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Linda C. Fentiman

Elisabeth Haub School of Law at Pace University

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Internet Pharmacies: Why State Regulatory Solutions Are Not Enough

By Linda C. Fentiman¹

Internet pharmacies are an economic and communications miracle—and a regulatory nightmare. It is estimated that Americans spent some \$3.2 billion in 2003 on medications from the Internet, but Internet pharmacies permit consumers to evade long-standing regulatory protections, particularly those that rely on the oversight of drug prescribing and dispensing by licensed physicians and pharmacists.

Dispensing Drugs in Cyberspace

There are two major kinds of Internet pharmacies: the Internet versions of a “bricks and mortar” pharmacy, and so-called “life-style” or “rogue” pharmacies. The first is simply an online version of a traditional pharmacy, such as drugstore.com. Visiting these pharmacies online, customers deliver their prescriptions to a pharmacist electronically, via facsimile, or by mail, and the drugs are sent to them.

The second type is a specialty Web pharmacy. These typically feature prescription drugs with mass appeal, such as Viagra, Prozac, Propecia, or Meridia, to help aging baby boomers do more, feel better, have more, or have less. Many of these “lifestyle” pharmacies do not require the patient to present a physician’s prescription, but instead permit prescriptions to be filled after an Internet “consultation.”

Most consumers choose Internet pharmacies because they offer easy access to desired drugs, saving time, and some-

times money. Internet pharmacies have the potential to increase access to health care, particularly for consumers for whom transportation or communication is difficult, but there are reasons to be concerned about Internet pharmacies. Some dispense expired, subpotent, superpotent, contaminated, or counterfeit drugs, particularly foreign Internet pharmacies. Controlled substances may be available from foreign Internet pharmacies, and neither the U.S. Customs Service nor the Drug Enforcement Administration can intercept more than a fraction of illegally imported drugs.

Another major concern is the lack of medical oversight, which has long been an essential part of drug prescribing in the United States. Although online “consultations” purportedly ensure that patients receive medically appropriate drugs, in fact they are frequently a charade.

The Current Regulatory Framework

Responsibility for ensuring that a drug is safe, effective, and appropriate for a particular patient is now allocated among an array of agencies. The federal government oversees and regulates drug safety, efficacy, labeling, and advertising, as well as the importation of pharmaceutical products and medical devices. State governments license and discipline physicians and other drug prescribers, and the pharmacies and pharmacists who dispense these medications.

In order to prescribe medication in a particular state, the prescriber must be licensed there. If physician oversight is to be meaningful, the physician must examine the patient before prescribing. This may be undercut when Internet pharmacies offer online medical “consultations” through questionnaires. Often the “correct” answers are pre-checked, so

there is no way to verify the patient’s vital signs, symptoms, and overall medical condition to ascertain if the medication is appropriate and physicians are often paid only when they prescribe a requested drug.

More than half the states have adopted at least some requirements, either by statute or by medical licensing board decision. More than twenty states have initiated disciplinary proceedings against physicians who have engaged in Internet or telephone prescribing without an appropriate examination.

State Oversight of Pharmacists and Pharmacies

Pharmacists and pharmacies must be licensed by the state where they are physically located in order to dispense medication. States have adopted various regulatory schemes. A few have enacted new statutes, some have enforced existing laws in the Internet context, and others have adopted new policies via pharmacy board action.

California illustrates the first approach. Its statute forbids pharmacists to dispense drugs unless the prescriptions are the product of “a good faith prior [medical] examination,” in essence imposing a duty to inquire about the nature of the physician-patient interactions that led to the prescription.²

Some states, including Illinois, New Hampshire, and New York, require Internet pharmacies to register with that state’s board of pharmacy and make appropriate on-line disclosures, but defer to the state board of pharmacy where the Internet pharmacy is licensed before taking enforcement action.³ Other states’ boards of pharmacy have adopted policies prohibiting the dispensing of medication without a prescription obtained from a legitimate physician-patient encounter.

¹ Professor at Pace University School of Law in New York. A fuller discussion of this subject may be found in *Internet Pharmacies and the Need for a New Federalism: Protecting Consumers While Increasing Access to Prescription Drugs*, 56 Rutgers Law Review 119 (2003).

² CAL. BUS. & PROF. CODE § 4067 (2001).

³ ILL. COMP. STAT. § 85/16a (2001); N. H. REV. STAT. ANN. § 318:37 (Supp. 2002); N. Y. COMP. CODES R. & REGS., tit. 8 § 63.6 (2003).

Obstacles to Successful Prosecution

Civil jurisdiction

Lack of civil jurisdiction is an obstacle because a court can only exercise personal jurisdiction over an out-of-state defendant if the defendant has had "minimum contacts" with the forum state. In light of Supreme Court due process analysis and recent lower court decisions, plaintiffs should be able to assert jurisdiction over out-of-state or foreign Internet pharmacies, under a theory of "purposeful availment"⁴ or "foreseeable tortious effects."⁵

Two seminal decisions have established the parameters of "purposeful availment" in the Internet context, *Cybersell, Inc. v. Cybersell, Inc.*,⁶ and *Zippo Manufacturing Co. v. Zippo Dot Com, Inc.*⁷ The *Zippo* court articulated, and the *Cybersell* court applied, a "sliding scale" of personal jurisdiction, with at least three discrete points:

At one end of the spectrum are situations where a defendant clearly does business over the Internet, [by forming] contracts with residents of a foreign jurisdiction that involve the knowing and repeated transmission of computer files over the Internet. . . . [Here,] . . . jurisdiction is proper. At the opposite end, . . . [a] passive Web site that does little more than make information available . . . is not grounds for the exercise [of] personal jurisdiction. The middle ground is occupied by interactive Web sites where a user can exchange information with the host computer.⁸

Establishing jurisdiction over a foreign Internet pharmacy should be relatively straightforward under *Cybersell* and *Zippo*. After all, the *raison d'être* of Internet pharmacies is to enter into commercial transactions to sell drugs to buyers in various states, putting them at the "jurisdiction is proper" end of the spectrum.

⁴ *Hanson v. Denckla*, 357 U.S. 235, 253 (1958).

⁵ *Calder v. Jones*, 465 U.S. 783, 788–89 (1984).

⁶ 130 F.3d 414 (9th Cir. 1997).

⁷ 952 F. Supp. 1119 (W.D. Pa. 1997).

⁸ *Id.* at 1124 (citations omitted).

⁹ 397 U.S. 137 (1970).

¹⁰ 969 F. Supp. 160 (S.D.N.Y. 1997).

¹¹ See, e.g., *Hatch v. Superior Court*, 94 Cal. Rptr. 2d 453 (Ct. App. 2000), *State v. Heckel*, 24 P.3d 404 (Wash. 2001), and *Brown & Williamson Tobacco Corp.*, 320 F.3d 200 (2d Cir. 2003).

An Internet pharmacy will satisfy the "purposeful availment" test by entering into sales contracts and thus choosing to do business in the states where the consumers reside. Similarly, Internet pharmacies providing online medical "consultations" should be subject to jurisdiction in the consumer's state because they can anticipate the tortious effects of their conduct, which is arguably the unlicensed practice of medicine.

Criminal jurisdiction

State prosecutors can establish jurisdiction over an Internet defendant by demonstrating either that one of the defendant's actions took place within the state or that the defendant, although acting outside the state, intended those actions to have effects within the jurisdiction. Federal prosecutors can establish jurisdiction over Internet pharmacies, since it is a felony under the Food, Drug, and Cosmetic Act to dispense a drug that has not been properly prescribed. Using the Internet to defraud will also violate the federal wire fraud statute, and may support a RICO prosecution if a pattern of racketeering activity is shown.

Dormant Commerce Clause

By far the greatest potential challenge to state action against Internet pharmacies is the Constitution's "dormant" Commerce Clause. Federal power to regulate interstate commerce is broad because of the need for a uniform, national approach to activities that affect either foreign or interstate intercourse. Even when Congress has not acted, state legislation may not unduly burden interstate or foreign commerce through its extraterritorial effects, reflecting the latent, or "dormant," aspect of federal commerce power. Under the balancing test set forth in *Pike v. Bruce Church, Inc.*,⁹ when a statute is facially neutral and "regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits."

In recent years, lower courts have split in evaluating the states' exercise of traditional police powers when they regulate conduct on the Internet. *American*

Libraries Association v. Pataki,¹⁰ enjoined a New York criminal law prohibiting the communication of sexual material to a minor via a computer, stating because "the Internet is . . . [an] area . . . of commerce that must be marked off as a national preserve to protect users from inconsistent legislation that, taken to its most extreme, could paralyze development of the Internet altogether. . . . [O]nly Congress can legislate in this area."

In contrast, other courts have upheld the exercise of state power against out-of-state defendants, whether they were purveying arguably indecent speech, tobacco products or spam email.¹¹ Given this trend, it is likely, but by no means certain, that a state law regulating Internet pharmacies' interactions with its residents would survive a commerce clause challenge.

Practical obstacles

Even when theoretical obstacles to state actions against Internet pharmacies are absent, prosecutors still face substantial hurdles in finding defendants and their assets and bringing them into the forum state. Once human defendants are located, they must be brought to the forum for trial. Obtaining the physical presence of American defendants in the forum is relatively simple, but non-United States citizens can only be extradited to an American court if the United States has an extradition treaty with the country where the defendant is located.

Why a New Federal Approach Is Necessary

The current patchwork system of federal and state regulation of pharmaceuticals is inadequate to address either the health and safety concerns raised by Internet pharmacies or the jurisdictional, commerce clause, and practical law enforcement problems. Because the Internet is indisputably a medium of interstate and foreign commerce, it should be regulated by the authority best able to achieve comprehensive and effective law enforcement—the federal government.

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Today, the diffusion of regulatory authority between the states and the federal government makes it easy for Internet pharmacies to escape effective government oversight. While many states have promulgated new statutes, regulations, or policies, bringing actions under them is expensive and inefficient. The fact that even a successful judgment or consent decree is only effective within one state means that state attorneys general will husband their scarce resources and that many dangerous Internet pharmacies will escape detection and/or prosecution.

Even successful actions against Internet pharmacies raise important federalism issues, whether they are framed as “due process,” “minimum contacts,” or “the dormant commerce clause.” How far should a state’s jurisdiction extend, either

legislatively or adjudicatively? Should the outcome depend, as stated in *American Libraries Ass’n v. Pataki*, on whether the state statute invoked mentions the “I word” (the Internet), or is the underlying substantive concern more basic: *i.e.*, under what circumstances may a state adopt a domestic policy which affects other states?

The challenge posed by Internet pharmacies is an opportunity to creatively rethink how to expand access to affordable medication while protecting consumers from the adverse consequences of an unpoliced marketplace. Congress should adopt comprehensive changes in the Food, Drug, and Cosmetic Act to protect the public from unsafe and ineffective pharmaceutical products. First, the Act should provide that a drug is “misbranded” unless it is

prescribed by a physician who holds a state license to practice medicine and has examined the patient within the last six months. Second, the law should prohibit pharmacists from dispensing prescription medications without evidence that the prescribing physician has performed a recent physical exam. Third, the law should authorize the securing of electronic information generated in the course of an Internet pharmacy transaction, to permit prosecutors to follow a defendant’s “electronic trail.”

By enacting this law, Congress will be taking an important step toward ensuring that legitimate commerce in pharmaceutical products can take place over the Internet, thus increasing competition while protecting the public’s health. ○