania). The case settled before trial.

As in the case cited, there are guidelines for the medical practitioner who prescribes medications. The American Medical Association (AMA) requires an "established valid patient-physician relationship."³² The Federation of the State Medical Boards (FSMB) specifies that this relationship requirement is not met solely by an online questionnaire and that to prescribe exclusively on the basis of such a questionnaire would not constitute an acceptable standard of care. It also specifies that the physician be licensed in the state where the patient resides.³³ As telemedicine continues to grow and concerns increase pertaining to providing online psychotherapeutic interventions,³⁴ ethics principles have evolved for the provision of mental health services.³⁵ There are no guidelines, however, that pertain to treating a patient who is engaged, with or without the physician's advice, in Internet-based medication acquisition. There are several entities that have arisen to bridge this gap and ensure that online availability of

medications offers a safe alternative for those who truly need it. For several years, the states of Nevada, Minnesota, Illinois, and Wisconsin have run official state programs to help their residents order lower-cost drugs from abroad. United Health Alliance (UHA) in Vermont created MedicineAssist, a Web service to help elderly patients to obtain medications at affordable prices by using Canadian online pharmacies. The National Association of Boards of Pharmacy has an online verification program that stipulates proper licensing and procedures.

Ethics Principles

In the pursuit of best practices in medical care, we seek to offer the best alternative for treatment, within the frames of safety and ethics. Ethics guidelines that speak to the physician-patient relationship incorporating the digital dimension are scant.

Speaking to Web-based medication purchases in particular, the AMA Code of Ethics states, "In all instances, physicians should respect the patient's freedom of choice in selecting who will fill their prescriptions as they are in the choice of a physician and, therefore, have the right to have a prescription filled wherever they wish".³⁶ The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration,"³⁷ and the International Code of Medical Ethics declares, "A physician shall act in the patient's best interest when providing medical care."³⁸

Thus, the question arises as to whether the physician should continue to treat a patient who is engaged in self-sought psychopharmacological treatment. This conduct may be discouraged in many cases, if the physician suspects abuse, misdiagnosis, or unwarranted risk. This situation could be considered somewhat analogous to the ongoing treatment of a patient who is known to be engaged in illicit substance use. However, in other instances, the physician may find that the best treatment alternative for a particular patient is in fact a medication that he or she is not able to offer his patient via U.S.-based pharmacies. In this case, the physician is not able to prescribe such medication under legal constraints, but may have to be capable of monitoring the ongoing treatment, should the patient procure the medication.

Some Internet-based therapeutic interventions, including telepsychiatry, online programs for smok-

ing cessation, and the treatment of sexual impotence, have been gaining more widespread acceptance and use. These interventions are endorsed and condoned (even encouraged), even though they carry certain risks.³⁹ Yet the acquisition of medications without a physician's prescription appears to be a particularly hard problem to address or resolve.

One could hypothesize that this difficulty is not due to ethics or legal implications, but to matters that inherently threaten the doctor-patient relationship, the foundation on which we base any form of treatment. It calls for exploration of dynamic themes that may have to be understood. If, for example, the dynamic is one of lack of trust in the treating physician, the problem would have to be resolved before additional treatment could be undertaken. However, how would psychiatrists address a dynamic involving lack of trust of a regulating system, such as the FDA, which is currently under scrutiny?

We may also have to consider a range of possibilities in which the physician might find it hard to trust the patient's choice. Are suspect or dangerous choices the result of character pathology, such as attempts at self-sabotage, narcissistic enactments, or passive-aggressive defenses against the doctor and the mental illness itself? On the other hand, are such suspicions the result of a narcissistic threat to the doctor, who is now expected to be knowledgeable of all available treatments and doubts his or her own skill or capacity based on lack of experience with certain medications? Does the doctor feel vulnerable in practicing without a safeguarding agency?

Within a working therapeutic alliance, there is a point of confluence among physicians, regulating agencies, best alternatives for patient care, and ethics guidelines—the informed consent, autonomously given in the absence of coercion. It has been proposed that the Internet has served as a means of skyrocketing direct-to-consumer marketing of pharmaceuticals,⁴⁰ which is then followed by misleading information and undue influence, especially on a vulnerable population with impaired decision-making capacities. Physicians find themselves under pressure to prescribe medication that their patients have discovered online and are demanding.

Illustrative Vignettes

The following vignettes are not exhaustive or definitive, but are offered to stimulate further discussion.

Vignette A

An immigrant patient has been receiving a medication in his country of origin with good tolerance and symptom response. The medication is not available in the United States, but is available without a prescription through the Internet. The patient is faced with having to undergo trials of new psychotropics (or prior failed ones) and risk decompensation. The patient chooses to continue the medication that has been helpful but must be obtained online and declines the psychotropics offered by the psychiatrist, who then discharges the patient from care. The patient then faces the decision of withholding information regarding prescriptions bought online from the doctor or continuing treatment without medical monitoring.

The doctor should not be liable for negligence or malpractice if he continues to monitor this patient. Adherence to a commonly agreed on regimen favors the collaborative dimension of a working alliance and the patient's autonomy in choosing a treatment option. The role of the physician is to provide ongoing education, to monitor for side effects and decompensation, and to ensure the safety of the patient and others. Similar to a psychiatrist who continues to prescribe a psychotropic regimen for a patient who is known to be actively involved in illicit substance use, forthcoming information about the substance use should be encouraged so that a working alliance is fostered and, above all, ongoing monitoring for safety is facilitated. The physician should not be required to report the patient's conduct (unless within the context of the duty to protect).

Vignette B

An immigrant doctor has been treating a patient with a refractory illness. There is a psychotropic medication available in his country of origin, which he has prescribed to patients there. He feels comfortable managing dose regimens and possible side effects and believes it will offer the patient a benefit not offered by psychotropics available in the United States. A physician in the United States cannot prescribe medications not currently approved for the market; doing so is punishable by law. The physician would be engaging in illegal activity if he provided a prescription, and would be encouraging a patient to engage in illegal activity (by virtue of the importation of a medication that violates 21 USC, § 301(aa), because the

medication is not available from a Canadian pharmacy).

Vignette C

A patient who has been fully compliant with treatment recommendations for years is relocated to the opposite side of the country for one year because of work requirements. The patient states that she has registered as a member of an online pharmacy, through which the psychiatrist could continue to prescribe her medications while she is away. A physician cannot prescribe medications without an established doctor-patient relationship (which they did have in this case), and appropriate examination (which was lacking). Furthermore, the physician must be licensed in the state in which the patient is residing. If the psychiatrist were to prescribe, he is subject to malpractice allegations, particularly if side effects that were not appropriately identified or managed result in injury to the patient. From an ethics standpoint, conflicts of interest must also be taken into account, as most online pharmacies offer the prescribing physician compensation for each prescription ordered.

Conclusions

The Internet has changed many areas of our social culture, including the nature of interpersonal relations. As it pertains to medicine, the Internet has shown the potential for changing the traditional doctor-patient relationship and offering the possibility of going outside standard regulatory structures to provide legitimate treatment. The concerns that may be raised need further exploration. At the individual level, the assessment of cyber behavior should become an intrinsic part of every psychiatric encounter. Beyond this sphere, academic research to explore the ethics and clinical ramifications must be developed. Finally, promoting ongoing discussion to revisit the legal standards and parameters that pertain to these concerns appears to be warranted.

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