

Policing the “Wild West” World of Internet Pharmacies

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I. INTRODUCTION

Do you feel like you need a little Viagra, but you are too embarrassed to talk to your doctor? Do you want to combat that baldness with some Minoxidil, but you just do not have time to see your personal physician? Perhaps you want to shed a few pounds with the help of one of those prescription diet drugs? No problem—if you have access to the Internet and a credit card.¹ Today, healthcare consumers can go online and purchase virtually any type of prescription medication, with or without a valid prescription from their physician.²

An Internet pharmacy sells medications through its website.³ Some of these pharmacies are simply the cyberspace version of traditional brick and mortar pharmacies.⁴ Other pharmacies only exist in the cyberworld and prescriptions are filled and shipped from a warehouse.⁵ Legitimate, law-abiding Internet pharmacies benefit modern healthcare in numerous ways.⁶ Some Internet pharmacies, however, conduct illegal and unsafe prescribing and dispensing practices that can endanger the health of the patients the pharmacy serves.⁷

Essentially, three types of Internet pharmacies exist:⁸ 1) pharmacies that only fill prescriptions written by a patient’s physician; 2) pharmacies that charge for a physician “cyber-consultation”⁹ (usually nothing more than the patient completing a simple questionnaire) and then the cyber-doctor writes a prescription;¹⁰ and 3) pharmacies that dispense prescription drugs without a physician’s prescription.¹¹ The first type of pharmacy is a valuable addition to the healthcare consumer industry and is considered to be the cyberspace equivalent of a mail order pharmacy.¹² The latter two types of pharmacies, however, can present a significant danger to healthcare consumers and are proving to be a regulatory nightmare.

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¹ See generally Carol Ukens, *Internet Pharmacies*, DRUG TOPICS, May 17, 1999, at 63, available in LEXIS, News Library, DRUGTP File.

² See *id.*

³ See *id.* See also Keith M. Korenchuk, *Online Pharmacies Present a Host of Regulatory Issues*, NAT’L L.J., Nov. 29, 1999, at B11, available in LEXIS, News Library, NTLAWJ File.

⁴ See Korenchuk, *supra* note 3.

⁵ See Angela Gunn, *Behind the Scenes at an Online Pharmacy* (Oct. 5, 1999) (last visited Oct. 22, 2000) <www.cnn.com/tech/computing/9910/05/web.pharmacy.idg/index.html>.

⁶ See *infra* notes 28-38 and accompanying text.

⁷ See *infra* notes 39-67 and accompanying text.

⁸ See Michael F. Conlan, *Net Watchers: Congress Weighs New Laws as It Probes the Practices of Online Pharmacies*, DRUG TOPICS, Aug. 16, 1999, at 71, available in LEXIS, News Library, DRUGTP File.

⁹ See Ukens, *supra* note 1, at 63.

¹⁰ See *id.* At one pharmacy, affiliates received a \$10 referral fee for every new Viagra sale, plus 2.5% of the product price. These affiliates also could earn an extra \$400 to \$8,000 each month, with top prescribers earning \$15,000 per month. *Id.*

¹¹ See Ukens, *supra* note 1, at 63.

¹² See *id.*

The number of Internet pharmacies has increased from less than 30 in January 1999 to more than 400 in July 1999.¹³ Furthermore, a July 1999 report issued by the American Medical Association's (AMA) Board of Trustees estimated that at least 400 "instant prescription" websites exist.¹⁴ Typically, instant prescription sites require that the consumer accept the terms of a liability waiver, select a quantity of the drug to be purchased, and complete a brief online questionnaire.¹⁵ The pharmacies claim that completed questionnaires are evaluated by a physician, who prescribes the medication if it is medically indicated.¹⁶

A special regulatory problem arises when the Internet pharmacy is located outside the United States. Foreign-based sites fall outside the regulatory jurisdiction of the United States.¹⁷ The Customs Service,¹⁸ the Postal Service, the Food and Drug Administration (FDA), and the Drug Enforcement Administration (DEA) all play important roles in taking action against the illegal importation of drugs.¹⁹

Controversy exists over which regulatory body should govern the sale of prescription drugs over the Internet and how Internet pharmacies should be regulated.²⁰ This article contends that cooperation by state and federal regulatory agencies and careful updating and utilization of current regulatory avenues adequately can promote the safety of Internet pharmacies. This article further contends that dangers posed by foreign Internet pharmacies will grow until international regulatory cooperation is established.

Part II of this article begins with background information and statistics regarding the healthcare consumer's use of the Internet. It outlines both the beneficial and detrimental effects of Internet pharmacies, and discusses privacy issues encountered upon utilization of Internet pharmacies. Part III discusses the related issue of regulation of the practice of cyber-medicine. Part IV explores the regulatory issues and problems encountered in governing Internet pharmacies and their prescribing and dispensing practices. This discussion includes the regulatory stance of several agencies and associations. It concludes with current statutory information, caselaw, and pending legislative action. Part V discusses the opposing views of the critics and supporters of federal legislation, and proposes model state legislation designed to promote the safety of online prescrip-

¹³ See William Glanz, *FDA Warns Against Cyber-Drugs; Agency Vows to More Closely Scrutinize Online Pharmacies*, WASH. TIMES, July 31, 1999, at C7.

¹⁴ See Douglas Carnall, *American Medical Association Moves to Regulate Prescribing on the Internet*, 319 BRIT. MED. J. 213, 213 (1999).

¹⁵ See *id.*

¹⁶ See Ukens, *supra* note 1, at 63. One company pays two independent physicians on a percentage basis to assess its questionnaire forms. See Carnall, *supra* note 14, at 213. The company's managing director stated that, "Our business is to sell lifestyle treatments to people who have proven their intelligence by accessing the internet and owning a credit card." *Id.*

¹⁷ See Marilyn Larkin, *US Online Pharmacies Strive for Respectability*, 354 LANCET 782, 782 (1999).

¹⁸ Even though it is illegal to ship undeclared drugs into the United States, it is impossible for the United States Customs Service to screen all incoming packages. See Katrina Armstrong et al., *Direct Sale of Sildenafil (Viagra) to Consumers Over the Internet*, 18 NEW ENG. J. MED. 1389, 1391 (1999).

¹⁹ See *Drugstores on the Net: The Benefits and Risks of Online Pharmacies Before the Subcomm. on Oversight and Investigations Comm. on Commerce*, 106th Cong. (1999) (statement of Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA) [hereinafter Woodcock Statement].

²⁰ See Valentine Cardinale, *In Step With Online Pharmacies*, DRUG TOPICS, Aug. 2, 1999, at 10, available in LEXIS, News Library, DRUGTP File. See also Larkin, *supra* note 17, at 782. See also Craig L. Fuller, *No Need to Expand Rules Yet*, USA TODAY, Jan. 3, 2000, at 18A ("Rushing to expand the authority of the FDA to regulate Internet pharmacies prior to any indication that current regulatory and voluntary certification programs have failed may be a bit premature.").

tion purchasing. Finally, Part VI discusses avenues for dealing with Internet pharmacies based abroad.

II. THE ADDITION OF INTERNET PHARMACIES TO THE INTERNET CONSUMER HEALTHCARE ARENA

Consumers frequently utilize the Internet to obtain health information and products,²¹ and Internet pharmacies join a wide variety of healthcare-related websites. These pharmacies can be greatly advantageous to the modern healthcare system. The unlawful practices of some pharmacies, however, can affect a consumer's health detrimentally.

A. *The Healthcare Consumer's Use of the Internet and the Economics of Prescription Purchasing*

It is estimated that 48 million people accessed the Internet in 1998 and that number is expected to increase to at least 320 million by 2005.²² Furthermore, 20% of people using the Internet are age 50 or older, and this age group represents the fastest-growing segment of the Internet community.²³ More than one-third to almost one-half of these people seek medical and health information online.²⁴ Thus, a significant number of people currently utilize the Internet as a health resource, and it is likely that this trend will continue.

An upward trend also is expected in prescription writing. In 1998, U.S. doctors wrote 2.8 billion prescriptions; this number is expected to rise to 4 billion by 2005.²⁵ The increase in prescription purchases will foster an already profitable pharmacy business.²⁶ The lucrative pharmaceutical industry could make online drugstores "one of the hottest categories in e-commerce."²⁷

²¹ See *infra* note 24 and accompanying text.

²² See Michael Casey, *The Internet Writes Its Own Prescription*, MED. INDUSTRY TODAY, Mar. 24, 1999, available in LEXIS, News Library, MEDTDY File.

²³ See Rita Rubin, *Easier-to-Swallow Way to Get Your Pills Refilled, E-Pharmacies Offer Convenience but Raise Safety Concerns*, USA TODAY, Oct. 6, 1999, at 1D.

²⁴ See Casey, *supra* note 22. See also *Online Service Growing Rapidly; Net Pharmacy Signs Medicare*, MED. INDUSTRY TODAY, Apr. 8, 1999, available in LEXIS, News Library, MEDTDY File.

²⁵ See Michael Menduno, *Apothecary Now; Online Pharmacies*, HOSP. & HEALTH NETWORKS, July 1, 1999, at 34, available in LEXIS, News Library, HOSPTL File; see also Casey, *supra* note 22. Approximately 75% of all prescriptions are written for consumers with chronic conditions, and many of these consumers are interested in buying their prescriptions online. See Kim Roller, *Pharmacy and the Internet: Danger or Opportunity?*, DRUG STORE NEWS, Aug. 30, 1999, at CP6, available in LEXIS, News Library, DRGSTR File. The largest consumers of prescription drugs are over the age of 55. See Reuters Health Information, *Online Drugstore Growth Predicted* (Aug. 26, 1999) <www.drkoop.com/news/stories/august/online_drugs.html> (website no longer valid, information is on file with author). However, as discussed *supra*, this age group still represents a small percentage of Internet users. See Rubin, *supra* note 23, at 1D. It is predicted that the aging, "technology savvy" baby boomers will fuel future growth of Internet pharmacies. See Reuters, *supra*.

²⁶ U.S. consumers spend approximately \$230 billion per year for prescription drugs and other healthcare items. See Casey, *supra* note 22. The mail-order drug business makes approximately \$15 billion annually. See Reuters, *supra* note 25. Estimates predict an increase in online drug sales, from eleven million dollars in 1998 to \$890 million in 2002, provided more insurance companies agree to pay for prescription medication ordered and dispensed this way. *Id.*

²⁷ See James Ledbetter, *No Prescription? No Problem: Online Drugstores Don't Always Work the Way You'd Expect* (June 30, 1999) (last visited Oct. 22, 2000) <www1.pcworld.com/pcwtoday/article/0,1510,11633,00.html>. But see The Economist, *Online Pharmacies Suffering Some Profit Queasiness*, CHI. TRIB., Dec. 20, 1999, at 4 (discussing the minimal revenues and large losses of certain Internet pharmacies).

B. *Positive Effects of Internet Pharmacies*

Internet pharmacies offer a host of benefits. They are convenient and allow customers to avoid nuisances such as going out in bad weather, parking hassles, standing in line, and the inevitable wait for the prescription to be filled.²⁸ Patients with limited mobility or those living far from a pharmacy can benefit tremendously from legitimate Internet pharmacies by eliminating travel to a traditional pharmacy.²⁹ Many Internet pharmacies offer overnight shipping, allowing customers to avoid the delay of regular mail.³⁰

Another benefit is that some Internet pharmacies offer lower prices on medications than those charged by traditional pharmacies.³¹ One way lower costs are made possible is through an increase in competition.³² In addition, many Internet pharmacies lack fixed costs such as property leases, maintenance, and property taxes.³³

Furthermore, Internet pharmacies can offer privacy that is often lacking in a traditional pharmacy.³⁴ Many patients feel uncomfortable asking a pharmacist questions in front of other customers.³⁵ Some Internet pharmacies have a licensed pharmacist available 24 hours a day to answer questions by phone or by e-mail.³⁶ This allows patients to ask personal medication questions without fearing that their neighbors might overhear.

A final benefit is that Internet pharmacies can offer perks not found in traditional pharmacies. Some companies send e-mail alerts when the prescription is due for a refill,³⁷ such a reminder may improve patient compliance with drug therapies. Improving therapy compliance not only is beneficial to the patient's physical health, it is possible that the cost of healthcare paid by insurers, employers, and third-party payers could be reduced by improving patient outcomes.³⁸

C. *Negative Effects of Internet Pharmacies*

Although Internet pharmacies can provide many benefits, the unlawful activities of many of these sites produce deleterious effects. Distinguishing legitimate Internet pharmacies from illegitimate pharmacies raises difficulties due to the ease of creating a website that looks like it represents a valid company.³⁹ Furthermore, obscuring the source of the medication and the companies responsible for producing and dispensing it is simple with Internet technology.⁴⁰

²⁸ See Rubin, *supra* note 23, at 1D.

²⁹ See Woodcock Statement, *supra* note 19.

³⁰ See Ukens, *supra* note 1, at 63.

³¹ See John Henkel, *Buying Drugs Online: It's Convenient and Private, but Beware of 'Rogue Sites'*, FDA CONSUMER, Jan.-Feb. 2000, available in LEXIS, News Library, FDA File. See also Rubin, *supra* note 23, at 1D.

³² See Woodcock Statement, *supra* note 19.

³³ See Casey, *supra* note 22.

³⁴ See generally Ukens, *supra* note 1, at 63. However, there is some question as to the degree of anonymity the Internet provides. For a discussion of the "trail of data" left behind while surfing the Web see Jerry Berman & Dierdre Mulligan, *The Internet and the Law: Privacy in the Digital Age: Work in Progress*, 23 NOVA L. REV. 549, 558-59 (1999).

³⁵ See generally, Ukens, *supra* note 1, at 63; see also Rubin, *supra* note 23, at 1D.

³⁶ See Gunn, *supra* note 5.

³⁷ See Casey, *supra* note 22.

³⁸ See *id.*

³⁹ See Woodcock Statement, *supra* note 19. See also White House Press Release, *The Clinton Administration Unveils New Initiative to Protect Consumers Buying Prescription Drug Products Over the Internet*, Dec. 28, 1999 [hereinafter White House Press Release]. But see Fuller, *supra* note 20, at 18A ("[I]t is an overstatement by the White House to suggest that consumers have "no way of telling" whether an online pharmacy is a legitimate operation."). See also Virginia Postrel, *Sometimes the Patient Knows Best*, N.Y. TIMES, Jan. 3, 2000, at A19 ("Brand reputations, contact numbers and street addresses, and a pharmacy association certification program are all indicators that a business is sound.").

⁴⁰ See Woodcock Statement, *supra* note 19.

Two dangers that go hand-in-hand are self-diagnosis and self-medication because consumers can purchase prescription drugs without ever speaking to a pharmacist or physician.⁴¹ In these days of managed care, it might be weeks before a patient can see a physician for non-emergency purposes.⁴² Patients might choose to treat themselves rather than wait for an appointment, or the patient simply may be too embarrassed to discuss the health problem with his physician.⁴³

These dangers are especially significant given that numerous Internet pharmacies are willing to dispense prescription drugs without a valid prescription.⁴⁴ When a patient utilizes an Internet pharmacy, which provides a medication, based on a cyber-consultation, or if the pharmacy directly dispenses the medication without a prescription, important safeguards are missed.⁴⁵ Not only does the patient miss an examination by his physician, the possibility exists that a licensed pharmacist may never review the prescription.⁴⁶ The patient bypasses the two professionals who traditionally inform patients of proper utilization, dangerous side effects,⁴⁷ and drug interactions.⁴⁸

In addition to the safety issues raised by illegitimate dispensation of medication, the prescription label itself can pose potential dangers. Medicines obtained through rogue Internet pharmacies might contain unreliable or out-of-date prescription use and dosage instructions.⁴⁹ The instructions might even be printed in a foreign language.⁵⁰

Another drawback to Internet pharmacies may be cost, as some consumers pay more for prescription medications obtained over the Internet.⁵¹ High shipping costs and

⁴¹ See White House Press Release, *supra* note 39. *But see* Postrel, *supra* note 39 ("Regulators also tend to idealize in-person exams, as though every doctor took a careful history and thoroughly examined a patient before prescribing any drug.").

⁴² See Ledbetter, *supra* note 27.

⁴³ One Internet pharmacy, PrescriptionRx.com, an information source on foreign pharmacies, offers a listing of more than one thousand pharmacies worldwide that provide medications without a prescription. See Ukens, *supra* note 1, at 63. PrescriptionRx.com also sells the "Self-Diagnostic Symptom Cross Reference," a CD-ROM that provides a list of possible ailments and suggests medications after users type in their symptoms. *Id.* Thus, healthcare consumers can diagnose their medical problem and subsequently order medication without ever seeing or talking to a doctor.

⁴⁴ See Carnall, *supra* note 14, at 213 and accompanying text.

⁴⁵ See Armstrong et al., *supra* note 18, at 1389. See also White House Press Release, *supra* note 39. One instance of where these important safeguards were missed was when a 52-year-old Illinois man with a history of chest pain and a family history of heart disease died of a heart attack after using Viagra, which he had purchased via the Internet after completing an online questionnaire. See Henkel, *supra* note 31. Officials believe that a traditional doctor-patient relationship and physical examination could have uncovered health problems such as heart disease, which is a contraindication to using Viagra. *Id.* Another example emphasizing the necessity of a face-to-face physician consultation is where a person suffering from anorexia nervosa or another eating disorder attempts to receive a diet drug prescription. See Jane E. Henney, M.D., Commissioner of Food and Drugs, U.S. Food & Drug Administration, prepared statement at the National Association of Boards of Pharmacy Executive Officers Conference (Sept. 28, 1999). A physician prescribing the medication on the basis of an online consultation would be unable to determine the inappropriateness of the prescription. *Id.*

⁴⁶ See Armstrong et al., *supra* note 18, at 1389. See also White House Press Release, *supra* note 39.

⁴⁷ See Steven N. Gange, *Viagra: The Risks of Getting It Off the Internet* (Oct. 1, 1999) (last visited Oct. 22, 2000) <www.cnn.com/health/men/9910/01/viagra.men.wmd/>.

⁴⁸ See also Armstrong et al., *supra* note 18, at 1389.

⁴⁹ See World Health Organization, *Medical Products and the Internet: A Guide to Finding Reliable Information* (last visited Feb. 1, 2000) <www.who.int/medicines/docs/Medicines-on-Internet-Guide.html> [hereinafter WHO Guide].

⁵⁰ See *id.*

⁵¹ A study of 46 Internet pharmacies that sell prescription medications directly to the public indicated that drug prices were actually higher than those found in a traditional pharmacy. See Bernard S. Bloom & Ronald C. Iannacone, *Internet Availability of Prescription Pharmaceuticals to the Public*, 131 ANN. INTERNAL MED. 830, 830 (1999). For example, the price for Viagra from the Internet pharmacy was approximately \$5.49, plus the cost of shipping, whereas the price was \$4.50 per pill from a local Philadelphia pharmacy. *Id.* Thirty-seven of the sites required a prescription from a personal physician or an online physician, however, nine sites located outside the United States required neither a prescription nor an online consultation with a physician. *Id.*

an inability to participate in many insurance plans add to the cost.⁵² Furthermore, it is unlikely that health insurance plans cover the cost of an online medical consultation.⁵³ Online consultations with a physician typically cost more than a visit to the patient's own primary care physician.⁵⁴ The cost escalates if the patient has to pay for additional cyber-consultations for prescription refills.⁵⁵ In comparison, if the patient's personal physician writes the prescription, it is more likely that the prescription could be refilled without the cost of an additional office visit.

Another area of concern involves the prescribing-physician's credentials. The cyber-doctor's qualifications and his experience may be questionable, yet the patient has no way to screen the physician.⁵⁶ The possibility exists that the prescribing physician is practicing out of his area of specialty; in the non-cyberworld, patients typically would not visit an orthopedist to obtain a prescription for Viagra.⁵⁷

Furthermore, the online medical consultation questionnaires utilized by many Internet pharmacies pose several dangers. The AMA voiced concern that terms used in the online questionnaires may be beyond the technical comprehension of the layperson, and that there is no mechanism to ensure that the questions have been answered correctly or to confirm the proffered history with a physical examination.⁵⁸ Moreover, patients may underestimate the importance of the questions being asked.⁵⁹ Finally, many online questionnaires have the answers preselected for the patient.⁶⁰ This is hazardous because it facilitates the patient providing false or incorrect information.⁶¹

An additional danger is consumer access to unapproved drugs,⁶² counterfeit medications, and products marketed with fraudulent health claims.⁶³ Patients suffering from a serious medical problem and desperately searching for a cure are particularly vulnerable to false claims and unapproved drugs.⁶⁴ Furthermore, rogue sites might not send

⁵² See Ukens, *supra* note 1, at 63. Some Internet pharmacies can contract with prescription insurance plans, however, many other pharmacies do not participate with insurance plans and the consumer must pay for the medications out-of-pocket. See WHO *Guide*, *supra* note 49. Health Maintenance Organizations (HMOs) and insurance companies pay for more than eighty percent of all prescription drug costs. See Casey, *supra* note 22.

⁵³ See *The Pain of Online Drugstores*, KIPLINGER'S MAG. <www.drkoop.com/news/stories/august/online_drugs2.html> (Aug. 28, 1999) (website no longer valid, information is on file with author).

⁵⁴ See Bloom & Iannacone, *supra* note 51, at 832. See also Reuters Health Information, *Internet Pharmacy Sites Under Fire* (Sept. 30, 1999) <www.drkoop.com/news/stories/october/net_pharmacy.html> (website no longer valid, information is on file with author).

⁵⁵ See Bloom & Iannacone, *supra* note 51, at 831. For example, of the U.S.-based Internet pharmacies in one study, prescriptions could only be refilled twice, after which another online consultation was required. *Id.*

⁵⁶ One Internet pharmacy claims they have a "board-certified" physician, but does not give the physician's name, location, or even the board certification area of specialty. See ePrescribe (last visited Feb. 1, 2000) <www.eprescribe.com>.

⁵⁷ See generally Sheryl Gay Stolberg, *Virtual Druggists: A Special Report, Internet Prescriptions Boom in the 'Wild West' of the Web*, N.Y. TIMES, June 27, 1999, at 1.

⁵⁸ See Carnall, *supra* note 14. AMERICAN MEDICAL ASSOCIATION, *Report of the Board of Trustees*, 35-A-99, at 1, (last visited Mar. 28, 2000) <www.ama-assn.org/meetings/public/annual99/reports/onsite/bot/rtf/bot35.rtf> [hereinafter AMA BOT REPORT].

⁵⁹ See Armstrong et al., *supra* note 18, at 1390.

⁶⁰ See Bloom & Iannacone, *supra* note 51, at 833.

⁶¹ See *id.*

⁶² Internet pharmacies based outside the United States enable patients to obtain medications that have not been approved by FDA. See *Drugstores on the Net: The Benefits and Risks of Online Pharmacies Before the Subcomm. on Oversight and Investigations Comm. on Commerce*, 106th Cong., (1999) (statement of Herman I. Abramowitz, M.D., American Medical Association) [hereinafter Abramowitz Statement]. Although FDA requires rigorous clinical trials prior to approving medications in the United States, drugs from outside the United States typically escape such testing. *Id.*

⁶³ See *id.*

⁶⁴ See *id.*

the real medication.⁶⁵ Patients actually might receive counterfeit drugs that contain inactive ingredients, expired legitimate medications diverted to illegitimate sellers, or "dangerous sub-potent or super-potent versions that were improperly manufactured."⁶⁶ Finally, if drugs are manufactured, packaged, transported, or stored under substandard conditions, they could contain impure or unknown ingredients.⁶⁷

D. *Privacy Issues Encountered With Internet Pharmacies*

Although there is no guarantee of privacy at a traditional pharmacy, the information transmitted and stored by Internet pharmacies is vulnerable to hackers.⁶⁸ Much of this vulnerability can be overcome if the pharmacy uses secure server technology, maintains strict policies against sharing or selling patient personal data, and encrypts transactions during transmission.⁶⁹ Not all Internet pharmacies, however, make such a commitment to privacy.⁷⁰

Furthermore, certain practices of both Internet pharmacies and traditional pharmacies raise privacy concerns.⁷¹ Some drug stores sell confidential patient information to third parties conducting marketing campaigns for drug manufacturers.⁷² This inappropriate or inadvertent disclosure of private medical or prescription information can lead to a variety of problems, such as employment discrimination, increased health or life insurance premiums, and even denial of insurance coverage.⁷³

III. RELATED ISSUE: CURRENT REGULATION OF CYBER-MEDICINE

The current physician licensing system is state-based.⁷⁴ Some critics argue that the state-based physician licensing system should be abolished because of the common nature of providing healthcare.⁷⁵ Physicians can be licensed by more than one state,

⁶⁵ When a website offers medications at a cost significantly lower than average, the pills might not contain the active drug. See Armstrong et al., *supra* note 18, at 1391.

⁶⁶ See Woodcock Statement, *supra* note 19.

⁶⁷ See *id.* See also WHO Guide, *supra* note 49.

⁶⁸ See generally Berman & Mulligan, *supra* note 34, at 566.

⁶⁹ See *id.* One Internet pharmacy, Drugstore.com, reportedly has policies against selling information to third parties, stores health information and personal information in different places than patients' names, and encrypts information before it is sent over the Internet. See *Confidentiality and the Virtual Pharmacy; Confidentiality of Prescription Information Given to Online Pharmacies*, BUS. & HEALTH, Apr. 1, 1999, at 7, available in LEXIS, News Library, BHLTH File [hereinafter *Confidentiality and the Virtual Pharmacy*].

⁷⁰ See WHO Guide, *supra* note 49.

⁷¹ See generally Rubin, *supra* note 23, at 63. Some drug manufacturers and pharmacies combine technology, marketing techniques, and patient prescription information to increase medication sales. *Id.* One technique currently used by drug advertisers and manufacturers involves gathering and storing personal information about people calling toll-free numbers for information on medications. *Id.*

⁷² See *Confidentiality and the Virtual Pharmacy*, *supra* note 69, at 7. The U.S. Department of Health and Human Services recently published proposed standards for privacy protection of electronic health information. See 64 Fed. Reg. 59,918 (1999). Furthermore, some states are trying to combat this trend of releasing prescription information. For example, Virginia legislators are working on legislation to expand prohibitions against the release of confidential prescription information by pharmacists, pharmacy owners, insurers and others with access to the data. See Robert O'Harrow, Jr., *Giant Food Stops Sharing Customer Data; Prescription-Marketing Plan Drew Complaints*, WASH. POST, Feb. 18, 1998, at A01.

⁷³ See Cheryl Clark, *Medical Privacy Is Eroding, Physicians and Patients Declare*, SAN DIEGO UNION-TRIB., Feb. 21, 1998, at 1.

⁷⁴ See generally Brian Darer, *Telemedicine: A State-Based Answer to Health Care in America*, 3 VA. J.L. & TECH. 4 (1998).

⁷⁵ See *id.* at 13 n.36.

however, the process is often both difficult and time-consuming because physicians must take additional exams, submit paperwork for credentialing, and pay fees.⁷⁶

Because the licensing system is state-based, state regulatory boards and agencies can reprimand⁷⁷ physicians who sell or prescribe medications to patients the physician has not physically examined.⁷⁸ In light of these newly encountered problems, the practice of medicine likely will face regulatory adaptations designed to counter any deleterious effects arising from technological advances. The regulation of cyber-medicine is a necessary parallel to successful regulation of Internet pharmacies.⁷⁹

IV. REGULATORY ISSUES AND PROBLEMS ENCOUNTERED IN GOVERNING INTERNET PHARMACIES

The general regulatory problem is two-fold: how should Internet pharmacies be regulated and who has the authority to do so? Several agencies claim that the problems presented by rogue pharmacies do not fall within their jurisdictional authority,⁸⁰ thus the issue has become something of a regulatory hot potato. Furthermore, Internet pharmacies raise a choice-of-law problem.⁸¹ Such a situation arises where an Internet pharmacy licensed in California contracts with a physician licensed in New York to write a prescription for an online patient in Michigan. Controversy exists over which state law should apply in these multistate situations.⁸²

Rogue pharmacies present two additional regulatory problems: 1) the ease of creating and operating an Internet website allows these companies to close down their current site and open up a new site within a matter of hours,⁸³ thus making the pharmacies difficult to track; and 2) many of these pharmacies are foreign companies and out of reach of the regulatory arm of the United States.⁸⁴

A. *An Overview of the Regulatory Stance of Interested Agencies and Associations*

Various federal and state authorities occupy specific, parallel roles in the regulation of physicians and pharmacies. In an effort to coordinate these separate entities, an interagency working group, comprised of federal and state representatives, began meet-

⁷⁶ See *id.* at 17.

⁷⁷ Reprimands vary in their degree of severity. For example, in October 1999, the Colorado State Board of Medical Examiners sent a letter of admonition to a Colorado physician for selling Viagra online. See Russ Colchamiro, *Internet Rx's Cause Safety, Ethics Uproar*, AM. DRUGGIST, Jan. 1, 1999, at 14. In another instance, California state regulators shut down two websites <www.drpropecia.com> and <www.deyarmanmedical.com> run by a San Diego osteopath who was prescribing Propecia for baldness treatments without first examining the patient. See Ledbetter, *supra* note 27. Finally, a state of Washington orthopedic surgeon was fined \$500 and cited by the Washington Medical Quality Assurance Commission for unprofessional conduct for prescribing medication to people he had not physically examined. See Stolberg, *supra* note 57, at 1.

⁷⁸ For a further sampling of state medical board reprimands stemming from Internet prescribing see VIRGINIA BOARD OF MEDICINE, DEPARTMENT OF HEALTH PROFESSIONS STUDY REPORT, STUDY OF THE SALE OF PRESCRIPTION DRUGS VIA THE INTERNET, at 8-11, (last visited Mar. 28, 2000) <www.dhp.state.va.us/BHP/internet_prescribing_study_report.htm> [hereinafter VIRGINIA STUDY REPORT].

⁷⁹ See *infra* notes 80-192 and accompanying text.

⁸⁰ See Ukens, *supra* note 1, at 63.

⁸¹ See *id.*

⁸² See VIRGINIA STUDY REPORT, *supra* note 78, at 2.

⁸³ See Ukens, *supra* note 1, at 63.

⁸⁴ See Larkin, *supra* note 17, at 782.

ing in April 1999 to discuss regulation of Internet pharmacies and consider other issues relating to the sale of drugs over the Internet.⁸⁵

1. *The Regulatory Stance of the Food and Drug Administration Regarding Internet Pharmacies*

Under the Federal Food, Drug, and Cosmetic Act, FDA has the legal authority to take action against: 1) the importation, sale, or distribution of an adulterated or misbranded drug; 2) the importation, sale, or distribution of an unapproved new drug; 3) illegal promotion of a drug; 4) the sale or dispensing of a prescription drug without a valid prescription; and 5) counterfeit drugs.⁸⁶ FDA officials believe that because it is the drug industry's products being sold, those companies should play a more active role in monitoring Internet pharmacies.⁸⁷ FDA further believes that issues raised by Internet pharmacies should be handled by state regulatory boards and other appropriate agencies.⁸⁸

FDA purports to lack both the resources and staff needed to deal with the issues raised by Internet pharmacies and online prescribing.⁸⁹ FDA's Office of Regulatory Affairs and Office of Compliance in the Center for Drug Evaluation and Research, however, are reviewing drug sales of Internet pharmacies that are reported to appear violative of current federal law.⁹⁰ FDA plans to install a search engine⁹¹ to help its staff quickly find sites selling prescriptions.⁹² Additionally, FDA has sent warning letters to companies illegally selling unapproved new drugs online and has contacted online sellers of illegal foreign pharmaceuticals.⁹³ FDA considers foreign-based Internet pharmacies to be the most challenging problem.⁹⁴

FDA also contacts website managers and asks for their voluntary cooperation in removing violative sites.⁹⁵ FDA further targets sites making unsubstantiated claims or misrepresentations of drugs, and sites failing to provide a fair balance of information regarding the

⁸⁵ See *Drugstores on the Net: The Benefits and Risks of Online Pharmacies Before the Subcomm. on Oversight and Investigations Comm. on Commerce*, 106th Cong., (1999) (statement of Jodie Bernstein, Director of the Bureau of Consumer Protection of the FTC) [hereinafter Bernstein Statement]. The working group is comprised of representatives from FTC, FDA, DOJ, DEA, and other federal and state agencies. *Id.*

⁸⁶ See Woodcock Statement, *supra* note 19. See also Federal Food, Drug, and Cosmetic Act, Pub L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 et seq. (1994)).

⁸⁷ See Colchamiro, *supra* note 77, at 14. At least one drug manufacturer declared its stance against rogue pharmacy practices. Pfizer, the manufacturer of Viagra, reports to have written letters to every state medical and pharmacy board to enlist their support in discouraging the practice of online prescribing. *Id.* Pfizer has also filed a complaint with the FTC asking it to monitor improper dispensation of Viagra. See Gange, *supra* note 47.

⁸⁸ See Carol Ukens, *NABP Maps Plans to Verify Internet Pharmacy Licenses*, DRUG TOPICS, Mar. 1, 1999, at 17.

⁸⁹ See *NABP Standards for Online Rx Expected*, CHAIN DRUG REV., Apr. 26, 1999, at RX29, available in LEXIS, News Library, CHNDRG File. See also Ukens, *supra* note 88, at 17.

⁹⁰ See *id.*

⁹¹ A search engine is an Internet tool that looks for websites containing words or phrases specified by the computer user. See Mark Sableman, *Link Law: The Emerging Law of Internet Hyperlinks*, 4 COMM. L. & POL'Y 557, 576 (1999).

⁹² See Conlan, *supra* note 8, at 71.

⁹³ See Woodcock Statement, *supra* note 19. When FDA sends a warning letter to a foreign-based pharmacy, FDA also sends a copy to government of the country in which the pharmacy is located. *Id.*

⁹⁴ See Stephen Barlas, *FDA Threatens to Turn Up Heat on Internet Pharmacies*, 21 DRUG STORE NEWS, Aug. 30, 1999, at CP3.

⁹⁵ See *id.* In one instance, a foreign site was selling an abortion kit that contained several dangerous drugs. FDA contacted the foreign drug company's U.S. Internet service provider and as a result, the advertisements were removed voluntarily. *Id.*

drugs' risks and benefits.⁹⁶ Finally, FDA plans to focus its enforcement activities on the areas of unapproved new drugs, health fraud, and prescription drugs sold without a valid prescription.⁹⁷ Of particular concern is the sale of illegal and non-FDA approved products.⁹⁸

2. *The Regulatory Stance of the AMA Regarding Internet Pharmacies*

The AMA is not opposed to Internet pharmacies, although it has voted to develop model state legislation to limit Internet prescribing.⁹⁹ The AMA believes that prior to writing a prescription a physician must:

1) have access to the patient's medical history; 2) discuss treatment alternatives with the patient and determine the best course of treatment; 3) educate the patient about the benefits and risks of the medication; 4) under most circumstances perform an examination; and, 5) where necessary, provide additional treatment interventions and follow-up visits, especially when the medication may have serious side effects.¹⁰⁰

The AMA recognizes that the Internet can be used for legitimate electronic prescribing purposes.¹⁰¹ For example, after a physician takes an adequate history and performs a physical examination, he might enter a prescription order into a computer and transmit the encrypted prescription to the patient's pharmacy.¹⁰² A second example of Internet prescribing that the AMA considers legitimate is where the patient or the physician uses an Internet pharmacy to order medication refills.¹⁰³

A final example of legitimate prescribing is an electronic consultation between a physician and a patient that results in a prescription order.¹⁰⁴ According to the AMA, there can be a "legitimate clinical decision" even in a situation where the physician does not see the patient at the time a new prescription is ordered.¹⁰⁵ However, the "key here is that the physician and patient have an ongoing relationship, the patient routinely uses this physician, and history and physical examination are already in the medical record."¹⁰⁶ Thus, prescribing medications without an in-person consultation should occur only when the patient already is under the physician's care, the physician has the patient's medical history and physical examination information in the patient's medical record, and the patient recently has visited that physician.¹⁰⁷

3. *The Regulatory Stance of the NABP Regarding Internet Pharmacies*

The National Association of Boards of Pharmacy (NABP) assists state licensing boards in "developing, implementing, and enforcing uniform standards to protect the

⁹⁶ See *id.*

⁹⁷ See Woodcock Statement, *supra* note 19.

⁹⁸ See *Internet-based Pharmacies Raising Regulatory Questions*, MED. INDUSTRY TODAY, Apr. 7, 1999, available in LEXIS, News Library, MEDTDY File.

⁹⁹ See Abromowitz Statement, *supra* note 62.

¹⁰⁰ See *id.* The AMA does establish standards for the practice of medicine, however, it does not have the authority to sanction or discipline physicians. Individual state boards of medicine regulate the practice of medicine and have disciplinary authority. See AMA BOT REPORT, *supra* note 58, at 5.

¹⁰¹ See Abromowitz Statement, *supra* note 62.

¹⁰² See *id.*; See also AMA BOT REPORT, *supra* note 58, at 4. This process could reduce prescription errors caused by illegible handwriting.

¹⁰³ See Abromowitz Statement, *supra* note 62.

¹⁰⁴ See *id.*

¹⁰⁵ See *id.*

¹⁰⁶ See AMA BOT REPORT, *supra* note 58, at 4.

¹⁰⁷ See Abromowitz Statement, *supra* note 62.

Public Health."¹⁰⁸ The NABP considers the use of online medical consultation questionnaires without a legitimate physician-patient relationship to be illegal.¹⁰⁹ The NABP further believes that no new laws are needed to regulate online pharmacies,¹¹⁰ and emphasizes the necessity of cooperation between state pharmacy and medical boards.¹¹¹

In 1999, the NABP established its Verified Internet Pharmacy Practice Sites (VIPPS) program. The VIPPS program and website are designed to assist the public in identifying properly licensed Internet pharmacies that have agreed to comply with federal and state laws and regulations governing pharmacy practice.¹¹² The NABP does not regulate Internet pharmacies, rather VIPPS is a voluntary program for which Internet pharmacies may apply.¹¹³ To become certified, pharmacies "must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals,"¹¹⁴ and if there is a conflict between individual state laws the pharmacy must agree to comply with the more stringent law or regulation.¹¹⁵ Furthermore, VIPPS-certified pharmacies must respect a patient's right to privacy, authenticate and secure prescription orders, adhere to a recognized quality assurance policy, and provide "meaningful consultation between patients and pharmacists."¹¹⁶

In addition to its efforts with VIPPS, the NABP organized a summit in November 1999, comprised of several Internet pharmacies, government officials, consumer advocates, and medical groups, to discuss the future of Internet pharmacies.¹¹⁷ Participants supported the formation of an industry-wide coalition (Operation Safe Net)¹¹⁸ that would develop "rational legislative and enforcement initiatives" and create both a consumer education program and a vehicle to report violative Internet pharmacies.¹¹⁹

4. *The Regulatory Stance of FTC Regarding Internet Pharmacies*

The Federal Trade Commission (FTC) takes action¹²⁰ if a website advertisement makes false or misleading claims about the safety or efficacy of the offered medica-

¹⁰⁸ See *VIPPS* (last visited Aug. 3, 1999) <www.nabp.net/vipps/intro.asp>.

¹⁰⁹ See Stolberg, *supra* note 57, at 1.

¹¹⁰ See Richard Monks, *Congress Looks Into Internet Rx*, CHAIN DRUG REV., Aug. 16, 1999, at 1, available in LEXIS, News Library, CHNDRG File. Many legitimate Internet pharmacies prefer self-regulation to new legislation and urge that no new laws are needed to combat rogue Internet pharmacies. See Conlan, *supra* note 8, at 71.

¹¹¹ See *VIPPS Most Frequently Asked Questions* (last visited Aug. 3, 1999) <www.nabp.net/vipps/faq.asp> (website no longer valid, information is on file with author). See also Ukens, *supra* note 1, at 63.

¹¹² See *VIPPS Disclaimer* (last visited Aug. 3, 1999) <www.nabp.net/vipps/vippsDisclaimer.asp>. See also Cardinale, *supra* note 20, at 10.

¹¹³ See *VIPPS FAQ*, *supra* note 111. The fee schedule is divided into two groups. See *VIPPS Program Fee Calculations* (last modified Aug. 3, 1999) <www.nabp.net/vipps/appinfo/fees.asp> (website no longer valid, information is on file with author).

¹¹⁴ See *VIPPS*, *supra* note 108.

¹¹⁵ See *VIPPS Criteria* (last modified Sep. 13, 1999) <www.nabp.net/vipps/criteria.asp> (website no longer valid, information is on file with author).

¹¹⁶ See *VIPPS*, *supra* note 108. Some additional VIPPS criteria include steps to prevent an individual from submitting the same prescription to more than one pharmacy, establishment of a process to verify the identity of the patient, prescriber, and, if necessary, caregiver, and compliance with standards established by U.S. Pharmacopeia for the storage and shipment of medications to patients. See *VIPPS Criteria*, *supra* note 115.

¹¹⁷ See *Internet Pharmacies Addressed at Summit*, DRUG STORE NEWS, Nov. 29, 1999, at 4, available in LEXIS, News Library, DRGSTR File.

¹¹⁸ See Carol Ukens, *New Coalition Set to Monitor Internet Pharmacy Practices*, DRUG TOPICS, Dec. 6, 1999, at 116, available in LEXIS, News Library, DRGTP File.

¹¹⁹ See *Internet Pharmacies Addressed at Summit*, *supra* note 117, at 4.

¹²⁰ If FTC finds a site to be in violation of the law, it can enter into a consent order with the pharmacy, in an effort to obtain voluntary compliance. By signing a consent order, the pharmacy is not admitting they violated the law, but it must cease performing the practices detailed in the complaint. If a consent agreement is unobtainable, the FTC can issue an administrative complaint, which is heard before an administrative law judge. The judge can then issue a cease and desist order against the pharmacy. See *How the FTC Brings an Action* (last visited June 17, 1999) <www.ftc.gov/ftc/action.htm>.

tion.¹²¹ FTC also can take action if the Internet pharmacy misrepresents its privacy practices or gives false statements about the site's collection and use of consumer medical information.¹²² FTC believes that judgments about the practice of medicine and what constitutes appropriate practices by an Internet pharmacy are best left to the state licensing authorities.¹²³

FTC monitors the practices of Internet pharmacies, makes referrals to state and federal authorities, and assists those authorities in their enforcement efforts.¹²⁴ Finally, it launched Operation Cure-All, a "comprehensive consumer education and enforcement initiative to combat health fraud on the Internet."¹²⁵ FTC has reached settlements against a few Internet sites for deceptive or unsubstantiated health claims.¹²⁶

5. *The Regulatory Stance of WHO Regarding Internet Pharmacies*

The World Health Organization (WHO)¹²⁷ recognizes the potential benefits and problems of Internet prescribing practices.¹²⁸ In 1997, the World Health Assembly (WHA)¹²⁹ urged the international community to work cooperatively to control the online promotion, advertising, and sale of unauthorized medicines that could lead to public health risks.¹³⁰ During a May 1998 meeting, WHA urged member states¹³¹ "to review existing legislation, regulations, and guidelines to ensure that they are applicable and adequate to cover questions of advertising, promotion, and sale of medical products using the Internet and to develop, evaluate, and implement strategies for monitoring, surveillance and enforcement."¹³²

Finally, WHA requested that the Director-General of the WHO encourage member states to monitor and survey such cross-border activity and report problem incidents to WHO.¹³³ WHA also requested the Director-General to develop a guide to educate Internet

¹²¹ See Bernstein Statement, *supra* note 85. FTC derives its authority from section 5 of the Federal Trade Commission Act. *Id.* See also 15 U.S.C. § 45 (a).

¹²² See Bernstein Statement, *supra* note 85. FTC has "engaged in extensive monitoring of the privacy practices of websites, has conducted workshops on the issue, [and] prepared reports to Congress on the self-regulatory efforts of industry on this topic . . ." *Id.*

¹²³ See *id.*

¹²⁴ See *id.* The FTC's computer equipment enables FTC staff to locate and preserve websites for evidentiary purposes. *Id.*

¹²⁵ See *id.*; see also Cardinale, *supra* note 20, at 10.

¹²⁶ See Cardinale, *supra* note 20, at 10.

¹²⁷ WHO is defined as the "directing and coordinating authority on international health work." See *About WHO: Objectives and Functions*, (last visited Feb. 1, 2000) <www.who.org/aboutwho/en/objectiv.htm>. The WHO's responsibilities include: 1) proposing international conventions and agreements on health matters; 2) developing international standards for pharmaceutical products; and 3) assisting in the development of an informed public opinion regarding health matters. *Id.*

¹²⁸ See World Health Assembly, *Cross-Border Advertising, Promotion and Sale of Medical Products Using the Internet*, WHA51.9, May 16, 1998, at 1 <www.who.int/wha-1998/pdf98/ear9.pdf> (website no longer valid, information is on file with author).

¹²⁹ WHA is the supreme decision-making body of the WHO. See *Structure of WHO* (last visited Feb. 2, 2000) <www.who.org/aboutwho/en/structure.htm>.

¹³⁰ See Alexandra Marks, *Snake Oil for Sale on Web; Pharmaceutical "Wild West" Worries Officials*, CHI. SUN TIMES, May 20, 1997, at 29.

¹³¹ A list of current member states can be found at *WHO Member States* (last visited Feb. 1, 2000) <www.who.org/aboutwho/en/member.htm/>.

¹³² See *Cross-Border Advertising*, *supra* note 128, at 2. Further, WHA appealed to industry, health professional, and consumer organizations "to monitor and report problem cases and aspects of cross-border advertising, promotion, and sale of medical products using the internet," and "to maintain legal and ethical standards in the cross-border advertising, promotion, and sale of medical products using the Internet." *Id.*

¹³³ See *id.*

users in obtaining "reliable, independent and compatible" medical products information.¹³⁴ That request resulted in the WHO guide, *Medical Products and the Internet: A Guide to Finding Reliable Information*.¹³⁵

B. Current Statutory, Caselaw, and Pending Legislative Action

The U.S. legislative and judicial systems are making serious attempts to control the problems set forth by rogue Internet pharmacies.¹³⁶ These endeavors occur on both a state and federal level.

1. Federal Attempts to Regulate Internet Pharmacies

In late July 1999, the House of Representatives Commerce Committee's Oversight and Investigations Subcommittee initiated hearings regarding the practices of Internet pharmacies and heard testimony regarding both the legitimate and illegitimate use of the Internet to prescribe and sell medications.¹³⁷ The House Commerce Committee also commissioned the General Accounting Office (GAO) to conduct a study on the scope of the Internet prescription drug trade.¹³⁸

One federal attempt to regulate Internet pharmacies was Representative Ron Klink's (D-PA) introduction of the Internet Pharmacy Consumer Protection Act in August 1999.¹³⁹ The Act requires Internet pharmacies to post certain kinds of information, such as the address for the physical location of the pharmacy dispensing the drug and the pharmacy's licensing state or states.¹⁴⁰ Critics argue that this bill simply repeats the NABP's VIPPS program requirements, and that the proposal will not remedy the problem of rogue pharmacies or foreign-based Internet pharmacies.¹⁴¹

President Clinton also jumped into the battle. In December 1999, he proposed a new initiative that would "establish new Federal requirements for all Internet pharmacies to ensure that they comply with state and Federal laws [and] create new civil penalties for the illegal sale of pharmaceuticals."¹⁴² Additionally, the government would launch a new

¹³⁴ See *id.*

¹³⁵ See WHO *Guide*, *supra* note 49.

¹³⁶ Other countries are also beginning to take an active role. Europe has been considering the issue of Internet drug sales for some time now, and the European Commission (EC) admits that the European Union has limited power to ban these sales. See N.J. Greenaway, *Internet and European Drug Regulation*, 353 LANCET 330, 330 (1999). Recently, Thai police and drug officials, following a tip from Internet surfers, raided a pharmacy and confiscated a large quantity of tranquilizers and psychotropic drugs. See *Net Surfers' Tip-Off Yields Drugs Haul*, NATION, Nov. 27, 1999. The drugs, which were smuggled in from Switzerland and offered to consumers via the pharmacy's website, were packed for shipment to e-commerce consumers in Europe, the United States, and Canada. *Id.* Finally, the New Zealand Medical Association has condemned the practices of an Australian-based website that offers RU486, also known as the "morning-after" pill, free to any person wanting to take part in a "worldwide scientific trial." See *Internet Pill A Big Hazard Say Doctors*, DOMINION, Dec. 30, 1999, at 3, available in LEXIS, News Library, DOMIN File.

¹³⁷ See Monks, *supra* note 110, at 1.

¹³⁸ See *Internet-based Pharmacies Raising Regulatory Questions*, *supra* note 98; see also *Confidentiality and the Virtual Pharmacy*, *supra* note 69. The GAO also was asked to evaluate the adequacy of the NABP's VIPPS program as a self-regulatory device. See Ukens, *supra* note 1, at 63.

¹³⁹ See H.R. 2763, 106th Cong., 1st Sess. (1999).

¹⁴⁰ See Barlas, *supra* note 94, at CP3; see also 145 CONG. REC. E1754 (Aug. 5, 1999) (statement of Representative Henry Waxman (D-CA)).

¹⁴¹ See Barlas, *supra* note 94, at CP3.

¹⁴² See White House Press Release, *supra* note 39. FDA claims that the initiative will not preempt state law and that FDA will "continue to defer to states to regulate the practice of medicine and pharmacy." See FDA, *Online Pharmacies FAQs* (Jan. 28, 2000) (last visited Oct. 22, 2000) <www.fda.gov/oc/buyonline/faqs/html>. The proposal includes civil money penalties of \$500,000 per violation if a

public education campaign emphasizing the potential dangers of purchasing prescription medications over the Internet.¹⁴³ The President designated 10 million dollars in the Fiscal Year 2001 budget to fund these activities.¹⁴⁴

2. State Attempts to Regulate Internet Pharmacies

Individual states do have prosecutorial avenues, however, one noted difficulty is that few state pharmacy regulatory statutes have been updated to include reference to the Internet.¹⁴⁵ Several states have launched formal investigations of Internet websites selling prescription drugs.¹⁴⁶ For example, the Ohio Attorney General has filed cease-and-desist orders against several Internet pharmacy sites.¹⁴⁷

Furthermore, in November 1999, the Missouri Attorney General obtained a permanent injunction against an online clinic and other defendants who were using the Internet to sell prescription drugs.¹⁴⁸ Missouri alleged that the individuals, who were fined a total of \$15,000 in civil penalties, violated state law by providing prescription drugs to Missouri consumers without a license and on the basis of information provided in online consultations.¹⁴⁹ Missouri also obtained an injunction against and fined a Texas-based Internet pharmacy¹⁵⁰ and its owner \$15,000 for the same reasons.¹⁵¹

Kansas also is taking legal action against certain Internet pharmacies.¹⁵² The Kansas Attorney General, the Kansas State Board of Healing Arts, and the Kansas Board of Pharmacy joined together to file consumer protection lawsuits and restraining orders against seven companies selling prescription-only drugs over the Internet to Kansas consumers.¹⁵³

In October 1999, the Illinois Attorney General and the Illinois Department of Professional Regulations filed four lawsuits against out-of-state doctors, pharmacies, and Internet-based companies.¹⁵⁴ Illinois alleges that the doctors and pharmacies were not

prescription drug is sold to a consumer without a valid prescription. *Id.* President Clinton's proposal requires that Internet pharmacies demonstrate their compliance with federal and state laws to FDA in order to receive approval to operate. *Id.* If the pharmacy operates without prior FDA approval the site will be subject to sanctions. *Id.* Finally, under this proposal FDA would have administrative subpoena authority when investigating potentially illegal Internet medication sales, which is expected to streamline the investigative process. *Id.* Previously, FDA has had to rely on the issuance of grand jury subpoenas in order to obtain records necessary for investigating suspect Websites. *Id.*

¹⁴³ See *Online Pharmacies FAQs*, *supra* note 142.

¹⁴⁴ See *id.*

¹⁴⁵ See AMA BOT REPORT, *supra* note 58, at 2. Illinois and Ohio have updated their statutes. See *infra* notes 165, 166.

¹⁴⁶ See Casey, *supra* note 22.

¹⁴⁷ See NABP Standards for Online Rx Expected, *supra* note 89, at RX29.

¹⁴⁸ See Missouri Attorney General Press Release, *Nixon Obtains Order to Stop Illegal Internet Prescribing and Sale of Drugs by Second Online Clinic and Pharmacy*, (Nov. 29, 1999) (last visited Oct. 22, 2000) <www.ago.state.mo.us/112999.htm>.

¹⁴⁹ See *id.* The order provides for additional fines of up to \$5,000 for any violation of the injunction. *Id.*

¹⁵⁰ See Janet Gemignani, *Cyber-Pharmacies Zapped by State Regs*, BUS. & HEALTH, Dec. 1, 1999, at 12, available in LEXIS, News Library, BHLTH File.

¹⁵¹ See *Missouri v. Stallknecht*, No. 99-CV212429, (Mo. Dist. Ct. 1999). See also Gemignani, *supra* note 150.

¹⁵² See Michael F. Conlan, *Show Me State Moves to Bar Lone Start Online Pharmacy*, Aug. 16, 1999, DRUG TOPICS, at 74, available in LEXIS, News Library, DRGTP File.

¹⁵³ See Fred Charatan, *Kansas Sues Internet Medicine Suppliers*, BRIT. MED. J., June 26, 1999, at 1720.

¹⁵⁴ See Douglas Holt, *State Sues Out-of-State Internet Drug Dispensers*, CHI. TRIB., Oct. 22, 1999, at 1. State investigators established a sting operation and searched the Web for Viagra, Celebrex, and Proscar. *Id.* The cases seek to prohibit the companies from shipping medications to Illinois and includes fines starting at \$50,000 per transaction. *Id.*

licensed to operate in Illinois and that the websites failed to disclose that the sites were not licensed to serve Illinois consumers.¹⁵⁵ The Department of Professional Regulations also issued a cease-and-desist order against the same Texas-based Internet pharmacy that Missouri sued.¹⁵⁶

Finally, the state of Michigan has also joined the battle against illegal Internet prescribing practices. In December 1999, the Michigan Attorney General filed Notices of Intended Action against ten Internet pharmacies.¹⁵⁷ Michigan alleges violation of the Michigan Consumer Protection Act because the pharmacies sent prescription-only drugs to Michigan consumers without a proper prescription or physician supervision.¹⁵⁸

V. INTERNET PHARMACIES: DEVISING AN EFFECTIVE REGULATORY PLAN

A. *A Response to the Federal Versus State Regulation Debate*

Controversy exists over whether the federal government should implement legislation regulating Internet pharmacies, or whether the task should be left entirely up to the individual states. Some critics of federal involvement argue that there currently is no need for federal regulation of Internet pharmacies because individual states are regulating the industry¹⁵⁹ and that federal "intrusion" could "hobble [e-commerce's] growth and development."¹⁶⁰ Furthermore, critics fear that such involvement would lead to federal regulation of the practice of medicine.¹⁶¹

On the other hand, proponents of federal involvement argue that the current state regulatory structure lacks the ability to counter challenges posed by Internet prescribing.¹⁶² Furthermore, federal involvement could result in effective and efficient regulation. For example, if each state individually attacks the same illegal Internet pharmacy, eradicating that pharmacy form could be a slow, painstaking process. Whereas, if the federal government prohibited an illegal Internet pharmacy from doing business, "that operation is out of business."¹⁶³

There need not be a single, exclusive answer to the question, "who should regulate Internet pharmacies?" In order to both protect consumers and maintain states' autonomy in regulating pharmacy and medicine, the best plan combines state regulation

¹⁵⁵ See *id.*

¹⁵⁶ See *id.* The Internet pharmacy was The Pill Box (last visited Oct. 22, 2000) <www.thepillbox.com>.

¹⁵⁷ See Michigan Attorney General Press Release (Dec. 15, 1999) <www.167.240.254.37/AGWebsite/press_release/pr10157.htm> (website no longer valid, information is on file with author).

¹⁵⁸ See *id.* Knowing and persistent violation of the Michigan Consumer Protection Act can result in fines of up to \$25,000 per violation. *Id.*

¹⁵⁹ See Fuller, *supra* note 20, at 18A. One argument against federal involvement is that "state-based regulation safely has served consumers with respect to community-pharmacy and multi-state mail-service operations." *Id.* See also *States Should Control Internet Drug Sales*, S.F. CHRON., Jan. 3, 2000, at A18. ("States should be given every opportunity to control drug sales within their jurisdictions before the federal government steps in.").

¹⁶⁰ See S.F. CHRON., *supra* note 159. See also *Controversy Ensues Over Online Drug Sales*, SEATTLE POST-INTELLIGENCER, Dec. 29, 1999, at C2, ("It is a mistake to rush to regulate this industry before we understand its full potential.")(quoting a spokesman for House of Representatives Commerce Committee Chairman Tom Bliley (R-VA)).

¹⁶¹ See Postrel, *supra* note 39 ("The Internet partially restores patients' rights to choose how they buy their medications and from whom. No wonder the drug censors are so upset.").

¹⁶² See *Risks Demand Greater Oversight*, USA TODAY, Jan. 3, 2000, at 18A ("This is a national problem, and it deserves a federal solution."). Some state medical boards and state pharmacy boards express concern that their existing enforcement tools are not adequate to police Internet prescribing and dispensing practices. See Bernstein Statement, *supra* note 85.

¹⁶³ See Henkel, *supra* note 31.

with a limited degree of federal regulation. Cooperation among state and federal regulators is essential in such a joint regulatory scheme. Already, steps have been taken to foster such a relationship. FDA has developed formal agreements with the NABP and the Federation of State Medical Boards that outline the respective roles of each of these groups.¹⁶⁴

B. Model Legislation for State Regulation of Internet Pharmacies

Following is a draft of model legislation that a state should use to strengthen its regulatory position regarding Internet pharmacies. Each section of the legislation is accompanied by an explanation of the section's intent and key points.

A MODEL ACT FOR THE REGULATION OF INTERNET PHARMACIES

1. All persons selling or offering to sell drugs, medicines, or other pharmaceutical services, at retail or wholesale cost in the State, including pharmacies providing services via the Internet, must be licensed or registered as a drug distributor with the State Board of Pharmacy.¹⁶⁵

a) The State Board of Pharmacy shall require and provide for an annual non-resident special pharmacy registration for all pharmacies located outside of the State that dispense medications for State residents and mail, ship, or deliver prescription medications into the State.¹⁶⁶

Section one clearly establishes licensing and registration requirements for Internet pharmacies. Arguably, meeting such a requirement could be a major task for pharmacies servicing a large number of states. Current technological advances, however, can streamline the application process.¹⁶⁷ For example, the NABP is initiating a multistate, Internet-based licensure and renewal system that allows pharmacies and pharmacists to submit their initial license application and renewal through the Internet.¹⁶⁸

2. Nonresident special pharmacy registration shall be granted by the Board upon disclosure and certification by the pharmacy:

a) that it is licensed in the state in which the dispensing facility is located and from which the drugs are dispensed;¹⁶⁹

b) of the location, names, and titles, and proof of licensure where applicable, of all principal corporate officers and all pharmacists dispensing drugs to residents of the State;¹⁷⁰

¹⁶⁴ See *Online Pharmacies FAQs*, *supra* note 142.

¹⁶⁵ Support for this requirement can be found in retail and wholesale sales of dangerous drugs online, OHIO ADMIN. CODE § 4729-9-24 (1999).

¹⁶⁶ Support for this requirement can be found in the Pharmacy Practice Act of 1987, 225 ILL. COMP. STAT. 85/16a (West 1999).

¹⁶⁷ See News Releases, *NABP to Initiate Multi-state, Internet-based Licensure and Renewal System* (Dec. 22, 1999) <www.nabp.net/whatsnew/pressreleases/webPR.asp?idValue=50> (website no longer valid, information is on file with author).

¹⁶⁸ See *id.*

¹⁶⁹ See Pharmacy Practice Act, *supra* note 166.

¹⁷⁰ See *id.*

c) that it is in good standing and complies with all lawful directions and requests for information from the Board of Pharmacy of each state in which it is licensed or registered. The pharmacy shall respond directly to all communications from the Board concerning emergency circumstances arising from dispensing of drugs to residents of the State;¹⁷¹

d) that it maintains its records of drugs dispensed to residents of this State so that the records are readily retrievable from the records of other drugs dispensed, in the event that a complaint should arise;¹⁷²

e) that it cooperates with the Board in providing information to the board of pharmacy of the state in which it is licensed concerning matters related to the dispensing of drugs to residents of this State;¹⁷³

f) that during its regular hours of operation, but not less than six days per week, for a minimum of forty hours per week, a toll-free telephone service is provided to facilitate communication between patients in this State and a pharmacist at the pharmacy who has access to the patients' prescription records.¹⁷⁴ The toll-free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this State.¹⁷⁵ And,

g) that the site provides for the security and confidentiality of the medical and payment information transmitted to and from, and stored by, the pharmacy.¹⁷⁶

Section two sets forth requirements that Internet pharmacies must meet in order to be registered and dispense pharmaceuticals to consumers within the state. One key requirement is that the pharmacy maintain its records in such a manner that records of drugs sent to the state are easily retrievable from other states' records. Such organization is necessary should a complaint arise or if the state should choose to investigate allegations of illegal dispensing practices.

3. All pharmacies registered or licensed with the State Board of Pharmacy and who sell or offer to sell drugs at retail or wholesale cost on the Internet to persons located within the State or any other state must make such sales only in compliance with all State and federal laws governing the legal distribution of drugs.¹⁷⁷ Failure to comply may result in revocation of the state license or registration.

Section three emphasizes the requirement that Internet pharmacies are subject to and must operate in compliance with all applicable federal and state laws.

4. Pharmacies registered or licensed with the State Board of Pharmacy and who sell or offer to sell drugs at retail or wholesale cost on the Internet to persons located within the State or any other state are strictly prohibited from providing such drugs

¹⁷¹ See Pharmacy Practice Act, *supra* note 166.

¹⁷² See Virginia Study Report, *supra* note 78, at 7. See also Pharmacy Practice Act, *supra* note 166.

¹⁷³ See *id.*

¹⁷⁴ See *id.*

¹⁷⁵ See *id.* See also Virginia Study Report, *supra* note 78, at 7.

¹⁷⁶ See OHIO ADMIN. CODE § 4729-9-24, *supra* note 165.

¹⁷⁷ See *id.*

on the basis of a prescription generated from the utilization of an online questionnaire physician consultation. Furthermore, all pharmacies included in this section are prohibited from affiliating the site with or relating the site, in any way, to any other site, business, or physician that provides prescriptions for medications on the basis of an online medical consultation questionnaire.¹⁷⁸

Section four prohibits dispensing a prescription promulgated from the use of an online questionnaire medical consult. This restriction is in accordance with the belief that a face-to-face consultation (or teleconference consultation, in certain circumstances), complete with history and physical exam, are a necessary and integral part of the physician-patient relationship. Prescriptions should only be dispensed when such a relationship exists.

This section restricts the Internet pharmacy from associating itself in any way with an Internet site or business that provides prescriptions to patients on the basis of an online medical consult questionnaire. "Associating itself" should not be interpreted only in terms of a business relationship, as providing a hyperlink¹⁷⁹ to or advertisement for such an Internet site would qualify as an association.

5. Internet sites owned and/or maintained by State registered or licensed drug distributors must clearly and prominently display the following information on the Internet site:

a) the name under which drug distributor is licensed or registered to do business in State, and the full address and telephone number of licensed or registered site;¹⁸⁰

b) the name of a responsible person as it appears on the drug distributor license or registration and the telephone number where responsible person may be contacted;¹⁸¹

c) the pharmacy's toll-free telephone number and notice of hours of operation;

d) a list of the states in which the drug distributor may legally sell prescription drugs at wholesale or retail,¹⁸² and a list of the states in which the drug distributor may not legally sell prescription drugs at wholesale or retail;

e) the name of each pharmacist dispensing the drugs;

f) the name, business address, phone number, and principal officers or owners of the online business offering prescription drugs, if different from the pharmacy or physician;¹⁸³

g) a privacy statement that assures the validity, accuracy, and security of electronically transmitted prescription orders. Furthermore, the pharmacy must

¹⁷⁸ See Abromowitz Statement, *supra* note 62.

¹⁷⁹ A hyperlink permits a viewer to jump from one webpage to another. Clicking on the link activates software code written in the language of the Web, which instructs the viewer's Web browser software to go to the linked location. See Sableman, *supra* note 91, at 559.

¹⁸⁰ See OHIO ADMIN. CODE § 4729-9-24, *supra* note 165.

¹⁸¹ See *id.*

¹⁸² See Bernstein Statement, *supra* note 85. See also OHIO ADMIN. CODE § 4729-9-24, *supra* note 165.

¹⁸³ See Bernstein Statement, *supra* note 85.

assure the security of personal information stored in and transferred between computers. This portion of the Internet site must also provide information regarding how the personal information will be used and ensure that such information is not used for purposes not disclosed without the written, informed consent of the patient or person submitting personal information;¹⁸⁴

h) the name, address, and contact information of the drug law enforcement agency in each state in which the person is authorized to do business.¹⁸⁵ This may include a link to the drug law enforcement agency's Internet site and/or their e-mail address;¹⁸⁶ and

i) the last date the information displayed on the site was updated.¹⁸⁷ Furthermore, this information must be updated on a monthly basis.

Section five requires that specific information be displayed on the Internet pharmacy website. Display of the pharmacy's address will alert consumers to the fact that they are doing business with an out-of-state company and a listing of serviceable and non-serviceable states will easily allow the patient to determine whether they can utilize the pharmacy for prescription purposes.

Additionally, prominent display of the privacy statement assists the patient in determining the degree of confidentiality involved. Pharmacies must inform the patient if the personal information transmitted to the pharmacy will be utilized for a purpose other than prescription fulfillment. Finally, displaying the last date the information was updated and requiring the Internet pharmacy to update the site on a monthly basis enables consumers to better gauge the reliability of the posted information.

C. Combating Foreign-Based Pharmacies

Cooperation with foreign countries and regulatory agencies is of key importance in regulating international Internet pharmacies.¹⁸⁸ Recently, FDA sent electronic warning letters to 12 foreign-based websites selling prescription drugs to United States' citizens.¹⁸⁹ Additional copies of the letters were sent to the website operators, the United States Customs Service, and to the regulatory officials in the countries where the operators are based.¹⁹⁰ The website operators were further warned that future shipments to the United States could be detained or denied entry.¹⁹¹

In addition to efforts by FDA and its regulatory counterparts in foreign countries, industry self-policing by legitimate Internet pharmacies and cooperation with foreign authorities will help combat some rogue pharmacies.¹⁹² Furthermore, encouragement

¹⁸⁴ Support for the privacy requirements can be found in the statements of scope of proposed rules of the Wisconsin Administrative Pharmacy Code, 503 WIS. ADMIN. REG. 13 (1997). See also OHIO ADMIN. CODE § 4729-9-24, *supra* note 165.

¹⁸⁵ See OHIO ADMIN. CODE § 4729-9-24, *supra* note 165.

¹⁸⁶ See *id.*

¹⁸⁷ Support for this requirement can be found in the WHO *Guide*, *supra* note 49.

¹⁸⁸ See *VIPPS FAQ*, *supra* note 111.

¹⁸⁹ See *FDA Warns Foreign Online Drug Sites That Sales to United States May Be Illegal*, 68 U.S.L.W. 2473 (2000).

¹⁹⁰ See *id.*

¹⁹¹ See *id.* FDA also maintains a list of international websites that are prohibited from shipping prescription medications to the United States. See *U.S. Food and Drug Administration Import Detention Reports for OASIS* (last visited Apr. 1, 2000) <www.fda.gov/ora/oasis/ora_oasis_det.html>.

¹⁹² See Korenchuk, *supra* note 3, at B11.

from bodies such as WHO to its member countries also will help. Unfortunately, the degree and methods of regulation enacted by countries other than the United States vary greatly. This fact, combined with the lack of FDA authority over foreign-based sites, makes it especially difficult to defeat the dangers posed by international pharmacies. Thus, the problems presented by these foreign-based Internet pharmacies are likely to persist to some degree.

VI. CONCLUSION

The Internet has revolutionized the way in which ordinary people conduct their everyday business. People can bank, pay bills, manage investments, order various products, and obtain information on an infinite number of topics online. It is not surprising that such an innovation would provide a vehicle for the layperson to educate himself and guide the direction of their health. Nor is it surprising that the healthcare industry would seize this opportunity to modernize a commonplace function—prescription dispensation.

Lawful Internet pharmacies benefit a consumer's healthcare experience in many ways. These pharmacies provide convenience and efficiency—two advantages coveted by people living busy lives. Consumers can take a few minutes out of their lunch break to place an order, or they can even order the prescriptions at 3 A.M., long after many conventional pharmacies have closed. Internet pharmacies can offer a degree of privacy not found at the local pharmacy, and patients can obtain prescriptions and ask questions away from the prying eyes and listening ears of neighbors, coworkers, and other parties. Finally, Internet pharmacies assist homebound patients and those living far from a traditional pharmacy.

Internet pharmacies that perform illegal dispensing practices, however, assert a wrath of potential dangers to a consumer's health. Pharmacies that provide prescription medication without a valid prescription or provide a prescription on the basis of an online questionnaire enable consumers to bypass a very important safeguard—a face-to-face consultation with a licensed physician. If a patient is not examined by a physician and bypasses contact with a legitimate pharmacy, he misses an important chance to be diagnosed correctly, to uncover contraindications to prescription use and possible drug interactions, and to learn about side effects.

Furthermore, there is no guarantee that a physician actually reviews the online questionnaires before providing the prescription. Even if a physician reviews the questionnaires, the patient usually lacks any knowledge regarding the professional background of the prescribing physician. The physician could be prescribing a medication far beyond the realm of his specialty.

A final danger raised by unlawful Internet pharmacies is that the pharmacy might dispense a drug manufactured by an underground company or a company outside the United States with questionable quality control standards. If drugs are manufactured, packaged, transported, or stored under substandard conditions, the drugs could contain dangerous, impure, or unknown ingredients.

It is clear that patients must be protected from such dangerous dispensing practices. Regulation, however, should not only eliminate unlawful Internet pharmacies, it should also enable the growth of a valuable addition to both the healthcare industry and e-commerce—the lawful Internet pharmacy. Such a goal is attainable only if the federal government and states jointly regulate the industry. The encompassing nature of federal regulations allows efficient protection against rogue Internet pharmacies. This efficiency,

combined with the years of experience and expertise the states have garnered in regulating the practices of pharmacy and medicine, should pose a powerful regulatory tool.

Unfortunately, this regulatory tool does not reach beyond the borders of the United States. Combating the unlawful activities of foreign-based Internet pharmacies requires worldwide cooperation among individual countries. Each country mandates and enforces its own set of medicine and pharmacy regulations. Thus, the goal of worldwide agreement on regulations is likely unattainable.

Although worldwide agreement on the regulation of Internet pharmacies is currently an impractical goal, other efforts significantly can diminish the dangers posed by unlawful pharmacies. Groups such as WHO can encourage their member countries to strictly enforce their existing regulations and advocate for the creation of safe dispensing practices for Internet pharmacies. Additionally, the United States, by establishing and enforcing an effective regulatory plan, can serve as a model for other countries. These efforts, combined with a consumer education campaign emphasizing the potential dangers of ordering prescription medication from foreign-based Internet pharmacies, will help curb the deleterious effects of such pharmacies.

