ON-LINE PRESCRIPTIONS AND DRUG SALES:
AN OVERVIEW OF EMERGING ISSUES

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INTRODUCTION

The Internet, the World Wide Web, and electronic commerce have revolutionized the prescription and purchase of pharmaceutical drugs in America.1 This technology has created a virtual storehouse where physicians and patients may easily access health-related information and products.2 As of the summer of 1999, over 400 Internet sites sold prescription drugs and sundry-related items over the Web.3 These "cyber-pharmacies" offer busy consumers

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1See Drugstore on the Net: The Risks and Benefits of On-Line Pharmacies, Hearings Before the Subcommittee on Oversight and Investigations of the House Comm. on Commerce, 106th Cong., at 6-7 (1999) [hereinafter Drugstore on the Net] (Statement of Hon. Tom Bilbo, Chairman, Committee on Commerce) (maintaining that the Internet marketplace has grown by "feet and bounds," revolutionizing the way Americans do business; 47 U.S.C. § 151(e) (2000) (defining the Internet as "collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio.").

2See Jackie Lookabaugh, On the Net, Its Reader Beware: Sites Vary in Medicinal Reliability from First Take to Prescription, THE MILWAUKEE SENTINEL, Dec. 29, 1999, available at 1999 WL 1595966 (reporting that the Federal Trade Commission has estimated that more than twenty-five million people use the Internet to search for health information; that the number of medical and health related sites number at least 30,000; and that forty-three percent of all adult Internet users use the World Wide Web for health and medical information); see, e.g., Rx Sheets.com Announces Major Increase in Pharmaceutical Sampling Requests and Physician Subscriber Base, 62(3) THE POST-STREET, Jan. 31, 2000, available at 2000 WL 8039592 (indicating that over 20,000 physicians subscribed to Rx Sheets.com to order drug samples over the Internet).

time-saving convenience, efficiency, and, in some cases, lower prices. Medications may be delivered to a home or office without waiting in line at the local drug store. These Web sites also provide the elderly and disabled with unprecedented access to vital medications.

Despite their numerous potential benefits, cyber-pharmacies present problems previously unknown to the pre-cyber-space world. For example, today, one may order drugs without even seeing a doctor "face-to-face." Indeed, a prescription may not even be required. Moreover, a cyber-pharmacy may open shop on the Internet, shut down without notice, and later re-open, under a different name or at a different Uniform Resource Locator (URL) address. Thus, the true location of a site and the identity of its maintainers may remain a mystery to consumers and regulators.

Current regulation of physicians or "cyber-druggists" who prescribe medications on-line occurs primarily within the state of licensure. State and federal agencies also regulate cyber-pharmacies but, to date, have not treated them as regular, "brick and mortar" pharmacies. Thus, existing safeguards to protect against unsafe,

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18 But see Jane E. Henney et al., Internet Purchase of Prescription Drugs: Buyer Beware, 131(11) ANNALS INTERM. MED. 861, 861 (1999) (noting that "although these sites are convenient, this benefit comes with a higher price tag...[T]he average cost of purchasing these drugs on-line was higher than at Philadelphia pharmacies and...the average cost of receiving an on-line consultation was higher than for a general practice visit in the Philadelphia area").

19 Drugstore on the Net, supra note 1, at 7 (Statement of Hon. Tom Bliley) (arguing that cyber-pharmacies have drastically improved access to medications for millions of disabled and elderly Americans).

20 Katrina Armstrong et al., Direct Sale of Sildenafil (Viagra) to Consumers over the Internet, 341(18) NEW ENGLAND J. OF MED. 1389, 1389 (1999) noting that patients can contact their physician over the Internet, request a medication, and have the physician send the prescription to the pharmacy (and...consumers can order medications directly over the Internet without seeing a physician or a pharmacist.").

21 Drugstore on the Net, supra note 1, at 2 (Statement of Hon. Fred Upton, Chairman, House Subcomm. on Oversight and Investigations) (reporting that the foremost concern with cyber-pharmacies arises from unscrupulous Web sites selling drugs without a valid prescription).

22 Id.

23 Id.

24 See, e.g., Texas Board of Medical Examiners Rules (enunciating the requirements for the practice of medicine over the Internet and for medical practice conducted across the Texas state line), available at http://www.tble.state.tx.us/rules/174.html (last visited Jun. 1, 2001).


unproved, or counterfeit drugs and devices may not suffice in the World Wide Web environment.

In fact, cyber-pharmacies have not proved themselves immune to such dangers. One man died from a heart attack after using the Viagra he had purchased over the Internet.22 Tom Gugliotta, a professional basketball player with the Phoenix Suns, stopped breathing after ingesting an herbal supplement readily available on the Internet.23 According to Gugliotta, "I didn't have any idea something like this could happen...I nearly lost my life...I've never worried about going to the store for vitamins over-the-counter. I've never heard of anybody getting sick from something like this."24 Additionally, at-home Human Immunodeficiency Virus (HIV) tests that were purchased on-line have led users to believe themselves uninfeected, when in fact they are HIV-positive.25 Hence, even sales not involving prescriptions present issues that need resolution.

This article surveys the legal issues surrounding cyber-pharmacies. Part I outlines the various types of cyber-pharmacies and presents the advantages and dilemmas accompanying each. Part II discusses existing state law regulating Internet drug promotion and sales, including licensure. Part III examines jurisdictional issues arising from interstate commerce over the Internet. Part IV details federal regulation and policy. Industry self-regulation is surveyed in Part V while Part VI discusses international legal questions. This article will conclude in Part VII with recommendations and possible solutions for the many legal gaps associated with the cyber-pharmacies.
I. THE ADVANTAGES AND DISADVANTAGES OF CYBER-PHARMACIES

A. Types of Cyber-Pharmacies

Cyber-pharmacies typically fall into four basic categories. Type I cyber-pharmacies are known as "brick and click" pharmacies; these sites are associated with a "brick and mortar" pharmacy that is registered by a state board of pharmacy in the United States.\(^\text{14}\) Type I cyber-pharmacies do not prescribe medication, but instead require presentation of a valid prescription before a drug is dispensed.\(^\text{15}\) Type I infrastructure and procedures are usually similar to walk-in and mail service pharmacies.\(^\text{16}\) The prescriptions are mailed to the patient, or the patient picks up the medication from a local pharmacy owned or affiliated with the Web site.\(^\text{17}\)

On Type I pharmacy sites, confidentiality and prescription integrity may be assured via cryptography, certification, and use of "Personal Prescribers," which are hand-held devices that route prescriptions directly from a physician to the pharmacy.\(^\text{18}\) Additionally,

\(^{14}\) Drugstore on the Web, supra note 1, at 248 (Statement of Carmen Cathec, Executive Director, National Association of Board Pharmacists) (describing Type I pharmacy based sites as those associated with an identifiable pharmacy licensed and registered by a state board of pharmacy in the United States).

\(^{15}\) Id. at 245-67 (Statement of William Razzouk, Chief Executive Officer, PlanetRx.com) (describing a Type I procedure as authenticating a prescription prior to fulfillment, confirming that the prescriber is a properly licensed physician, and only dispensing, prescribing drugs "We do not interfere in any way with the sanctity of the patient-physician relationship.").

\(^{16}\) Id. at 273 (explaining that the physician, customer, or another pharmacy provides the prescription to the Web druggist. The customer may request (1) the physician be called, (2) the prescription be mailed, or (3) another pharmacy be contacted. Any attempts to fill the order without a prescription will be refused. Physician verification is assured for all controlled substances. No orders for Schedule II medications are filled over the Web because of the potential for abuse. Patient profiles are taken and cross-checked with the physician and checks for drug interactions are part of the procedures for filling the prescription.).

\(^{17}\) Id. at 272. See also Drugstore, at http://www.drugstore.com (last visited Mar. 25, 2001) (demonstrating that Drugstore.com has an arrangement with the Site-Aid pharmacy chain whereby Internet customers may pick up their medications at local Site-Aid drug stores throughout the country).

\(^{18}\) Drugstore on the Net, supra note 1, at 275 (Statement of Peter Neupart) (explaining that credit card and personal information may be encrypted and that a privacy seal program, such as TRUSTe, are security options available for cyber-pharmacy sites); National Association of Boards of Pharmacy, Internet Pharmacy and Online Pharmacies Verification (describing Verified Internet Pharmacy Practice Site (VIPP) as a certification requiring compliance with licensure requirements of the states in which pharmacies are located as well as those in which the pharmacy practices and explaining that certification requirements were developed with input from "[a] coalition of state and federal regulatory orga- nizations, professional associations, and consumer advocacy groups [who] provided their expertise in developing the criteria which VIPP-certified pharmacies follow."); http://www.fgh.org/ vipp.htm (last visited Mar. 25, 2001); Carolyn Petersen, High-Tech Tips Offer Pharmacy Benefit Management Opportunity: E-Prescriptions Can Keep Costs Down by Helping with Therapeutic Switches, and Reducing Physician Office Costs, 10 MANAGED HEALTHCARE 3940, Mar. 1, 2000, available at 2000 WL 1645907 (noting that Albertsons Company markets an Internet-based prescription management system, a personal prescriber called TouchScript that "informs the formulary information for multiple plans and multiple-site copays, so one can alert physicians about formulary restrictions before the patient leaves").


\(^{22}\) Stevens, supra note 21.

\(^{23}\) Drugstore on the Net, supra note 1, at 2 (Statement of Fred Upton, Chairman, House Subcommittee on Oversight and Investigations) (contending that Type II pharmacies allow consumers to order medication without ever seeing a physician face-to-face, oftentimes without a valid prescription).


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“No-prescription sites” are the Type III cyber-pharmacies. Here, patients may buy remedies without a prescription over the Internet. Finally, Type IV cyber-pharmacies are the “business-to-business” entities. A “brick and mortar” pharmacy technically owns these cyber-pharmacies, but an insurance company actually controls them. The pharmacy customizes the website to meet the corporate image of the insurance company. The pharmacy takes orders, processes payments, and provides customer service for transactions and clinical questions. Payers, usually referring to an insurance company or Health Maintenance Organizations (HMO), participate in all revenue, including non-prescription sales, and also interact with their customers. In the future, these payers will likely operate or purchase their own cyber-pharmacies.

B. The Advantages of the Cyber-Pharmacy

The potential benefits of purchasing pharmaceuticals over the Internet include diverse consumer information, convenience, privacy, and, in some cases lower costs. Local drugstores with the friendly pharmacist, as typified in a Norman Rockwell print, have been replaced with conglomerated mega-drugstores with little customer service. With the potential benefits described above, customers may not necessarily mind the absence of personal customer service on the Internet. Indeed cyber-pharmacies may assist the potential purchaser with comparison shopping by providing information about usage, dosage, warnings, side effects, and drug prices. Moreover, a discussion with the local “friendly pharmacist” about one’s physical symptoms may not take place because of embarrassment; but, when the twenty-four hour cyber-pharmacist can be contacted anonymously from one’s living room, one may likely be more pro-active in healing their ailment. On-line drug purchases also save time; it is no longer necessary to stand in line, endure surly clerks, or wait while the pharmacist assembles the medication. By the simple click of a computer mouse, a pharmaceutical product is ordered and on its way to the customer’s doorstep.

C. The Problems with On-Line Cyber-Pharmacies

In a Philadelphia suburb, numerous high school teens were hospitalized after ingesting dextro-meth-orphan, a cough syrup ingredient purchased on the Internet. A television reporter’s two-month investigation revealed that a seven year-old child purchased a prescription diet drug not yet approved for sale in the United States. The same reporter identified another cyber-pharmacy that not only denied selling drugs to the investigators, but also operated without a United States license. Another investigative report of Internet pharmacies in Michigan discovered Web sites boasting of next-day delivery of Viagra, ordered through a meaningless application process. For instance, a reporter filled out an honest medical history for his cat, named Tom. The reporter indicated that Tom was neutered, weighed only fifteen pounds, and was six inches...

35 Id. at 260, 269-71 (Statement of Cynthia T. Colman, Director, Division of Drugs and Medical Devices, Texas Department of Health) (explaining that “lifestyle drugs” for improved sexual performance, weight loss, and treatment of hair loss are drugs available privately to the habitual consumer on-line).
36 Id. at 271 (Statement of Peter M. Neupert) (listing the common offerings of cyber-pharmacies as round-the-clock shopping; information on medications, health, and wellness; access to pharmacists; over-the-counter health and beauty products; on-line patient profiles; and a centralized source of information for consumers including a list of preferred Formulary drugs).
37 Id. at 10 (describing the time-saving opportunities of cyber-pharmacies as a “dream come true” especially as many medications arrive the very next day).
38 Id. at 16-17 (Statement of Kathy Eger, NBC10/WCAU Philadelphia).
39 Dragnet on the Net, supra note 1 (noting that when confronted with allegations that they had sold dangerous drugs to minors, the companies either put the burden of education on the consumer, or denied making the sales).
40 Id.
41 Id. at 17 (Statement of Christine Behrens, WWMT News 3 Reporter) (describing how the pharmacists and physicians who reviewed the applications paid little attention to the information that on-line drug purchasers entered into the blanks; for example, Viagra was dispensed to applicants, who listed heart disease in their medical histories, even though Viagra is contraindicated for such men.).
tall.\footnote{1} One day after the reporter tendered 167 dollars via Master Card, Tom received the Viagra.\footnote{2} Phredrick L. Schmauzer, a neutered dog, was not as lucky. He was turned over by drug store in the United Kingdom not because of his canine status, but because he lived in the United States.\footnote{3}

When such prescriptions bypass a primary care physician, adverse drug interactions are more likely.\footnote{4} Exacerbating this problem, overseas pharmacies usually will sell drugs to any buyer, distributing unapproved drugs to customers inside the United States.\footnote{5} For example, although banned in the United States, Phen-Fen is still advertised on the Web and imported to the United States from abroad.\footnote{6} Illegal steroids are also widely available on the Internet.\footnote{7} Ironically, no federal or state agency appears to assume full responsibility for regulation. A Philadelphia television reporter recently contacted the FDA, the FTC, the Pharmaceutical Manufacturers Association, other national pharmacy groups, and the State Boards of Pharmacy in New Jersey, Pennsylvania, and Delaware.\footnote{8} Each referred the reporter to another agency or group, and no agency was allegedly "up to speed" on the problem.\footnote{9}

\footnote{4} Drugstore on the Net, supra note 1.
\footnote{5} Id. (reporting the British firm's explanation: "CCNov cannot legally sell prescription drugs to customers who are in the United States.").
\footnote{6} See Sean F. Haney, Pharmaceutical Dispensing in the "Wild West": Advancing Health Care and Protecting Consumers through the Regulation of Online Pharmacies, 42 Wm. & Mary L. Rev. 575, 590 (2001) (citing problems with ensuring that the drug received by the patient is actually the drug requested, as well as difficulties with the lack of physical examinations and consultations).
\footnote{7} See Haney, supra note 4, at 861-62 (suggesting that "concerns arise with respect to foreign sites . . . drugs offered by foreign sites are more likely to raise safety concerns about contamination or subpotent strength resulting from poor manufacturing or improper storage conditions during distribution").
\footnote{8} See E.W. Scripps Publications, Banned Half of Phen-Phen Diet Combination Still Available Across the Border, Apr. 6, 1999, available at http://www.epaper-ew.com/1999/0406/phenphen.html (describing availability of Fenfluramine in Reynoso, Mexico pharmacies and that the U.S. ban does not prevent its secret importation into America); see, e.g., Therma Phen Phen (the Ultimate Weight Loss Product, available at http://www.thermaphenphen.com/ingredients.asp (last visited Mar. 25, 2001) (advertising "Therma Phen Phen" that contains 200mg L-Phenylalanine per tablet, but the veracity of whether this indeed contains the banned ingredient is subject to some dispute)).
\footnote{9} Drugstore on the Net, supra note 1, at 261 (Statement of Cynthia T. Calmo).
\footnote{1} Id. at 15 (Statement of Kathy Rign, NBC10/WCAU Philadelphia) (reporting that it was impossible to discern what agency, if any, regulates Internet pharmacies).

Specifically, Type II and Type III cyber-pharmacies present numerous problems, including the absence of the physician-patient relationship, mislabeled or counterfeit drugs, and outright scams. Type III Web sites, often based outside of the United States, may not comply with domestic laws and regulations.\footnote{10}

Another problem relates to the Web site architecture used by on-line pharmacies. Because the Web can appear "seamless" it is often challenging to discern if the pharmaceutical site is from the drug manufacturer, the physician, or the pharmacy. The integration of Hyper Text Markup Language (HTML) links, enables consumers to "click" their way from one entity to a different one without even knowing such a transition occurred. Moreover, portal and redirect pages which appear to be independent sites, may channel consumers into the distribution operations.\footnote{11} Such architecture is often used to increase accessibility to services but it misleads the consumer to believe that these intermediate sites are legitimate.\footnote{12} For example, if a consumer goes to the URL: http://www.cyberpharmacy.com, the site automatically sends the consumer to http://www.cyberdocs.com to arrange for a virtual appointment.\footnote{13} Physicians also use HTML links and redirects to lead their patients from the doctor's homepage to a drug manufacturer site for counter-indications or warnings for the drug the physician just prescribed.\footnote{14} For these reasons, an examination of existing law is in order to understand if and how on-line prescriptions and drug sales are regulated.

\footnote{10} An example of this problem can be noted with Pharmavest, a Swiss pharmacy that appears to be a serious enterprise, requiring prescriptions. But because it is a Swiss pharmacy, questions arise as to who or what entity verifies the credentials of "physicians" writing prescriptions, and how a patient's particular state would regulate the pharmacy. It might ship Class II drugs without filling a legitimate prescription, or it might only deal in influenza medications and herbs. See generally Pharmavest, at http://www.pharma- world.com (last visited Mar. 25, 2001).
\footnote{11} Drugstore on the Net, supra note 1, at 248 (Statement of Carmen Casanova) (maintaining that portals and redirect pages create a fraudulent "pyramid" operator in which a Web surfer views a number of site links that serve only as a means for the primary site to forward sales into its distribution operations).
\footnote{12} Id.
\footnote{13} Nicholas P. Terry, Cyberpharmacies: Legal Exposure for Cybermedicine, 25 Am. J. L. & Med. 327, 329-30 (1999) (emphasizing that in the real world, one can distinguish between a pharmacy and pharmaceutical manufacturer, between a physician group and a managed care organization but these distinctions are more blurry in "cyberspace").
\footnote{14} Id.
II. STATE REGULATION

A. The Physician: The Diagnosis and the Prescription

1. Physician Licensing

In most instances, a physician may not practice beyond the state in which a medical license has been obtained.55 Some states, however, have explicit statutory exceptions for physician-to-physician consultations, educational demonstrations and lectures, temporary assistance within the state, and emergencies.56 The Federation of State Medical Boards has approved the Model Legislation Regarding Licensure (Model Act).27 The Model Act permits a physician with a medical license in one state to apply for a special-purpose license to practice "by electronic or other means" across state lines.38 Despite criticism that the law is ambiguous,59 several states have adopted versions of the Model Act,60 while other states are considering its adoption.61

2. Physician-Patient Relationship

Is there a physician-patient relationship when no face-to-face contact exists between a physician and patient? Does an Internet

54 ALAN S. GOLDENBERG & JOCIEHN F. GORDON, TELEMEDICINE: EMERGING LEGAL ISSUES 3 (American Health Law Association 2d ed. 1999) (contending that a physician practicing across state lines will need a license to practice medicine in each state in which the physician is deemed to be engaging in the "practice of medicine").
55 Id. at 6-5 (referencing MASS. GEN. LWS. 112 § 7 and ALA. CODES §§ 34-24-47 to 49 as exceptions for physician consultations; MASS. CODES ANN. §§ 75-23-24 as a telemedicine exception and CODES GEN. STAT. § 20-9 for an educational or medical training exception).
56 Id. at 6.
57 Id. (assuming that the practice of medicine is deemed to occur in the state where the patient is located and that the standard of care of the patient's state will control).
58 For example, an ambiguity is that the Model Act gives to each state's Board of Medical Examiners the right to define what practicing medicine is and whether the practice over the Internet is frequent enough to require the special language. The Model Act, Section VII, provides that "the irregular or infrequent practice of medicine across state lines is deemed to occur if such practice occurs less than once monthly or involves fewer than ten patients on an annual basis, or comprises less than one percent of the physician's diagnostic or therapeutic practice." Is the one percent to be based on patient volume, time spent, amount billed, or collected billings? And how will it be audited?
59 GOLDENBERG, supra note 55, at 6, 7 n.11 (listing several Model Act statutes, including ALA. CODES §§ 34-24-500-8; TEx. ADMIN. CODES §§ 174.14, and TEx. CODES ANN. §§ 63-6-231).
60 Id. at 7 n.13 (listing state medical boards considering adoption of the Model Act, including Delaware, Idaho, Indiana, Iowa, Maine, Michigan, New Jersey, New York, Pennsylvania, Vermont, and Washington).
61 In general, courts consider the following factors to determine whether a physician-patient relationship has been established by a consulting physician: (1) whether the consulting physician and the patient have met; (2) whether the consulting physician examined the patient; (3) whether the patient's records were reviewed by the consulting physician; (4) whether the consulting physician knew the patient's name; and (5) whether the consultation was for a fee. Phyllis Granade, Medial Malpractice Issues Related to the Use of Telemedicine—An Analysis of the Ways in which Telecommunications Affects the Principles of Medical Malpractice, 73 N.D. L. REV. 65, 69 (1997).
63 See, e.g., Lyons v. Geether, 239 S.E.2d 103, 105 (Va. 1977) (holding that plaintiff had an appointment with defendant physician and that an appointment given for "the treatment of a vaginal infection" was sufficient to allege a consensual transaction giving rise to a physician-patient relationship).
64 Dougherty v. Gifford, 826 S.W.2d 608, 774-75 (Tex. App.-Texarkana 1992, no writ) (finding a patient-physician relationship created when the physician accepted the pathology work, conducted laboratory analysis, and billed the patient).
65 See, e.g., McLanev v. Schlett, 382 N.E.2d 1045, 1050 (holding that an on-call physician must (1) participate in the diagnosis of the patient's condition; (2) participate in or prescribe a course of treatment for the patient; and (3) owe a duty to the hospital staff who, in turn, owe a duty to the on-call physician for whose benefit he is on call). Fought v. Socal, 821 S.W.2d 218, 220-21 (Tex. App-Houston [1st Dist.] 1991, writ denied) (holding no physician-patient relationship exists in situations where the employment contract of the physician does not require such a consult and the specialist merely volunteers).
66 Texas Board of Medical Examiners, Prescribing Policy, available at http://www.tmb.state.tx.us (last visited Mar. 25, 2001). The Texas Board of Medical Examiners mandates that "[r]easonable counsel is required for a physician to prescribe any dangerous drugs or controlled substances without first establishing a proper physician-patient relationship, i.e., a proper relationship, at a minimum requires (1) verifying that the person requesting the medication is who they claim to be; (2) establishing a diagnosis through the use ofaccepted medical practices such as patient history, mental status exam, physical examination and appropriate diagnostic and laboratory testing; (3) discussing with the
Physician Malpractice Over the Internet

Given the inherent distance and lack of connection between the doctor and the patient, cyber-physicians may find themselves subject to more lawsuits than other doctors. Cyber-medicine may also suffer from the "penalty of personalization." As one commentator has stated, "[l]nteractivity brings targeting, and targeting bespeaks foreseeability." In plainer language, the more a Web site maintainer (albeit physician, drug company, or pharmacy) is able to target an audience and recognize its characteristics, the more the maintainer becomes accountable for symptoms and individuated risks.

In cyber-space, how will the standard of care be measured? Will it be the traditional standard of care of doctors in the community in which the physician practices, the similar community standard, or a national standard of care of a particular patient the diagnosis and the evidence for it, the risks and benefits of various treatment options, and (4) current availability of the physician or coverage for the patient for appropriate follow-up care." Id. "An on-line or telephonic evaluation by questionnaire is inadequate." Id. See also Harvey, supra note 4, at 861 (stating that the FDA agrees with the AMA position, and that more than a dozen states have already taken action against practitioners who prescribed drugs without ever having examined a patient).

Texas Board of Medical Examiners, supra note 67.

Goldberg, supra note 55, at 19 (maintaining that the practice of telemedicine raises myriad new malpractice issues not posed in traditional face-to-face medical settings).

Terry, supra note 53, at 333-34.

Id.

In general, if a cyber-physician has a site that provides medical advice for a particular patient for described symptoms, the liability potential will increase. Terry, supra note 53, at 332. For example, Internet clinics allow maintainers to collect profiling information to gain personal data on patients. Suit for negligence of defective content have not fared well where a third party published the information, but some exposure may exist where it is the author that is being sued for content. Id. Informational product liability, while rejected by the majority of the courts, provides another possibility for a potential cause of action where the information provided is detailed and technical. Id.

See, e.g., N.C. Gen. Stat. § 90-21.12 (1997) (stating that a physician will not violate the standard of care "unless the titer of the facts is satisfied . . . that the care of such health care provider was not in accordance with the standard of practice among members of the same health care community with similar training and experience . . . .”).

See, e.g., Turner v. Stowers, 289 S.W. 190 (Tex. Civ. App. - Eastland 1956, writ ref’d) (stating that "a physician and surgeon undertaking the treatment of personal injuries of a patient is not required to have or exercise the highest degree of skill possible, but is required to exercise only that degree of skill, learning, and care which are ordinarily possessed and exercised by other members of his profession in good standing, practicing in similar localities and under like and similar circumstances.").

If the physician is located outside the United States, does this alter the standard? How will any accepted standard apply to the Internet, where boundaries are hard to define and enforce? Until these issues are resolved, cyber-physicians should gauge their conduct by the highest of the foregoing standards. The news stories outlined in the introduction of this article suggest that the conduct of many cyber-physicians may even fail to meet the minimum of any standard.

In addition, the context of a product liability suit must be considered. According to the "learned intermediary doctrine," a pharmaceutical manufacturer usually discharges its duty to warn users about a drug’s dangerous propensities by supplying physicians with information. The physician must then pass that information on to the patient. However, when the manufacturer advertises directly to the consumer via the Internet or other media, the drug manufacturer may be held accountable for the duty to warn.
ment using real-time. These criteria are not satisfied by physician consultation on the Internet, where only the patient and the physician participate, the questionnaire is usually reviewed after submission, and the physician does not examine the patient.

Although managed care organizations encourage telemedicine and Medicaid provides reimbursement in eleven states, the government does not currently accept claims without a direct physician-patient consultation. Some private payers now provide coverage for telemedicine but will likely move cautiously when reimbursing patients for Internet examinations because the patient’s condition cannot be independently verified. Thus, reimbursement for Web consultations most likely remains in the distant future.

5. Physician-Pharmacy Ownership

A threshold state-level question is whether to allow a physician to own a pharmacy. If such ownership is permissible, a significant potential exists for violation of the federal Illegal Remuneration (anti-kickback) and Stark Laws if a physician refers patients to his or her own pharmacy. Further, if physicians may own a pharmacy, may they also own an Internet pharmacy? Do the Illegal Remuneration and Stark Laws also apply in this situation? What if the physician renders diagnoses and issues prescriptions from the same Web site? Conversely, if the pharmacy owns the Web site, would the pharmacy be generating referrals for the physician? The answers

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82 Goldberg, supra note 53, at 10 (noting that other electronic communication equipment such as telephones, facsimile machines, and electronic mail systems are not interactive telecommunication systems).

83 Id. at 12, 12 n.22 (referring to Medicare’s willingness to reimburse for telemedicine services provided through risk-based managed care contracts; and commenting that neither 42 U.S.C. § 1395 or 42 C.F.R. § 417 prohibit telemedicine).

84 Id. at 13 n.25 (listing the states Medicaid covers as the following: Arkansas, California, Georgia, Illinois, Kansas, Iowa, Montana, North Dakota, South Dakota, Virginia, and West Virginia).

85 Id. at 13 (indicating that while Massachusetts Blue Cross and Blue Shield have denied reimbursement because it believes telemedicine services are not necessary, the states of Kansas, North Dakota, Montana, and Iowa either are currently reimbursing for telemedicine consultations or are developing policies for reimbursement in the future). See also Cal. Health and Safety Code § 1374.1(c) (2003) (permitting reimbursement even without face-to-face examinations).

86 42 U.S.C. § 1320a-7(b) (Supp. IV 1998) (imposing civil and criminal liability for making or receiving referrals for health care goods and services paid for by the federal and state governments).

might be in the affirmative, based upon a telemedicine advisory opinion from the Office of Inspector General, but no absolute determination exists.91

6. Physician Risk-Management

Physicians may practice Web risk-management in several ways. For example, Health on the Net Foundation (HON)92 developed a self-regulatory code of conduct.93 The HON seal of approval indicates conformance with the HON Code, which could become important when the "seal bearer" desires to use custom and usage as a defense.94

Another method of risk-management is through the use of disclaimers. Well known in the product liability context, Internet disclaimers appear in two forms: exculpatory statements and pre-injury releases.95 It is unknown how the courts will interpret either of these, but if the real (as compared with the virtual) world is any indication, exculpatory statements may have at least a strategic litigation value,96 with pre-injury releases being of little significance.97

91 Covington, supra note 53, at 15-16, citing Office of Inspector General Advisory Opinion 98-18 (1998) (asserting that referrals between physicians and pharmacists are a real problem; common ownership often exacerbates the problem, as does the doctor charging a fee, advertising, and marketing where both parties benefit).

92 Created in 1995, Health on the Net Foundation is a not-for-profit Swiss organization whose primary mission is to guide lay persons or non-medical users and medical practitioners to useful and reliable on-line medical and health information and to provide leadership in establishing ethical standards for Web site developers. See generally Health on the Net Foundation, at http://www.hon.ch/Global.html (last visited Jan. 16, 2001).

93 Health on the Net Foundation, HON Code of Conduct (HONcode) for Medical and Health Web Sites (listing eight principles the HON finds of vital importance for medical or health Web sites, including authority, confidentiality, attribution, justifiability, transparency of authorship, transparency of sponsorship, and honesty in advertising and editorial policy), at http://www.hon.ch/ HONcode/Conduct.html (last visited Mar. 25, 2001).

94 Terry, supra note 53, at 360 (reciting the code, which has eight prongs including "any medical/health advice provided and hosted on this site will only be given by medically/health trained and qualified professionals unless a clear statement is made that a piece of advice offered is from a non-medically/health qualified individual/organization and "the information provided on this site is designed to support, not replace, the relationship that exists between a patient/site visitor and his/her existing physician.").

95 Id. at 360 (providing an example of an exculpatory statement: "The health information contained herein is provided for educational purposes only and is not intended to replace discussions with a health care provider. All decisions regarding patient care must be made with a health care provider and consider the unique characteristics of each patient.").

96 Id. at 360-63 (justifying that the defendant can use the disclaimer as a basis to counteract any representations or negate the plaintiff's expectations).

97 See, e.g., Tunkl v. Regents of the Univ. of California, 363 P.2d 441, 441-42 (Cal. 1961) (concluding that the public interest is affected by an agreement between a hospital and an entering patient such that an exculpatory clause is invalid).

98 Terry, supra note 53, at 363 (asserting that these territorial disclosures become increasingly necessary as health care sites become more closely hypertextual).

99 Id. (referring to the use of a password or member identification number to segregate between health care professionals and consumers).

100 Id. at 364 (providing the example of a separation of information between Americans and foreigners).

101 Op. Tex. Att'y Gen. No. MW-410 (1981) (mandating that it unlawful for a person to dispense or distribute prescription drugs unless he is a licensed pharmacist or is authorized by the Texas Pharmacy Act to distribute prescription drugs); Op. Tex. Att'y Gen. No. JM-204 (1985) (concluding that doctors in Texas cannot dispense drugs for profit or operate a retail pharmacy without first complying with the Texas Pharmacy Act).
spections. Many states are now passing Internet-specific pharmacy statutes. For instance, Illinois amended its Pharmacy Practice Act for mail order drugs by requiring Internet pharmacies to obtain an out-of-state license and to comply with the same rules as mail order drug companies.

2. Pharmacist Licensing

Professional licensing boards also require the licensing of pharmacists that dispense Internet medications. If claims of malpractice against such individuals are alleged or filed, some states require that their Board of Pharmacy be notified. Other states require peer review committees to evaluate the quality of the pharmacies’ services and to record and/or report errors. Whether the person

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161 Rita Rubin, Standards for On-Line Drug Sales May Soon Be Issued, USA TODAY, Feb. 9, 1999, available at 1999 WL 6839565 (noting that the National Association of Boards of Pharmacy began issuing seals of approval to on-line pharmacies in the spring of 1999; and listing New Mexico, New York, Ohio, Texas, and Wisconsin as some of the states requiring licensure of all pharmacies).

162 See, e.g., CAL. BUS. & PROF. CODE § 4057 et seq. (West 2000) (permitting the Board to issue citations and fines up to 25,000 dollars per violation for dispensing a dangerous drug or device on the Internet without a valid prescription; designed to target Internet drug sales that do not require a good faith examination prior to providing a prescription via the Internet site).

163 225 ILL. COMP. STAT. 85/16a (2000) (specifying requirements for Internet pharmacies in the state where the drugs are dispensed; releasing the names, titles, and locations of all officers and pharmacists dispensing drugs to the state; maintaining records for drugs dispensed to residents of Illinois cooperating with the Boards of Pharmacy of all states in which it maintains licensing; keeping hours of operation at least six hours a week; and maintaining a toll-free phone number for communication with patients).

164 See TEX. OCC. CODE § 558.001 (Vernon 2000) (detailing how the Texas Board of Pharmacy licenses pharmacists).


167 See Illinois Department of Professional Regulation, Notice of Proposed Amendments § 1530.05, Oct. 6, 1999, available at 1999 WL 2851590 (maintaining that any pharmacist who receives notice that a dispensing error has occurred shall correct the error, and shall be responsible for initiation of a dispensing error record that shall be delivered to the pharmacist in charge for review and retention). See also Proprietary Home Evaluation Guidance Will Detail New FDA Review Process, 14 Tex. Gemni Snare 6, Apr. 3, 2000, available at 2000 WL 8929603 (reporting that the FDA expects to publish guidelines explaining new procedures for evaluating proposed drug names to avoid medication errors). But see Across the U.S.A. (TEXAS), USA TODAY, Feb. 14, 2000, at 15A (reporting that pharmacists and physicians in Texas are not required to report errors, even fatal ones, to the Texas Board of Pharmacy; but under new legislation, health insurers are required to report malpractice claims to the Board).

168 See, e.g., TEX. HEALTH & SAFETY CODE § 461.075 (Vernon 2000).

169 Id.

170 See, e.g., TEX. MED. ENG. CODE § 60.001 (Vernon 2000) (requiring the Texas State Board of Pharmacy to provide the Department of Public Safety with a list of every person licensed by the agency, including name, birth date, and any other personal descriptive information required so that the Department may conduct frequent background checks to see if criminal convictions have been obtained by those who dispense controlled substances).

171 TEX. HEALTH & SAFETY CODE § 483.001 (Vernon 2000) (defining a dangerous drug as one that is not listed under “controlled substances,” is intended for self-medication and is also required to display a particular legend on its container).

172 See, e.g., TEX. HEALTH & SAFETY CODE § 431.021(a)-(e) (Vernon 2000) (stating that the “introduction or delivery for introduction into commerce of any food, drug, device, or cosmetic”) is unlawful and prohibited; TEX. BUS. & COM. CODE § 37.46 (Vernon 2000) (stating that “false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful and are subject to action by the Consumer Protection Division”).

173 Id.


175 TEX. HEALTH & SAFETY CODE § 431.005 (Vernon 2000) (explaining that the Texas Code regulates the sale of food, drugs, devices, or cosmetics).

Legislatures' Health Policy Tracking Service, nineteen state legislatures considered bills that regulate online sale of drugs.126

C. State Enforcement

Ohio adopted a tough stance against physicians prescribing drugs over the Internet.127 In January 2000, the Ohio Board of Medical Examiners threatened to revoke the license of a physician charged with sixty-four felony counts for prescribing drugs over the Internet.128 The Board alleged that the physician engaged in drug trafficking, sold dangerous drugs, and failed to meet the minimum standards of care by writing prescriptions for patients he had not examined.129

Kansas also initiated criminal actions against Internet pharmacies not properly licensed in that state.130 Six lawsuits have been filed against companies, cyber-physicians, and individuals who allegedly committed deceptive and unconscionable acts in violation of the Kansas Consumer Protection Act.131 The accused allegedly practiced medicine and operated pharmacies without the requisite licenses, dispensed drugs without any physician-patient relationship, and neglected to provide information about associated risks.132

These cases raise unique legal questions: Which state has the proper jurisdiction? How could defendants be located to serve process, given the prevalence of shell corporations133 and mail drops?134

126 Clinton Proposes Greater FDA Authority Over Online Pharmacies; Reaction Skeptical, HEALTH CARE DAILY REPORT (BNA), Dec. 29, 2000, at D2 (noting that former Health and Human Services Secretary Donna Shalala believes that states do not possess enough authority to regulate Internet prescription drug sales).

127 Tim Doolin & Mark D. Somerson, State Board Cites Doctor in Online Drug Case, THE COLUMBIA DISPATCH, Jan. 14, 2000, at 1D.

128 Id.

129 Id. (reporting that the doctor had prescribed diet drugs without performing a body mass index or monthly weigh-ins, or determining whether the patient suffered from a necessary pre-condition under Ohio law for issuing the prescription). The doctor also prescribed Viagra, as well as hair loss and anti-smoking medications without examinations. Id.

130 Kevin Blake, Consumer Notes, CONSUMER'S RESEARCH MAGAZINE, Nov. 1, 1999, at 38 (describing Kansas state's charges as a failure to meet the standards of care and violation of the state's Consumer Protection Act and the Pharmacy Practices Act).

131 Id.

132 Id. (stating that some of the pharmacies sold "lifestyle" drugs to minors without hesitation, and that none of the defendants was properly licensed or registered in Kansas).

133 "Shell companies" are legal entities that have no actual operations; they may exist as holding companies, or false fronts with no assets and exist only to fleece customers and provide a liability shield. Gordon Fairweather & Nikhil Desai, Does and Duds Makers For R.J.

134 Williams

Despite these obstacles, Kansas emphatically regulates online pharmacies and focuses on the fact that an illegal act does not become legal just because it was committed on the Internet.135 Kansas argues that a state does not become powerless simply because the threat to health and welfare is online rather than in person, by mail, or in some other traditional manner.136 Other states are beginning to take action as well, including Missouri, Washington, New Jersey, and Michigan.137

III. State Jurisdiction Over Out-of-State Defendants

A. Minimum Contacts

The Internet raises the vexing legal question of whether an individual or company generally becomes subject to state jurisdiction merely by making information available to the entire Internet world. This requires analysis of due process concerns and interpretation of the questioned forum's long-arm statute.138 Jurisdictions


127 A "mail drop" refers to an enterprise that does not have an official office; instead, the operation is merely a post office box. Andrew Higgins et al., Money Players: The Impeccable Cost Of Capitalist Conspicuous Behind Betsy Candie, WALL STREET JOURNAL, Dec. 30, 1999, available at 1999 WL-WSJ 2927659.

130 Indeed, some states have discovered sophisticated software that enables law enforcement officials to determine the server addresses and locations from the URL address of the Web sites. Such information can be helpful in tracking elusive cyber-pharmacies. Michael W. Theiss, Cyberpharmacists Police Internet Investigations under Florida Law, 54 U. MASS. L. REV. 405, 412 (2000).

128 Blake, supra note 123, at 38.

135 Missouri AG Files Suit Seeking to Halt Internet Prescription Sales, HEALTH CARE DAILY REPORT (BNA), July 15, 1999, at 1 (explaining that Missouri sought injunctions and civil penalties to halt instant sales from various Texas cyber-pharmacies and cyber-doctors based in San Antonio and Houston). Meanwhile in Washington, officials sought an injunction against a cyber-physician who prescribed Viagra to a sixteen-year-old boy. Id. New Jersey police arrested a Web site maintainer who sold a "date rape" drug kit for minor boys while Michigan’s Attorney General sent notices of intended action to various Internet drug companies alleging consumer law violations based upon similar “buys” of prescription drugs based upon scarce information provided by the “patient.” Id.

136 See generally Anish Metal Indus. Co. v. Superior Court, 480 U.S. 102 (1987) involving a defendant who sold defective products in Japan to a Taiwanese buyer, who then imported them into the United States). At issue was whether valid jurisdiction could be obtained over the defendant in a California court. Id. The United States Supreme Court reversed, finding that although the defendant placed his products into the “stream of commerce” in California, jurisdiction over the defendant would be unreasonable, considering the severe burdens the action would create for the defendant, the plaintiff, and both nations. Id.
are split over this question.\textsuperscript{132} Minnesota's Attorney General issued a warning that transmitting information via the Internet, with knowledge that the information will be disseminated within that state, subjects Internet providers to personal jurisdiction if they violate Minnesota's criminal and civil laws.\textsuperscript{133} This approach raises concerns about whether a state may have personal jurisdiction over an out-of-state physician, pharmacist, or drug company advertising, diagnosing, prescribing, or dispensing drugs over the Internet.

Missouri, for example, grappled with the issue of Web site orders placed by Missouri residents to a Beer-of-the-Month Club based in North Carolina.\textsuperscript{134} As part of the investigation, an eighteen year-old intern from the Missouri Attorney General's office ordered and received two six-packs of beer from the club.\textsuperscript{135} The club argued that Missouri did not possess personal jurisdiction over it because it because the sale occurred and title passed in North Carolina.\textsuperscript{136} The court disagreed, holding that the solicitation of customers in Missouri, delivery of the beer in Missouri, and an apparent direct relationship were sufficient to constitute "minimum contacts."\textsuperscript{137} Subsequent to the suit, the defendant designated North Carolina as the place of sale, but the court did not deem this determinative.\textsuperscript{138} The holding from this case suggests that advertising, diagnosis, treatment, and dispensing medicine to residents of a state, separately or in combination, would suffice for personal jurisdiction over an out-of-state physician, pharmacist, or drug company.\textsuperscript{139} But assuming that the state does have fact jurisdiction over them, may the state regulate their conduct under the Constitution?

\textsuperscript{132} One line of cases (adopting the Alaska rationale) holds that posting of the information on the Web with "something more," such as a toll-free telephone number, a contract in the forum, or seeking goods in the forum is enough for jurisdiction. Cyberzest, Inc. v. Cyberzest, Inc., 130 F.3d 414, 419 (9th Cir. 1997). The most literal "stream of commerce" cases find posting on the Web alone is enough to establish jurisdiction. i2e Systems, Inc. v. Instruction Set, Inc., 997 F. Supp. 161, 164-65 (E.D. Conn. 1996); Zipps Mfg. Co. v. Zipps Dive Com, Inc., 992 F. Supp. 1:19, 1125-26 (W.D. Pa. 1997). The result from this more liberal "stream of commerce" interpretation is, in essence, national jurisdiction. Markit, Inc. v. Cybergold, Inc., 947 F. Supp. 1328, 1335-34 (E.D. Mo. 1996). However, it is clear that a case can become the majority rule across each site and the level of commercial nature and activity involved. With this rule, if the defendant directed intentional actions at the forum state to cause harm, the extent of which is suffered in the forum state, the "efforts doctrine" establishes personal jurisdiction. Calder v. Jones, 466 U.S. 783 (1984). This doctrine has been applied to cases involving the Internet, but is usually intended to limited torts. Panavision Int'l L.P. v. Veeppeen, 141 F.3d 1316, 1321 (9th Cir. 1998); Euzco & Masters, Inc. v. Augusta Nat'l Inc., 65 F. Supp.2d 777 (N.D. Cal. 1999). Cases can also be classified by using a "sliding scale" approach to determine whether the site does something business over the Internet. Zipps, 992 F. Supp. at 1124; Compuserve, Inc. v. Patterson, 89 F.3d 1257, 1264-65 (6th Cir. 1996); Thompson v. Honda-Lopez, Inc., 998 F. Supp. 738, 742 (W.D. Tex. 1998).

\textsuperscript{133} Also, whether the site is a passive Web site that is accessible but only provides information, resulting in no jurisdiction. Cyberzest, 130 F.3d at 418. Finally, whether the site is an interactive site where a user exchanges information with the host computer. Millenium Enter., Inc. v. Millenium Music L.P., 33 F.3d 907, 920-21 (D. Or. 1999); Minn v. AAAAA Dev., L.L.C., 190 F.3d 333, 336 (5th Cir. 1999); Soma Mec. Int'l v. Standard Chartered Bank, 196 F.3d 1292, 1297 (10th Cir. 1999).

\textsuperscript{134} Minnesota Attorney General, Warning Regarding the Internet (describing a warning to all Internet users and providers as, "This memorandum sets forth the enforcement position of the Minnesota Attorney General's office with respect to certain illegal activities on the Internet. Persons outside of Minnesota who transmit information via the Internet are subject to jurisdiction in Minnesota courts for violations of state criminal and civil laws."). available at http://www.ag.state.mn.us/Home/default.htm (last visited Mar. 28, 2001).

\textsuperscript{135} The Attorney General relied on several precedents in his warning. See generally State v. Bonisch, 288 N.W.2d 714, 715-16 (Minn. 1980) (involving a defendant standing and businesses of an Indian Reservation who fired a rifle across the boundary line at a person outside the border of Minnesota). The court rejected the defendant's argument for no jurisdiction based on the act taking place outside Minnesota, and instead held that the intentional impact in Minnesota created jurisdiction.

\textsuperscript{136} See generally Euzco v. Philip Morris, No. 94 Civ. 2375, 1997 U.S. Dist. LEXIS 4853 (dealing with a district court in New York City has recently grappled with the issue of what constitutes sufficient revenue and sales for personal jurisdiction in a non-Internet context).

B. Extraterritoriality and the Commerce Clause

The United States Constitution's Commerce Clause invalidates state laws regulating markets outside the state's borders, even though the extraterritorial reach is unintended by the state legislature. The Supreme Court has held that a state liquor price law that directly controlled commerce occurring wholly outside state boundaries exceeded the inherent limits of the enacting state's authority. Opponents of state regulation argue that because drug commerce is national in nature, continued state regulation will only result in inconsistent standards and a burden that far outweighs any local benefits.

This doctrine may create a significant problem for state regulation of the Internet. For example, while some states will aggressively pursue out-of-state advertisers and service providers who reach their citizens through the Internet, other states will not. Thus, states with the most restrictive rules will control the conduct of Internet physicians and pharmacists, or those practitioners will avoid Internet pharmacy business in the most restrictive states. Either way, regulating states would affect out-of-state practitioners' conduct, and, according to well-settled case law, a state may not impose its notions of good policy on other states. In American Libraries Association v. Pataki, a New York district court held that a statute prohibiting the dissemination of pornographic materials to minors on the Internet violated the Commerce Clause. Practitioners, pharmacies, or drug companies subject to state regulation will no doubt highlight this case as a defense and seek to enjoin enforcement of the state statute in federal courts.

113 Lorillard Tobacco Co. v. Reilly, 84 F.Supp.2d 189, 212 (Mass. D. 2009) (holding that state regulation of tobacco products is within a state's purview when the regulations are fairly limited in scope, but also noting that those regulations reaching national audiences are too broad for state regulation).
114 BMV v. Gore, 517 U.S. 559, 571 (1996), citing Bonaparte v. Tax Court, 104 U.S. 592, 594 (1881) ("No state can legislate except with reference to its own jurisdiction.... Each state is independent of all the others in this particular.").
116 Id. at 183-84.

C. Federal Preemption

Federal preemption presents yet another problem with state regulation of the Internet. Absent a clear and manifest congressional purpose, a federal statute is not presumed to superecede the state's historical police powers. However, federal preemption may be (1) based on federal statutory language; (2) implied when Congress enacts comprehensive legislation on the issue; or (3) triggered if a state law conflicts with a federal law or is an obstacle to congressional objectives. Given the potential for federal preemption of present or future state law, federal agencies and laws may bear an important role in regulating the advertising, sale, and distribution of drugs on the Internet.

IV. Federal Action

A. Overall Federal Government Policy

As espoused in a Congressional hearing, entitled "Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies," the Clinton administration's policy on Internet laws treated physical and cyber-activity in the same manner. The rationale behind this policy is that without regulation, the Internet would quickly develop into a safe haven for criminal activity.

This policy intended that laws should be technologically neutral. Neutrality best serves regulation because the Internet not only allows point-to-point communication (like a telephone) but also permits wide dissemination of information (like a newspaper). The Department of Justice adopted the position that on-line drugstores should be regulated in much the same way as the physi-

117 See generally Lechner v. New York, 198 U.S. 45, 45-46 (1905) (implying in dicta that there are state police powers relating to the safety, health, morals and general welfare of the public but noting that these are not unlimited as the state enactment must be "fair, reasonable, and appropriate").
119 Drugstores on the Net, supra note 1, at 87 (Statement of Ivan K. Feng, Deputy Associate Attorney General, Department of Justice).
120 Id.
121 Id. at 89 (stating that technologically neutral laws will not become as obsolete and require further change because they do not favor one type of technology over the other).
122 Id.
cal counterpart down the street.\textsuperscript{103} In terms of enforcement, the private sector has been urged to lead the effort.\textsuperscript{104}

B. Commercial Free Speech in Internet Drug Sales

Challenges to government regulation of obscenity on the Internet reached the Supreme Court rapidly. Immediately after Congress passed the Communications Decency Act (CDA)\textsuperscript{105} as part of the Telecommunications Act of 1996,\textsuperscript{106} the American Civil Liberties Union brought suit contending that the CDA was unconstitutional.\textsuperscript{107} A federal district court agreed, finding that the words "indecent" and "patently offensive" were vague and violated the First and Fifth Amendments of the Constitution.\textsuperscript{108} In finding the law unconstitutional, the district court did not find the Internet as invasive as radio or television.\textsuperscript{109} But the Supreme Court noted the free speech ramifications of the media: "Through the use of chat rooms, any person with a phone line can become a town crier with a voice that resonates further than it could from any soapbox. Through the use of Web pages, mail exploders, and newsgroups, the same individual can become a pamphleteer."\textsuperscript{110} The Supreme Court found no basis to change the First Amendment's rules or application for Internet free speech.\textsuperscript{111} The Court found the law unconstitutional because of vagueness and the overly broad regulation of speech content.\textsuperscript{112}

The Supreme Court has not addressed the interrelationship between commercial free speech and the Internet, and the relationship between commercial free speech and the advertising, sale, and distribution of drugs on-line. In Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.\textsuperscript{113} the Supreme Court held that pharmacists had the right to advertise the price of prescription drugs.\textsuperscript{114} The Court deemed Virginia's prohibition "highly paternalistic," stating, "people will perceive their own best interests if only they are well enough informed, and ... the best means to that end is to open the channels of communication rather than to close them."\textsuperscript{115} The Supreme Court noted that commercial speech could be regulated, however, if a legitimate state interest was served,\textsuperscript{116} and that a lower degree of Constitutional protection existed for commercial speech.\textsuperscript{117}

For the First Amendment to protect commercial speech, it must concern a lawful activity and cannot be misleading.\textsuperscript{118} If these criteria are met, a court then determines whether the regulation directly advances the governmental interest asserted or is more extensive than necessary to serve that interest.\textsuperscript{119} Applying these standards to Internet advertising of prescription and over-the-counter drugs, truthful advertising about the licensed distribution of drugs will most likely be upheld. The possibility of physician or pharmacist abuse, misuse, or unethical conduct does not justify the suppression of such advertisements.\textsuperscript{120}

\textsuperscript{103} Id.
\textsuperscript{104} Drugstore on the Net, supra note 1, at 95 (Statement of Janet Woodcock, Director, Center for Drug Evaluation and Research of the Food and Drug Administration).
\textsuperscript{107} American Civil Liberties Union v. Reno, 929 F.Supp. 824, 858 (E.D. Pa. 1996) (questioning the constitutionality of two statutory provisions enacted to protect minors from indecent and offensive Internet communications).
\textsuperscript{108} Id. Indeed, the judge was of the belief that because of the "special attributes of Internet communication" Congress lacked the power to regulate the content of protected speech on the Internet at all. Id. at 877. The court reasoned that "[t]hese related characteristics of Internet communication have a transcendent importance to our shared holding that the CDA is unconstitutional on its face. . . . First, the Internet presents very low barriers to entry. Second, these barriers to entry are identical for both speakers and listeners. Third, as a result of these low barriers, astonishingly diverse content is available on the Internet. Fourth, the Internet provides significant access to all who wish to speak in the medium, and even creates a relative parity among speakers." Id.
\textsuperscript{109} Id. at 884 (holding that Internet communications do not invade an individual's home or appear on one's computer screen "unbidden").
\textsuperscript{110} Id. at 885 (holding that "[f]or a matter of Constitutional tradition . . . we presume that governmental regulation of free speech is more likely to interfere with the free exchange of ideas than to encourage it.").
\textsuperscript{111} 425 U.S. 748 (1979).
\textsuperscript{112} Id. at 770 (holding that the state of Virginia could not suppress the flow of prescription drug prices from an unknowing public).
\textsuperscript{113} 506 U.S. 77 (1993).
\textsuperscript{114} Id. at 777 n.24.
\textsuperscript{115} Central Hudson Gas & Elect. Corp. v. Public Serv. Comm'n, 447 U.S. 557, 564 (1980) (indicating that the governmental interest must be quite substantial to restrict commercial speech when it is both lawful and accurate).
\textsuperscript{116} Id.
\textsuperscript{117} 84 F. Supp. 2d 190, 199-200 (Mass. D. 2000) (holding that unethical business conduct does not automatically turn a market into one requiring national uniformity in regulation). See also Carey v. Population Serv. Int'1, 431 U.S. 678, 700 (1977) (holding that prohibition of any advertisement or display of contraceptives is unconstitutional).
At this juncture, in the absence of public harm, "brick and click" advertising will probably pass constitutional muster. Such will not be the case with other Internet pharmacy models, where doctors prescribe over the Web or not at all. As reflected above, news stories about public harm abound. Narrowly drafted regulation of the Internet (applying existing federal and state agency regulations) or new regulations solely applicable to drug advertising on the Internet (under Type II and Type III situations) will probably be deemed constitutional.

Where advertisements are misleading or false, the risk of substantial injury exists even in the context of "brick and click" pharmacies. The FDA or attorney general of any state may argue that the risk to the state created by advertising and direct sales support the state's personal jurisdiction over the offending physician or pharmacist.215 Factors constituting a substantial risk will have to be determined on an ad hoc basis.

C. The Food and Drug Administration

The FDA regulates the advertising of prescription drugs.216 In 1998, pharmaceutical companies spent $3.1 billion dollars on direct-to-consumer advertising.217 Pursuant to a liaison agreement,218 the FTC primarily monitors over-the-counter drug advertising, while the FDA primarily regulates prescription drug labeling and advertising.219


217 21 U.S.C. § 353(b)(4) (2000) (stating that a prescription drugs is mislabeled if it does not contain the following warning: "Caution: Federal law prohibits dispensing without prescription.").

218 Drugstore on the Net, supra note 1, at 90 (Statement of Ivan K. Fong) (stating that for a criminal conviction, the government must prove that the defendant acted with intent to defraud or deceive).

219 Id. (stating that civil cases or misdemeanor prosecutions do not require intent to mislead or defraud).

220 Id. (noting that the Department of Justice has prosecuted doctors and veterinarians for dispensing drugs without a valid prescription, particularly in cases involving steroids that were administered to professional athletes and entertainers without examination and for cosmetic purposes).


222 21 U.S.C. § 321(h) (2000) (describing "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro agent, or other similar related article, including any component, part, or accessory, which is (I) recognized in the official Formulary, or the U.S. Pharmacopoeia, or any supplement to them; (2) intended for use in the diagnosis of disease
Center for Devices and Radiological Health (CDRH).198 The FDA provides no guidelines as to how the Internet or a physician or patient’s computer constitute a “device” under the Act.199 New authority for the FDA to review and certify drug Web sites has been proposed.200 Legal sanctions would result if a Web site did not comply with FDA guidelines.201 The FDA would obtain subpoena power to secure records of sites under investigation, and a tough, first-time penalty of 500,000 dollars would exist for any Web site that sells a drug without a prescription.202

D. The Federal Trade Commission

The FTC regulates deceptive and unfair acts and practices in commerce.203 On-line marketing of over-the-counter drugs is deceptive if it involves a misrepresentation or omission likely to mislead or any other condition, or the cure, mitigation, treatment or prevention in man or other animals; or (3) intended for use in the diagnosis of disease or other conditions and which is not dependent on being metabolized for the achievement of its primary intended purpose).

196 Center for Devices and Radiological Health, supra note 182, at 5.
197 Id. at 6-7 (noting that the Centers for Disease Control, however, provide that “[a]products (e.g., software and computer products) that are not sold with a medical purpose, but that are incidentally used with a medical purpose, are legally general purpose articles and are exempt from all requirements of the Act except for the prohibitions against adulteration and misbranding.”)
199 Dembeck, supra note 12.
200 Id. at 6-7 (noting that the Centers for Disease Control, however, provide that “[a]products (e.g., software and computer products) that are not sold with a medical purpose, but that are incidentally used with a medical purpose, are legally general purpose articles and are exempt from all requirements of the Act except for the prohibitions against adulteration and misbranding.”)

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203 The FTC’s “Operation Cure-All” is an ongoing federal and state law enforcement and consumer education project to combat health care fraud on the Internet.204 This campaign arose after the FTC found 400 Web sites with questionable claims of curing or treating cancer, arthritis, HIV, multiple sclerosis, diabetes, and heart disease.205 As a result of the campaign, the FTC filed several suits against companies marketing non-prescription health products on the Internet and against several dietary-supplement Web sites purporting to cure disease.206

The FTC recently settled with four companies that made inadequately substantiated claims that their non-prescription products

consumers acting reasonably to their detriment.207 The FTC may bring an enforcement action when an on-line pharmacy makes false and misleading claims about the safety and efficacy of any drug it provides.208

The FTC may show that an advertisement is deceptive by either proving that it makes a false claim or by showing that its proponent lacked a reasonable basis for asserting the advertisement’s truth. If the FTC adopts the latter strategy, the court must establish a level of substantiation for the claims and determine if that level is met.209 Valid scientific evidence, including well-controlled, double-blind clinical trials, must support the advertisement’s claims.210

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The FTC recently settled with four companies that made inadequately substantiated claims that their non-prescription products


207 FTC v. Pastoren I Corp., 33 F.Supp. 1988, 1995-96 (9th Cir. 1994), citing In re Cliffsdale Assoc., 183 F.T.C. 110, at 164-65 (describing two theories—the “validity” and “reasonable base” theories—by which the government may prove claims of misrepresentation or false advertising); FTC v. U.S. Sales Co., 785 F. Supp. 737, 748 (N.D. Ill. 1992) (stating that the FTC need only show that a reasonable consumer, upon hearing the advertisement, likely would be misled to her detriment), Thompson Med. Co. v. FTC, 791 F.2d 889, 894-94 (D.C. Cir. 1986) (holding that in general an advertisement is deceptive if the advertiser lacks a reasonable basis to support the claims made in it).

208 See, e.g., In re Global Media Corp., 121 F.T.C. 426, 431 (1989) (involving an FTC challenge to the safety of “Herbal Ecstasy” advertised as producing a natural high).


207 M. See also David Ho, Three Internet Companies Settle Federal Fraud Charges, ASSOCIATED PRESS, Apr. 5, 2000, available at http://www.ancone.ca/Tech/New20040505_fraud.html (reporting that the FTC forced these companies to accept settlement for advertising cure-all, miracle drugs on the Internet).

E. Drug Enforcement Agency

At the federal level, the Drug Abuse, Prevention, and Control Act prohibits the dispensing of a controlled substance without a valid prescription. The regulations define "prescription" in a way that excludes an on-line questionnaire. Regulations also require the registration of pharmacies and physicians, and mandate specific requirements for the manufacture, distribution, handling, and record-keeping of controlled dangerous substances. Non-compliance with these requirements may result in an enforcement action.

F. The Department of Health and Human Services

The Department of Health and Human Services (DHHS) is responsible for Medicare fraud because it is a third-party payer for Medicare recipients. The Web may become a vehicle for Medicare fraud if physicians bill for "questionnaire examinations" or for non-existent examinations. Prescriptions dispensed from the Web may also be billed to a third party insurance company, especially Medicare or Medicaid. Self-referral to a pharmacy where the physician has an interest via the same site or a hyperlink will undoubtedly tempt some physicians into the realm of illegality. Part of the temptation is over-billing the federal or state government for drugs that are purchased with deep discounts due to volume and lack of pharmacy overhead.

G. Department of Justice Enforcement Actions

The Department of Justice (DOJ) has initiated investigations of practitioners and pharmacists that dispense drugs based upon on-line questionnaires. The DOJ has the authority to pursue criminal charges when drugs are sold based upon an on-line questionnaire. The DOJ may also pursue civil actions under Racketeer Influenced and Corrupt Organization (RICO) laws, including mail and wire fraud statutes, when consumers are defrauded. Web site operators who sold bogus HIV self-test kits over the Internet were sentenced to sixty-three months of confinement for mail fraud, wire fraud, and money laundering. The DOJ also has the authority to prosecute Web site operators who sell drug elements that the buyer can manufacture into formulas such as gamma-hydroxybutyrate (GHB), which is used to incapacitate sexual-assault victims. Finally, if the cyber-physician missteps in billing federal insurance programs such as Medicare and Medicaid, the Illegal Remuneration, Stark laws, or False Claims Act may be violated. In such cases, the DOJ can seek civil penalties and treble damages.

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107 Lookasis, supra note 2 (reporting that the fraudulent claims included a bone tailor product as an arthritis cure, and magnetic therapy and shark cartilage for cancer treatment). Simultaneously, the state of Arizona settled with a homoeopath who made claims dealing with intravenous hydrogen peroxide therapy. Federal Trade Commission, supra note 194.

108 Federal Trade Commission, supra note 194 (describing "metatags" as invisible responses to requests on Internet search engines; if the consumer searches by disease and a drug is displayed as a result of the disease search, the consumer can be misled into thinking that the drug is effective in treating the disease searched).

109 Id. (indicating that if a consumer rolls a mouse over a specific part of a site, text will appear, offering additional unfounded claims for the medication).

110 Id. (describing HTML links that direct consumers to other sites that look as if they are independent from the prior site but in reality are owned and operated by the same proprietor).


22 U.S.C. § 829 (2000); 21 C.F.R. § 1306.04(a) (2000) (stating that "an order purporting to be a prescription issued not in the ordinary course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of . . . the Act . . . and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.").

201 C.F.R. §§ 1306.05, 1306.09 (2000) (describing persons entitled to issue pharmaceutical prescriptions and the manner in which they drugs may be issued).

202 Williams, supra note 201 (describing how the DHHS administers the Medicare program, by contracting with public and private intermediaries to perform certain duties—including processing and reviewing claims).

203 Drugstores on the Net, supra note 1, at 89 (Statement of Ivan K. Ferguson) (describing DOJ actions against conduct that has been long been viewed as illegal, but only recently reopened on the Internet).

204 M. at 90 (describing the burden of proof that the DOJ must satisfy to successfully prosecute federal and misdemeanor criminal charges).


206 Drugstores on the Net, supra note 1, at 92.

207 Id.

208 42 U.S.C. § 1320a-7(a) (Supp. IV 1998).

209 42 U.S.C. §1320a-7(b) (Supp. IV 1998).

cases, the DOJ would also be the vehicle to ensure enforcement of these laws.

H. Which Agency Has Federal Jurisdiction?

From a political science perspective, it appears that the cyber-pharmacy issue is too big for any one agency, at either the state or federal level, to handle alone.213 Federal government branches must cooperate inter se. It is equally incumbent that federal agencies cooperate with the states to foster points of contact, share information, and form policies and mechanisms.214 Although the FDA designation provides a potent penalty for nefarious Web-physicians or Web-pharmacists, it does little to assure the requisite safety and efficacy that the United States food and drug laws mandate to appropriately regulate prescriptions and drug distribution at the state level. The question remains whether Operation Cure.All will indeed cure all.

V. PRIVATE ACTION

The private sector has responded to Internet problems and worked toward providing solutions. The government, law enforcement, and pharmaceutical industry are applying innovative solutions to jurisdictional, security, infrastructure, and law enforcement problems inherent in this new technology.215 For instance, the Better Business Bureau and the Electronic Commerce and Consumer Protection Group (including AT&T, Dell, Microsoft, America Express, and America Online) are presently developing innovative approaches to jurisdictional issues.216

213 Charles Marvick, Several Groups Attempting Regulation of Internet Rx, 281(11) JAMA 975, 975-76 (1999) (reporting that the FDA has called on physicians and pharmacists for help in controlling use of cyber-pharmacies).

214 The Electronic Frontier, supra note 139, at 34-35 (asserting that the cooperation of all American jurisdictions and those abroad is crucial to investigating and prosecuting cyber-crimes).

215 The Electronic Frontier, supra note 139, at 17.

216 Id. (describing the development of voluntary codes that provide on-line merchants with guidelines for implementation of consumer protection and other innovative approaches to facilitating e-commerce).

217 Id. at 16 (examining the private sector’s initiative to design new technology to protect children, to develop self-regulatory consumer protection, and to coordinate and cooperate with the law enforcement).


219 Dragostea on the Net, supra note 1, at 273 (Statement of Peter Neuper). !


221 Id. (stating that the National Association of Pharmacy was created to assist state licensing boards to determine the qualifications of those seeking licensure).

222 Id.

223 Id.

224 Id. The problem with the VIPPS program is that the standards are vague and ambiguous. The approval that is granted as a result has vague and ambiguous meaning. These rules need to be tightened and be more specific. In addition, the VIPPS program has no way to enforce the program. It cannot remove the offending pharmacy from the Internet all it can do is remove the seal. Moreover, the seal may not be recognized by the public and thus may be of little consequence to them.

225 Id. (purporting that a pharmacy must comply with licensing and inspection requirements of its state to become VIPPS certified and that each VIPPS pharmacy site is identified by a special hyperlink displayed on their Web site).
NABP database.\textsuperscript{227} The certification process assures consumers that the on-line pharmacy is legitimate. In October 2000, the NABP website listed only thirteen cyber-pharmacies as VIPPS certified.\textsuperscript{228} However, New Zealand has already adopted the certification program and it is under consideration by New South Wales, Australia, Canada, and the International Pharmaceutical Federation that represents pharmacies throughout the world.\textsuperscript{229}

Various cyber-pharmacies, pharmaceutical benefit managers, federal and state regulators, consumer advocates, and medical groups attended the 1999 Health Care Summit in Washington, D.C., to discuss on-line pharmacy fraud.\textsuperscript{230} The Summit established a technology task force to determine the extent of on-line pharmacy abuse and fraud and to work with the FDA, FTC, and DOJ to combat illegal pharmacy sites.\textsuperscript{231} PlanetRx.com proposed the creation of “Operation Safe Net” to allow consumers to report fraudulent pharmacy sites on the Internet.\textsuperscript{232} Finally, the NABP assumed responsibility to investigate and prosecute the purportedly fraudulent sites.\textsuperscript{233}

VI. INTERNATIONAL LAW

The problems of enforcement are exacerbated by the Internet’s infinite scope. Messages may pass through wireless and satellite communication networks over many countries, different time zones, and unique legal systems. Cyber-offenders must first be located and then served with a search warrant for cyber-records in a particular jurisdiction under applicable laws. Real-time investigations must occur on an international scale, using preserved evidence.\textsuperscript{244} Current

\textsuperscript{227} Id. (describing the verification process and how legitimate cyber-pharmacies will be listed on the NABP’s official website and allowed to display the NABP seal).

\textsuperscript{228} Id.

\textsuperscript{229} Id.

\textsuperscript{230} Pharmacist: Senate Committee Extensive E-Pharmacy: Some Questions Need for Federal Regulation, HEALTH CARE DAILY REPORT (BNA), Mar. 22, 2000, at 12.

\textsuperscript{231} Pharmacist: Online Pharmacies Concern Summit, You to Stop Fraudulent Pharmacy Web Sites, HEALTH CARE DAILY REPORT (BNA), Nov. 12, 1999, at 7 (reporting a summit that discussed the formation of “Operation Safe Net,” an entity that would allow consumers to report fraudulent pharmacy activities on the Internet, and proposals to educate online consumers).

\textsuperscript{232} Id.

\textsuperscript{233} Id.

\textsuperscript{234} Id.

\textsuperscript{244} The Electronic Frontier, supra note 139, at 31 (arguing that real-time tracking may only be possible when the party is actually on-line).
and harmonization efforts.\textsuperscript{240} One commentator, Uwe Trager, a physician with Otto-Von Greizene University in Germany, has called for the establishment of an international agency to certify the accuracy of Web sites.\textsuperscript{241} Any site meeting the international agency's standards would be given a standard of approval similar to the United States' VIPS program.\textsuperscript{242}

International issues and enforcement problems thus appear larger than the state and federal governments' law. How is jurisdiction determined between countries if the cyber-physician, pharmacy, and patient are in separate countries? The answer remains undeveloped. The American Bar Association's Jurisdiction in Cyberspace Project presented its proposed solutions in October 1999.\textsuperscript{243} Moreover, jurisdiction in Europe for commercial transactions is governed by two treaties, which have not been updated to address on-line Internet phenomena.\textsuperscript{244} Criminal law is largely a matter of cooperation, rather than compliance with overriding treaties. In other areas of the world, there is a dearth of law and custom that would provide an enforcement framework for commercial or criminal conduct on the Web.\textsuperscript{245}

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{240} Id.
\item \textsuperscript{241} Lochaus, supra note 2 (reporting that approved Web sites would receive a stamp of approval, providing consumers with a larger measure of confidence).
\item \textsuperscript{242} Id.
\item \textsuperscript{243} American Bar Association, noting that the goals of the project are to describe current jurisdictional principles, evaluate the impacts of such principles in key commercial areas, and generate specific recommendations including harmonizing jurisdictional rules to meet the demands of electronic commerce and facilitate the creation of legal certainty, at http://www.abanet.org/tools/cyber/jurisdiction/press.html (last visited Mar. 25, 2001).
\item \textsuperscript{244} Id. (describing The Brussels Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters and the Rome Convention on the Law Applicable to Contractual Obligations).
\item \textsuperscript{247} Drugstores on the Net, supra note 1, at 266 (Statement of William Razooyak).
\item \textsuperscript{248} The Electronic Frontier, supra note 12, at 98.
\item \textsuperscript{249} Id., at 49.
\item \textsuperscript{250} Id., at 48 (stating that the Department of Commerce has developed codes of conduct and mechanisms for consumer dispute resolution, redress, and enforcement for businesses).
\end{itemize}
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The FDA has partnered with organizations, consumer groups, and the Internet industry to provide information to consumers through public service announcements, brochures, newspaper articles, and media interviews. The FDA Web site provides information on FDA enforcement efforts, FDA-regulated products, and frequently asked questions about on-line drug sales.

For the long-term, state medical and pharmacy licensing laws should be strengthened with required disclosure of current, accurate, and accessible information about the addresses and identities of pharmacies, physicians, and principals when the Internet site is involved in particular practices. This information should be displayed on Web pages. States should require each Internet pharmacy to register as an additional pharmacy location. States have issued guidelines, developed certification programs, and adopted other non-legislative approaches. Still, pursuit of out-of-state physicians and pharmacies prescribing or dispensing drugs over the Web can be difficult and costly. States should be able to issue cyber-licenses to physicians and pharmacists. Alternatively, national licenses for these professionals should be seriously considered.

Both House and Senate Committees have held hearings on the issue of cyber-pharmacies. The Senate held hearings during March 2000 and considered suggestions such as: (1) increasing consumer education on safely buying prescription drugs over the Internet; (2) disclosure of a Web site's pharmacy license; and (3) allowing state attorney generals to obtain national injunctive relief.

Wasted time,

204 Id. at 53.
206 See Drugstore on the Net, supra note 1, at 19. The FTC has recommended legislation that would disclose the following: (1) the name, business address, and phone number of the pharmacy that will dispense the prescription and the state or states where such pharmacy is licensed or registered to do business; (2) the name, address, and phone number of each physician providing the on-line prescribing services and the state or states where such physicians are licensed or authorized to practice medicine if such service is offered; (3) the name, business address, phone number and principal officers or owners of the on-line business offering prescription drugs, if different from the pharmacy and physician, and (4) the state or states from which the Web sites will accept orders for prescription drugs. Id.
207 See Drugstore on the Net, supra note 1, at 264 (Statement of Cynthia T. Cuno).
208 Id. at 260.
209 Id. at 264.

\[\text{Williams} \quad 187\]

effort, and resources result if each state’s attorney general must take separate action to insure enforcement. The possibility of a national injunction would obviate such a problem and should be considered. The real problems associated with cyber-pharmacy enforcement are not due to the lack of federal and state regulation, but from the lack of funding, the lack of jurisdiction over foreign sites, and the need for federal and state cyber-tracking technology. A need to tread softly before complicating the Internet environment remains industry and government’s foremost concern.

Unfortunately, many suggested solutions would burden legitimate Web sites while leaving the rogue Web sites untouched. The rogue site problem appears bigger than both the state and federal governments. However, legitimate Type 1 sites typically are not mentioned in news headlines. Thus, emphasis needs to be placed on the offenders, not on Web sites that are compliant with existing law. Indeed, a study requested by the Clinton Administration in March 2000 reported that existing laws are adequate to regulate Internet crimes.

The FTC has suggested legislation to assist the states with extraterritorial jurisdiction issues, but that is not enough. Harmonization of laws must extend beyond national borders to the international arena. Once the United States obtains uniform, effective ways to handle Internet on-line drug sales, it must turn to the international arena and work with other nations to ascertain ways to control foreign sites, products, and therapies. Enforcement initiatives must be designed in a way to deter illegal pharmacy practices on the Internet, without stifling the growth of the Internet or chilling its growth as a commercial and communication medium. As a new century begins, a variety of opportunities exist, but: whether they will insure safety and efficacy for drug sales on the Internet remains to be seen.

211 Drugstore on the Net, supra note 1, at 19.
212 Id. at 273.
213 Id. at 283.
214 Net Policy: Report Unveiled; Critics Say Study Is Threat to CyberPrivacy, NEWSDAY, Mar. 9, 2000, at A25. Currently the government must get separate “tap-and-issue” warrants for each Internet provider who relays a signal in order to find a hacker.
215 Id.
216 Drugstore on the Net, supra note 1, at 87 (Statement of Ivan K. Fong).