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Internet Prescribing Limitations and Alternatives

*Kara M. Friedman**

I. INTRODUCTION

The personal computer and the Internet have drastically reformed the way people interact. The capabilities of the Internet as a communication medium are offering previously unimaginable resources for individuals and businesses. Of greatest significance in the context of this article, the Internet allows businesses to sell their supplies and services without face-to-face encounters with consumers.¹ While the Internet provides such groundbreaking advances, however, it also creates regulatory challenges as it facilitates numerous, legally-questionable activities which are aided by its near anonymity as a medium.² In the pre-World Wide Web era, such restricted activities were more readily subject to regulatory enforcement and were less capable of providing anonymity. Further, jurisdictional boundaries were more clearly defined. The Internet has affected these fundamental details.

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1. The use of telephones, facsimile machines and courier services can also facilitate sales without a face-to-face encounter. Each of these methods of communication, however, have certain encumbrances that do not accompany Internet communications.

2. These activities, when accomplished via the Internet, are sometimes referred to as "cybercrimes." Computer Crime and Intellectual Property Section of the Criminal Division of the U.S. Department of Justice, at <http://www.cybercrime.gov>. (last visited Feb. 23, 2001). Today, crimes such as credit card theft, securities fraud, child pornography, defamation, and corporate espionage and sabotage can be accomplished using a computer in the privacy of one's home with a mere click of a mouse. *Id.* Along with these other cybercrimes, Internet prescribing activities are also under scrutiny. Jones Multimedia Encyclopedia Update, *Cybercrime*, at <http://www.digitalcentry.com/encyclo/update/crime.htm> (last visited Feb. 23, 2001).

A multitude of Internet websites now facilitate the delivery of innovative health care services and products.³ In increasing numbers, participants in the market—patients, providers, researchers, insurers and regulators alike—are utilizing the Internet to access health care information, supplies, and services.⁴ Through the Internet, the disabled, the elderly, adolescents and patients living in remote areas can easily obtain information, products and services that were previously acquired with great difficulty. Given the highly regulated nature of health care, the delivery of health care information and services via the Internet raises special issues.

Prior to the Internet revolution, prescription drugs were not readily available to consumers absent the existence of a physician/patient relationship. Minimally, such a relationship traditionally involved a face-to-face encounter between the individual seeking treatment and a licensed health care professional. Using Internet technology, it is now possible for a consumer to procure prescription drugs without establishing a traditional physician/patient fiduciary relationship.⁵ An attrac-

3. There are numerous examples of the Internet's use as a health care services resource. For example, hospitals are integrating vast amounts of patient information on the Internet, enabling them to provide each patient's entire medical record in a centralized place online. Jennifer Steinhauer, *A Health Revolution in Baby Steps*, N.Y. TIMES, Oct. 25, 2000, at E1. Physicians are using hand-held computers to download disease and drug information for diagnosis and treatment, search medical literature, and read abstracts and full-length articles published in online journals instantaneously. Sandeep Jauhar, M.D., *Residents Discover a Handy Helpmate*, N.Y. TIMES, Oct. 25, 2000, at E13. Kaiser Permanente, a not-for-profit health maintenance organization, is offering its members 24-hour access to "Advice Nurse," an online service featuring answers to medical inquiries within 24 hours. Eric Nagourney, *If a Site is All About Your Health, Who Else Might Be Peeking?*, N.Y. TIMES, Oct. 25, 2000, at E16. Advice Nurse also allows members to research information about medical conditions, order prescriptions, and make doctor's appointments. *Id.*

4. Jodie Bernstein, Director of Bureau of Consumer Protection for the Federal Trade Commission, *Drug Stores on the Net: The Benefits and Risks of Online Pharmacies*, Address Before the House Subcommittee on Oversight and Investigations, Washington, D.C. (July 30, 1999). In 1998, 22.3 million adults in the United States sought health and medical information online. *Id.* Nearly 70% of them did so before personally consulting a physician. *Id.* This number is predicted to increase to 30 million by the year 2001. *Id.* Consumers are turning to the Internet not just for health information but also to purchase health care products. *Id.*

5. Notwithstanding the fact that a "traditional" physician/patient relationship may not be established by an Internet consultation, there is support in legal holdings that this fiduciary relationship may be established in certain circumstances in the absence of a face-to-face consultation. See, e.g., *McKinney v. Schlatter*, 118 Ohio. App. 3d 328 (1997). In *McKinney*, a patient was admitted to the emergency room and examined by the emergency room physician who telephoned a cardiologist on call at the time. *Id.* at 330. The cardiologist, without any personal examination of the patient,

tive feature of Internet “drug shopping” is the privacy factor inherent in Internet usage. A proliferation of websites vending “lifestyle drugs”⁶ such as Propecia, Zyban, Paxil, Xenical and Viagra indicates a strong demand for Internet drug sales. At an increasing rate, consumers are embracing the opportunity to buy these drugs in the privacy of their own homes.⁷

This article focuses on the existing legal limitations placed on a consumer’s ability to obtain drug prescriptions via the Internet and considers the policies that underlie those limitations. Specifically reviewed in Part II are state and federal regulatory efforts to proscribe the practice of ordering prescription drugs via the Internet absent an established physician/patient relationship between the individual seeking the drug and the health care professional prescribing the drug.⁸ As will be discussed, there is a current movement to condemn Internet prescribing practices. In light of regulators’ current objections to the sale of prescription drugs on the Internet and consumers’ apparent desire to obtain various classes of drugs outside of the traditional physi-

told the emergency room physician the patient’s problem was not cardiac. *Id.* at 330-31. The patient, who was released based on the opinion of the cardiologist, died soon thereafter. *Id.* The Ohio appellate court held that a physician/patient relationship can exist by implication even when the physician has never spoken to, met or consulted with the patient. *Id.* at 336. A physician/patient relationship exists, the court held, if the consulting physician “(1) participates in the diagnosis of the patient’s condition, (2) participates in or prescribes a course of treatment for the patient, and (3) owes a duty to the hospital, staff or patient for whose benefit he is on call.” *Id.* In *Hand v. Tavera*, a physician under a managed care contract refused to admit a patient to the hospital. *Hand v. Tavera*, 864 S.W.2d 678, 679 (Tex. Ct. App. 1993). The court held that a physician/patient relationship existed even though the two never met or spoke. *Id.* A physician/patient relationship existed because the physician was designated as the doctor acting for the insurance plan under which the patient was enlisted. *Id.* The contract between the insurance plan providers and the hospital at which the physician was employed obligated the hospital’s doctors to treat the plan’s enrollees as they would treat their other patients. *Id.*

6. The term “lifestyle drug” provides a distinction between drugs which are used to treat a medical condition or illness and drugs which are primarily designed to *enhance* a person’s health or well-being. Joseph Weber, et al., *The New Era of Lifestyle Drugs: Viagra and Other Blockbusters Are Transforming the \$300 Billion Industry*, Bus. Wk., May 11, 1998, at 92. While lifestyle drugs may often be used to treat serious medical conditions, their use has become widespread for less serious conditions which may not warrant drug therapy given the availability of effective alternative options, such as diet, exercise and other lifestyle adjustments. *Id.*

7. *An Approach to Identifying and Regulating the Internet Pharmacy: A White Paper*, (March 2000), at http://www.businesswire.com/cnn/cvs/cvs_white_paper.htm (last visited February 23, 2001). According to CVS.com, the Internet pharmacy market is expected to generate more than \$4 billion in retail revenues by 2001. *Id.* At that level, it would exceed Internet book sales, CD sales or the sales any other single product currently sold via the Internet. *Id.*

8. *Infra* Part II.

cian/physician relationship, Part III of this article briefly explores the efficacy of an alternative regulatory scheme for the oversight of drug sales.⁹ This alternative regulatory scheme involves the expansion of pharmacists' prescriptive authority by creating, in effect, a "third class" of drugs.

In concluding, the author suggests that regulators might be able to satisfy the policy objective of ensuring that a learned intermediary is involved in prescription drug therapies by establishing and expanding the prescriptive authority of licensed pharmacists. The current movement to limit Internet drug sales has some appropriate policy goals behind it. Given the increasing demand for medical interventions involving drug therapies, however, alternative means of drug prescribing should be explored to ensure that constituents health requirements are being met in a manner that addresses their needs.

II. REGULATORY INITIATIVES REGARDING INTERNET PHARMACIES

A. *Overview of Regulatory Considerations*

Under current state and federal law, many drugs may be prescribed and dispensed only by licensed health care professionals. This requirement is based on the principle that certain drugs have such significant inherent risks that they should be administered only under the supervision and recommendation of a licensed practitioner with the education and training necessary to oversee the administration of potentially harmful drug products. Moreover, prescription drugs may only be dispensed by a licensed professional who can help assure proper dosing and administration and can provide important information on the drug's use to patients.

As previously stated, the absence of a face-to-face interaction between the patient and the health care professional makes the Internet an attractive alternative to visiting a health care provider's office. Thus, a question the Internet drug transaction invokes is: what information does a health care professional require prior to ordering a patient's drug prescription?¹⁰ Federal law relies on state law for making this determination. If the standards of the state having jurisdiction in a particular matter

9. *Infra* Part III.

10. Another related issue beyond the scope of this article is: what counseling services does a patient require from the drug dispenser relating to the administration of a drug?

are not met, federal regulation provides a basis for an enforcement action separate and apart from state law remedies.

1. Distinction Between Dispensing and Prescribing Drugs

In reviewing the regulatory issues involved in Internet drug sales, a distinction should be made between Internet *dispensing* and Internet *prescribing*. Internet drug dispensing involves the delivery of a valid prescription by a patient's personal physician to a pharmacy operating a website and the pharmacy's delivery of the drug to the patient.¹¹ Internet drug prescribing, on the other hand, is the act of providing the patient with an order for a legend drug that would entitle the patient to receive the drug. At a minimum, most Internet drug transactions involve the dispensing element, but a portion of these sales also involve drug prescribing. Generally, provided pharmacy practice rules are followed, Internet drug dispensing is now an accepted practice. The Verified Internet Pharmacy Practice Site ("VIPPS") accreditation program, the regulatory scheme implemented and overseen by the National Association of Boards of Pharmacy ("NABP"), seems to be an adequate regulatory scheme for Internet *dispensing* activities.¹² By attaining VIPPS certification, Internet pharmacies ensure their customers that they are in compliance with state and federal Internet pharmacy laws.

Conversely, while the majority of state regulators agree that Internet *prescribing* activities should be restricted, there is no clear policy that can be followed on a national basis, and a good deal of variation in schemes designed to oversee Internet pre-

11. Under the Illinois Pharmacy Practice Act, the definition of "dispense" is: to interpret, verify computer entry of, select the prescribed product for, prepare and/or deliver a prescription medication to an ultimate consumer or to a person authorized to receive the prescription medication by or pursuant to the lawful order of a practitioner, including the compounding, packaging, and/or labeling necessary for delivery and any recommending, advising and counseling concerning the contents, therapeutic values, uses and any precautions, warnings and/or advice concerning consumption. Dispense does not mean the physical delivery to a patient or a patient's representative in a home or institution by a designee of a pharmacist or by common carrier or the physical delivery of a drug or medical device to a patient or patient's representative by a pharmacist's designee within a pharmacy or drugstore while the pharmacist is on duty and the pharmacy is open.

ILL. ADMIN. CODE tit. 68, § 1330.05.

12. A full description of the VIPPS program can be found at the VIPPS web site, at <www.nabp.net/vipps/intro.asp> (last visited Mar. 26, 2001).

scribing activities exists.¹³ An examination of state and federal regulation of Internet drug prescribing reveals considerable congruence between the different states' regulatory policies on this issue. Most state medical boards have either taken a position against Internet prescribing or are actively developing an enforcement policy. However, a few state medical boards, including boards in Alaska and Minnesota, have not actively pursued oversight of Internet drug prescribing.

Existing principles, embodied in professional licensure laws and regulations, provide a basis for determining how jurisdictions might address scenarios involving Internet prescribing. Some states, such as Illinois,¹⁴ monitor Internet pharmacies under the existing regulatory scheme. Other states have enacted or are considering enacting legislation or rules specifically designed for Internet pharmacy regulation.¹⁵ Due to the current dynamic nature and constant developments in this regulatory environment,¹⁶ a general survey of the area, rather than a comprehensive state-by-state analysis, is appropriate.

2. Regulators' Policy Considerations in Internet Prescribing

Although the development of telecommunications technology now makes it possible for physicians to prescribe medication via the Internet, such prescription writing may fall outside of pro-

13. Thus, this article focuses on the prescribing aspect of Internet drug sales. A summary overview of current Internet prescribing enforcement efforts is set forth below. The reader should note that many of the regulatory activities are quite recent; numerous bills are now pending and before legislative committees charged with policy development.

14. Illinois Pharmacy Practice Act, 225 ILL. COMP. STAT. 85/16a.

15. For example, see legislation introduced in New York, Virginia, Kansas and New Hampshire aimed at regulating out-of-state pharmacies. New York SB 7760 requires out-of-state pharmacies filling prescriptions electronically to register with the state. S. 7760, 1999 Leg., 223d Sess. (NY 1999). It also requires physicians and pharmacists associated with such pharmacies to be licensed in New York; and physicians cannot issue prescriptions without a consultation or examination. *Id.* Virginia HB 1437 allows for the issuance or filling of a controlled substance for medicinal or therapeutic purposes only to persons with whom a practitioner has a bona fide practitioner/patient relationship. H.R. 1437, 2000 Leg. (Va. 2000). Kansas SB 385 requires Internet pharmacy sites filling prescriptions for Kansas residents to be in compliance with federal laws and to be properly licensed with the Kansas Board of Pharmacy. S. 385, 78th Leg., 2000 Sess. (Kan. 1999). Practitioners dispensing, distributing, or delivering prescription-only drugs over the Internet must be in compliance with the regulations of the Kansas Board of Healing Arts. *Id.*

16. As late as April 27, 2001, the Drug Enforcement Agency ("DEA") issued significant formal regulatory guidance addressing Internet drug sales via publication in the Federal Register. See DEA Guidance on Dispensing and Purchasing Controlled Substances over the Internet, 66 Fed. Reg. 21,181 (April 27, 2001).

fessional standards of care. There may be situations, however, in which Internet prescribing is appropriate. For example, some drugs, notwithstanding their prescription classification, are not as dangerous as many other drugs that fall into the same class. Some proponents of the expansion of prescriptive authority to allied health professionals categorize these less harmful drugs as constituting a third class of drugs. If a drug is relatively safe, and the condition that it is designed to treat can be self-diagnosed, little interaction with a health care provider is necessary to reasonably determine the appropriate drug therapy.¹⁷ Additionally, assuming basic health information is provided, there are limited circumstances in which a patient may be eligible for a prescription refill without an office visit.

Despite the few exceptions where Internet prescribing poses no real health risk to consumers, regulators tend to view this practice as encompassing undue risks to health care consumers.¹⁸ These risks include potentially harmful side effects from inappropriately prescribed medications, dangerous drug interac-

17. Arguably, if a drug really meets this criteria, it may be eligible for reclassification to nonprescription or "over-the-counter" status. In certain instances, however, there may be societal barriers to such reclassification. For example, medical literature and recent Food and Drug Administration ("FDA") hearings indicate that Preven, a form of emergency contraception, may be eligible for reclassification. FDA Center for Drug Evaluation and Research, Transcript of Public Hearing on FDA Regulation of Over-the-Counter Drug Products, June 28 - 29, 2000. Nevertheless, there are political and economic barriers to the immediate reclassification of the drug. Additionally, the drug has unique access issues due to the need to administer it as quickly as possible following unprotected intercourse. Thus, if Internet prescribing of this drug does not pose the risks that generally concern regulators and the Internet facilitates access to the drug in a way other mediums do not, perhaps Internet prescribing of emergency contraception should be encouraged by regulatory policy.

18. See, e.g., FDA, *Buying Medical Products Online*, at <http://www.fda.gov/oc/buyonline/default.htm> (last visited Feb. 23, 2001). Here, the FDA posts the following warning:

The FDA is concerned that the selection of prescription drug products or treatment regimens for a particular patient should be made with the advice of a licensed health care practitioner familiar with the patient's current health status and past medical history. In situations where a customary physician-patient relationship does not exist, the patient may be essentially practicing self-diagnosis. Consequently, the risk of negative outcomes such as harmful drug interactions, contraindications, allergic reactions or improper dosing is greatly magnified.

Id.; see also Katrina Armstrong, M.D., J. Sanford Schwartz, M.D., David A. Asch, M.D., *Direct Sale of Sildenafil (Viagra) to Consumers over the Internet*, 341 NEW ENG. J. MED. 1380, Oct. 28, 1999, available at <http://www.nejm.org/content/1999/0341/0018/1389.asp> (last visited on Feb. 23, 2001). The authors note that the availability of prescription medicines over the Internet may increase the inappropriate use of medications and the risk of adverse events by limiting physicians' ability to identify contraindications, patients' ability to learn about the risks and benefits of medica-

tions, and delay in seeking necessary medical intervention. Consumers, desperate for treatment of a serious medical problem, may be more susceptible to purchasing an unapproved and potentially harmful product.¹⁹ Also, a consumer may be willing to ignore potentially dangerous drug interactions and side effects in exchange for other perceived benefits of the drug selected by the patient.²⁰ As such, the direction of government regulators is to restrict Internet drug prescribing transactions. As set forth below, many different government agencies and private organizations have taken positions against prescribing drugs via the Internet.

B. Federal Law and Policy Regarding Internet Prescribing

1. The Food & Drug Administration

While only one of many government agencies and organizations involved in overseeing Internet prescribing, the Food & Drug Administration plays a chief role in coordinating drug regulation enforcement efforts.²¹ The FDA's jurisdiction over Internet prescribing activities arises from the federal Food, Drug, and Cosmetic Act²² ("FDCA"), the basic federal food and drug law of the United States.²³ In its enforcement of the FDCA, the

tions, and pharmacists' ability to identify drug interactions and educate patients. Armstrong, *supra* at 1389.

19. FDA, *Buying Medical Products Online*, at <http://www.fda.gov/oc/buyonline/default.htm> (last visited Feb. 23, 2001).

20. See Jane E. Henney, M.D., Address at the Committee on Health Education, Labor and Pensions, United States Senate Hearing on E-Drugs (March 21, 2000).

21. The FDA has cited concerns about the proliferation of web sites that substitute a simple online questionnaire for a face-to-face examination and patient supervision by a health care practitioner. The FDA has prioritized Internet drug sales enforcement activities as follows: (1) the sale of unapproved new drugs, (2) the elimination of health fraud, and (3) controlling the sale of prescription drugs sold without a valid prescription. William K. Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation, Food and Drug Administration, U.S. Department of Health and Human Services, Testimony on Enforcing the Laws of Pharmaceutical Sales Over the Internet Before the House Subcommittee on Oversight and Investigations, Committee on Commerce (May 25, 2000).

22. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-907 (West 2000).

23. Many of the fifty states have enacted laws similar to the FDCA. See, e.g., Texas Food, Drug, and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. §§ 431.001-431.279 (West 2000); Illinois Food Drug and Cosmetic Act, 410 ILL. COMP. STAT. 620/1-620/26 (West 2000); and California Sherman Food, Drug, and Cosmetic Law, CAL. HEALTH AND SAFETY CODE §§ 109875-111915 (West 2001). For example, section 111470 of the California statute requires prescriptions for the sale of the following categories of drugs:

(a) habit forming drugs; (b) drugs that, because of their toxicity or other potentiality for harmful effects, or the method of their use, or the collateral

FDA's primary purposes are to assure the safety of foods and cosmetics, and to assure the safety and efficacy of pharmaceuticals, biological products and medical devices.²⁴ To accomplish these goals, the FDCA sets forth a comprehensive regulatory scheme for drug sales and manufacturing.²⁵

The FDA prohibits the importation and distribution of articles that are adulterated or misbranded.²⁶ In particular, the FDA considers a drug to be "misbranded" if it is dispensed without a valid physician order completed in accordance with 21 U.S.C. § 353(b).²⁷ Legal action to curtail misbranding may be brought criminally or civilly.²⁸ For a felony conviction, the government must establish that the defendant acted with an intent to defraud or mislead either the consumer or the government, or that the defendant is a repeat offender.²⁹ Civil cases and misdemeanor prosecutions do not require proof of intent to defraud or mislead.³⁰ The types of unlawful conduct involving online drug sales that the FDA has identified are similar to unlawful activities that occur in other commercial transactions.

Under the FDCA, the 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

measures necessary to their use, are not safe for use except under the supervision of a practitioner licensed by law to administer the drug; (c) drugs for which adequate directions cannot be written for persons, who are not practitioners licensed by law to prescribe drugs, for safe and effective self-medication or treatment by those persons, who are not licensed to prescribe drugs.

CAL. HEALTH AND SAFETY CODE §111470. These FDCA-based state laws, while not discussed in detail, are assumed to bolster regulatory enforcement action available against Internet prescribing practices.

24. *Overview of the Food and Drug Administration*, at <http://www.fda.gov/opacom/hpview.html> (last visited Feb. 23, 2001).

25. See generally FDCA, 21 U.S.C. §§ 301-907 (West 2000).

26. 21 U.S.C. § 331(a) (West 2000). "Adulterated" articles include products that are defective, unsafe, filthy, or produced under insanitary conditions. *Id.* § 331(k). "Misbranded" articles include false or misleading statements, designs, or pictures, or such articles that fail to provide required information. *Id.*

27. Associate Attorney General, Ethan M. Posner, Address Before the Subcommittee on Oversight and Investigations Committee on Commerce, United States House of Representatives (May 25, 2000).

28. 21 U.S.C. § 332 (West 2000) (injunction may be granted upon violation of Section 331); 21 U.S.C. § 333 (West 2000) (imprisonment and or fine may be imposed upon the violation of Section 331); 21 U.S.C. § 334 (West 2000) (adulterated or misbranded goods in violation of Section 331 may be seized).

29. 21 U.S.C. § 333.

30. Posner, *supra* note 27.

a valid prescription; and (5) counterfeit drugs.³¹ Prescription drugs may only be dispensed pursuant to a prescription of a licensed practitioner, such as a physician, dentist, or veterinarian. In general, a drug is prescriptive if it is not safe for use except under professional supervision. Under the FDCA, this class includes habit-forming drugs and any drug which is unsafe "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use. . . ."³²

In addition to the FDCA, the FDA regulates Internet drug prescriptions through the Internet Drug Sales Action Plan adopted in July 1999. The Internet Drug Sales Action Plan makes Internet surveillance an enforcement priority.³³ The Plan targets health care fraud, the sale of unapproved, counterfeit, adulterated, or illegal drugs, and prescription drugs sold without a valid prescription.³⁴

In the realm of Internet prescribing oversight, former FDA Commissioner Jane Henney had expressed particular concern with websites that prescribe drugs based on questionnaire responses, bypassing the traditional relationship between the patient and health care practitioner.³⁵ In the FDA's view, patients who obtain their prescriptions via the Internet are more likely to receive inappropriate medication, thereby placing themselves at greater risk for side effects and drug interactions.

With the aim of regulating Internet drug sales, on February 2, 2000, the FDA announced a new enforcement program providing for the issuance of "cyber letters" to operators of potentially illegal foreign-based Internet sites selling online prescription drugs.³⁶ Implementing past FDA practices of warning individu-

31. 21 U.S.C. § 331.

32. 21 U.S.C. § 353(b)(1) (West 2000). Unlike the prescription class of drugs, nonprescription drugs are those generally regarded as safe for the consumer to use by following the required label directions and warnings. These are commonly called "over-the-counter" ("OTC") drugs. OTC drugs may be purchased by a consumer without a prescription. Nonprescription OTC drugs must also comply with the standards promulgated under the Fair Packaging and Labeling Act. 21 C.F.R. § 201.60 (West 2001) (proscribing rules on how principal display panels used to promote OTC drugs in package form ought to be constructed).

33. William Hubbard, Address at Subcommittee on Oversight and Investigations Committee on Commerce, U.S. House of Representatives (March 25, 2000).

34. *Id.*

35. Henney, *supra*, note 20.

36. FDA Talk Paper, *FDA Launches "Cyber" Letter Against Potentially Illegal, Foreign-Based Online Drug Sites* (Feb. 2, 2000), available at <http://www.fda.gov/bbs/topics/ANSWERS/ANS01001.html>. This is the first time the FDA has used the In-

als suspected of violating FDA laws, the cyber letters warn offending businesses that they may be engaged in illegal activities under the laws of the United States, and inform them of the laws governing prescription drug sales.³⁷ Cyber letters typically outline the nature of the alleged violation and request a formal response. While the cyber letter program was an offshoot of an older enforcement program targeted at non-U.S. based companies that was initiated in the pre-Internet era, the FDA plans to use this approach in its ongoing efforts to prevent illegal drug sales by domestic businesses as well.³⁸

In one of the first FDA prosecutions arising from its crack down on “rogue” Internet pharmacy operations, Steven Gross pleaded guilty in a U.S. District Court in Florida to charges related to unlawful Viagra sales through an Internet website. The drug was dispensed solely through a written questionnaire, and customers were charged a fee for medical review. Investigators claim, however, that many orders for Viagra were filled without a medical review. Gross’s plea agreement subjected him to up to one year of incarceration and a fine of up to \$100,000.³⁹ He was later sentenced to one year of probation and fined \$5,000.⁴⁰

2. The Federal Trade Commission

While the FDA’s goal is assure the safety and efficacy of drugs, the Federal Trade Commission’s (“FTC”) mission is to enhance the smooth operation of the marketplace by eliminating acts or practices that are unfair or deceptive. In general, the FTC’s efforts are directed toward stopping actions that threaten consumers’ opportunities to exercise informed choice. The basic consumer protection statute enforced by the FTC is the Federal Trade Commission Act (“FTC Act”).⁴¹ The FTC Act states that “unfair or deceptive acts or practices in or affecting commerce are declared unlawful.”⁴² “Unfair” practices are defined as

ternet as a means of reaching potential violators of the FDCA. Contacting potential violators via the Internet seems to be a good way of identifying or monitoring those who are engaged in illegal activities concerning prescription drugs.

37. *Id.*

38. *Id.*

39. Press Release, Office of the United States Attorney, Southern District of Florida (August 2000), available at www.usdoj.gov/usao/fls/Gross.html.

40. Susan Burke, *Stopping the Unauthorized Sale of Pharmaceuticals: An Argument for Private Enforcement Actions*, 1 Food and Drug Law Institute Update 12 (2001), available at <http://www.fdl.org/pubs/Update/2001/Issue1/Burke/print.html>.

41. 15 U.S.C. § 45 (2000).

42. *Id.* § 45(a)(1).

those that “cause. . . or [are] likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition.”⁴³

In addition to the FTC Act, the FTC enforces a variety of specific consumer protection statutes that prohibit specifically-defined trade practices and specify that violations are to be treated as if they were “unfair or deceptive” acts or practices under section 5(a) of the FTC Act.⁴⁴ Any violations of consumer protection law are enforced by the FTC through both administrative and judicial processes.

According to FTC spokesperson Jodie Bernstein, deceptive marketing of prescription drugs online would violate FTC law if it harmed consumers who acted reasonably under the circumstances to a misrepresentation or omission made by the marketers.⁴⁵ Thus, Bernstein explains, the FTC has authority to bring an enforcement action where an online pharmacy makes false or misleading claims about the products or services it provides.⁴⁶ For example, the FTC has authority to take action if a website operator made false or misleading claims about medical consultation it provided in connection with prescribing and dispensing a drug. Additionally, the FTC has authority under its unfairness jurisdiction to regulate marketing practices that cause or are likely to cause substantial consumer injury, not reasonably avoidable by consumers, and not outweighed by countervailing benefits to consumers or to competition.⁴⁷ Although it could be asserted that certain online prescribing practices by physicians may be so inadequate as to be unfair, the FTC has indicated that these practices raise difficult issues involving physician practices that the FTC has traditionally refrained from regulating.⁴⁸

As part of its efforts to protect consumers from online pharmacy fraud, the FTC organized several undercover operations. One publicized FTC action involved an undercover operation in Kansas in which a 16-year-old was able to buy Viagra and the

43. *Id.* § 45(n).

44. *Id.* § 45.

45. Jodie Bernstein, *Drugstores on the Net: The Benefits and Risks of On-line Pharmacies*: Oversight Hearing Before Subcommittee on Oversight and Investigations (1999), available at <http://com-notes.house.gov/cchear/hearings106.nsf>.

46. *Id.*

47. *Id.*

48. *Id.*

controlled substances Meridia and Phentermine online.⁴⁹ During this operation, it was discovered that the physicians reviewing online applications were not licensed by the Kansas Medical Board, and the pharmacies dispensing the drugs were not registered with the Kansas Board of Pharmacy.⁵⁰ In reviewing this operation, Kelli Benintendi, Assistant Attorney General in the Consumer Protection Division of the FTC, stated that many aspects of online drug prescribing and dispensing do not fall clearly within the FTC's traditional scope of authority or expertise; rather these duties have been the primary responsibility of other federal and states agencies.⁵¹ Benintendi also described two successful efforts by FTC staff to purchase prescription drugs online despite the fact that in one case the staff provided a medical history that should have raised serious concerns about the appropriateness of issuing a prescription.⁵²

In another publicized FTC prosecution, the defendants were charging \$75 for medical consultations for Viagra.⁵³ Suspiciously, the physician reviewing the medical information forms for the Viagra customers was only paid if he approved the prescription request.⁵⁴ The FTC alleged misrepresentations relating to the existence of an actual clinic and a network of physician affiliations.⁵⁵ As part of a settlement agreement, defendants were: (i) prohibited from making deceptive claims (ii) required to make disclosures about their collection and use of medical information and regarding medical and pharmaceutical relationships, and (iii) required to meet certain privacy standards.⁵⁶

Absent legislative measures, the FTC has suggested that its statutory authority may be too limited to fully address important consumer protection issues raised by Internet drug prescribing and dispensing. Thus, the FTC has recommended that Congress act to address the unique characteristics of the Internet medium and ensure greater protections for consumers. Specifically, the FTC recommends requirements for clear and prominent disclo-

49. Stacy Collett, *On-line Drugstores Face State Lawsuit*, CNN (June 15, 1999), available at <http://www.cnn.com/TECH/computing/9906/15/drugsuit.idg>.

50. *Id.*

51. *Id.*

52. *Id.*

53. FTC, Press Release, *Online Pharmacies Settle FTC Charges*, July 12, 2000, available at www.FTC.com.

54. *Id.*

55. *Id.*

56. *Id.*

sure of identifying information for the online prescribing physician and the online pharmacy.⁵⁷

3. The Department of Justice

Currently, the Department of Justice ("DOJ"), collaborating with the FDA and the FTC, patrols the Internet to constrain illegal activity.⁵⁸ The DOJ's Criminal Division has established the Computer Crime and Intellectual Property Section ("CCIPS"), the cornerstone of its cybercrime program.⁵⁹ CCIPS was founded in 1991 as the Computer Crime Unit, and was elevated into a section of the DOJ in 1996.⁶⁰ In February 1999, the DOJ established an Internet Fraud Initiative as part of an expansion of the federal government's efforts to combine criminal prosecution with coordinated analysis and investigation to combat Internet fraud.⁶¹ In addition, the FDA has established cooperative working relationships with the Federal Bureau of Investigation ("FBI") and the U.S. Postal Inspection Service.

Most recently, the Drug Enforcement Agency ("DEA"), a division of the DOJ, issued guidance, entitled *Dispensing and Purchasing Controlled Substances Over the Internet*, aimed at educating prescribers, pharmacists, law enforcement authorities, regulatory authorities and the public concerning the application of current laws and regulations as they relate to the use of the Internet for dispensing and selling controlled substances.⁶² This formal guidance provides a fairly comprehensive, yet concise, overview of the status of Internet drug sales regulation. Of par-

57. See Henney, *supra* note 20. On October 19, 2000, the United States General Accounting Office also issued similar recommendations on a report on Internet drug sales.

58. The Attorney General serves as head of the Department of Justice, 28 U.S.C. § 503 (West 2000), and as chief law enforcement officer of the federal government. *Marshall v. Gibson's Products, Inc. of Plano*, 584 F.2d 668 (5th Cir. 1978). In this capacity, the Attorney General enforces numerous consumer protection statutes such as the FDCA, the FTC Act and the Controlled Substances Act. *Id.*; 21 U.S.C. §801 *et seq.* The Attorney General and the DOJ work in collaboration with the FDA and the FTC, the administrative agencies that are the primary regulatory authorities over these statutes. The DOJ also works on Internet drug sales issues through the Drug Enforcement Agency ("DEA"), a division of the DOJ.

59. Attorney General Janet Reno, Testimony on "Cybercrime," before the United States Senate Committee on Appropriations (Feb.16, 2000).

60. *Id.*

61. See United States Department of Justice, *Internet Fraud*, available at [http://www.usdoj.gov/criminal/fraud/Internet.htm#Internet Fraud Initiative](http://www.usdoj.gov/criminal/fraud/Internet.htm#Internet%20Fraud%20Initiative) (last visited Feb. 23, 2001) (highlighting the goals set out by the Initiative).

62. DEA Guidance on Dispensing and Purchasing Controlled Substances Over the Internet, 66 Fed. Reg. 21,181 (April 27, 2001).

ticular note, the DEA explains that many states recognize a *bona fide* physician/patient relationship to exist when the following four elements have been established: 1) a patient has a medical complaint; 2) a medical history has been taken; 3) a physical examination has been performed; and 4) a some logical connection exists between the medical complaint, the medical history, the physical examination and the drug prescribed.⁶³

The DEA's test seems to have synthesized and simplified the rules of the various regulators and created its own criteria for the existence of a physician/patient relationship. For example, a psychiatrist arguably need not physically examine her patient before prescribing anti-depressants. Further, a patient need not have a complaint to require medication, rather, a patient may have signs of an illness that are only detectable upon testing and examination. In any case, the DEA states that Internet sites that do not require the consumer to obtain a prescription from his doctor, but instead require the consumer to complete a medical questionnaire online, are operating in a manner inconsistent with state laws and may be engaging in illegal sales of controlled substances.⁶⁴ Nevertheless, the DEA guidance does recognize the legitimacy of circumstances where a physician is engaging in telemedicine and does not personally examine the patients but rather relies on health care assistants to perform elements of the testing and examination.⁶⁵

4. Presidential Initiatives

The course of the research supporting this article spanned both the administrations of Bill Clinton and George W. Bush. Each administration is briefly described. Under the Clinton administration, illicit Internet transactions were the subject of a report by the President's Working Group on Unlawful Conduct on the Internet, entitled *The Electronic Frontier: The Challenge of Unlawful Conduct Involving the Use of the Internet*.⁶⁶ This lengthy report highlighted the significant challenges facing law enforcement in cyberspace. The report emphasized that: (i) conduct on the Internet should be treated in the same manner as similar conduct offline, in a technology neutral manner; (ii) the

63. *Id.* at 21,182.

64. *Id.* at 21,183.

65. *Id.*

66. James K. Robinson, Assistant Attorney General for the Criminal Division, Address Before the Senate Committee on Judiciary on Cybercrime and the Internet Integrity and Critical Infrastructure Act (May 25, 2000).

needs and challenges of law enforcement posed by the Internet, including the need for resources, up-to-date investigative tools and enhanced multi-jurisdictional cooperation⁶⁷ are significant; and (iii) enforcement agencies require continued support from private sector leadership in developing tools and methods to help Internet users to prevent and minimize the risks of unlawful conduct online.⁶⁸

At the end of 1999, the Clinton administration also announced a new initiative to study and regulate Internet drug sales.⁶⁹ The initiative was intended to establish new federal requirements for all Internet pharmacies to ensure that they comply with state and federal laws; to create new civil penalties for the illegal sale of pharmaceuticals; to give federal agencies new authority to swiftly gather the information needed to prosecute offenders; to expand federal enforcement efforts; and to launch a new public education campaign about the potential dangers of buying prescription drugs online. Ten million dollars in funding was targeted for the program.

Additionally, in his final annual budget request, President Clinton asked Congress to grant greater oversight authority to the FDA for online pharmacies, including giving the FDA authority to certify Internet sites before they can sell prescription drugs and impose penalties for sites that fail to be certified.⁷⁰ In that vein, on May 2, 2000, Secretary Donna Shalala introduced the Internet Prescription Drug Sales Act of 2000.⁷¹ If enacted, the Act would provide greater federal oversight to Internet prescription activities such as: imposing a requirement that an online pharmacy be licensed in each state in which it operates (*i.e.* to which it delivers prescription drugs); requiring compliance with all applicable federal and state laws governing the practice of pharmacy, including those laws that require proper storage and handling of prescription drugs, proper record keeping, and other consumer protections; and requiring online pharmacies to post on their web site a notice containing certain other identifying information and a statement that the online pharmacy shall

67. The participants in an Internet transaction can be widely dispersed geographically (in different states or countries) leading to jurisdictional questions.

68. Robinson, *supra* note 66.

69. Office of the Press Secretary, *The Clinton Administration Unveils New Initiative to Protect Consumers Buying Prescription Drug Products Over the Internet* (Dec. 28, 1999), available at <http://clinton3.nara.gov/WH/New/html/19991229.html>.

70. Posner, *supra* note 27.

71. *Id.*

dispense prescription drugs only upon a valid prescription by a licensed practitioner.⁷² Other Internet drug sales legislation has been introduced at the federal level,⁷³ but a congressional mandate for Internet drug regulation does not exist.

Other than the DEA's Federal Register publication addressing Internet drug sales, the Bush administration has not, in the first months of its governance, made any formal proclamations on Internet drug sales policies. The programs of the FDA were all initiated under the Clinton administration. As recently as March 8, 2001, the Acting FDA Commissioner, Bernard A. Schwetz, testified on the policy priorities of the FDA before the United States House of Representatives Committee on Appropriations, Subcommittee on Agriculture, Rural Development, and Related Agencies. Acting Commissioner Schwetz has not issued any formal statement of the new administration's policy on Internet drug sales.⁷⁴ Further, while President Bush issued a fiscal year 2002 budget request for the Food and Drug Administration totaling \$1.414 billion on April 9, 2001, such request did not specifically include an Internet drug sales enforcement budget.⁷⁵

5. Federal Collaboration with State Agencies

In addition to the federal agencies involved with Internet drug regulation, the FDA collaborates with a number of organizations representing state regulatory and law enforcement bodies, consumers, health care practitioners and health care organizations, such as the National Association of Boards of Pharmacy ("NABP")⁷⁶, the Federation of State Medical Boards

72. *Id.*

73. *See, e.g.*, Internet Pharmacy Consumer Protection Act, H.R. 2763, 106th Cong. (1999). H.R. 2763 provides that any website involved in the sale of prescription drugs must disclose the name, business address, and telephone number of the person selling the prescription drugs. *Id.* It must also list each state in which such person is authorized by law to dispense prescription drugs and the name and license status of each individual pharmacist. *Id.* If medical consultations are provided through the web site, the disclosure must also include the names of the individuals providing consultations, the states in which they are licensed, and licenses which they hold. *Id.*

74. FDA, Fiscal Year 2002 Congressional Budget Request, *available at* <http://www.fda.gov/oc/oms/ofm/budget/2002/TEST226omb.htm>. (last visited May 21, 2001).

75. FDA, FDA Talk Paper: FDA's Budget Request for FY 2002 (April 9, 2001), *available at* <http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01073.html>.

76. The NABP has implemented a voluntary program to verify the legitimacy of Internet sites dispensing prescription drugs. The program, known as the Verified Internet Pharmacy Practice Sites, or VIPPS, provides an NABP "seal of approval" to sites meeting state licensing requirements and NABP's standards. The NABP does

("FSMB"), the National Association of Attorneys General ("NAAG") and the American Medical Association ("AMA").⁷⁷ In collaborating with these organizations, the FDA is exploring (i) how issues relating to online drug sales should be addressed, (ii) what agencies should regulate and how they should regulate, and (iii) whether and what changes to the current law should be enacted.⁷⁸ At a February 1999 meeting with health professional organizations, the FDA, the FSMB, the NABP, the AMA and the Association of Food and Drug Officials, discussed the roles that each organization plays in regulating the prescribing and dispensing of drugs over the Internet. The agencies also discussed how their various roles could better complement each other.

C. State Law and Regulatory Efforts

Under state law, the practices of pharmacy and medicine are regulated to protect patients from harm resulting from the use of unsafe drugs, counterfeit drugs, and the improper practice of medicine and pharmacy. Historically, it has been primarily the responsibility of state governments, rather than the federal government, to regulate these licensed professions. As standards of medicine among various areas of the country become more similar and, as telemedicine practices enable long-distance physician oversight of patients, the basis for local regulation of the medical practice is becoming more ambiguous. There are no clear indications, however, that the emphasis on state regulation will succeed to federal regulation. Therefore, absent a movement toward federal medical practice regulation, the public will continue to rely on state regulatory entities for the oversight of physician licensing and practice.

As a preliminary matter, for a drug prescription to be "valid" under the FDCA, it must be ordered by a health care professional who is appropriately trained and licensed. There is a consensus among states that the treating professional must be licensed in the state where the patient, for whom the health care

not offer VIPPS certification to a website that sells or otherwise offers health care professional services for the purpose of ordering a prescription drug. See VIPPS web site, at <www.nabp.net/vipps/intro.asp> (last visited Mar. 26, 2001).

77. Other organizations including the American Pharmaceutical Association, the American Society of Health-Systems Pharmacists, and the Pharmaceutical Research Manufacturers Association, the American Association of Retired Persons have also played key roles in Internet drug regulation. Henney, *supra* note 20.

78. *Id.*

professional is prescribing, resides. Historically, the only practitioners permitted to write orders for prescription drugs were physicians. More recently, however, other categories of health care professionals—most notably physician assistants, nurse practitioners, and nurse anesthetists—have been granted the authority under state law to order prescription drugs.⁷⁹

Once the appropriate category of health care professional is involved in a patient's care, the question arises as to whether the medical standard of care requires a preliminary face-to-face consultation or physical examination with a licensed health care professional prior to the issuance of a prescription for an FDA-approved drug. If so, it is only after such consultation or examination that the health care professional, or registered pharmacist working in a licensed pharmacy meeting state practice standards, may dispense the prescribed drug to the patient.⁸⁰

Prior to Internet drug prescribing in health care services delivery, diagnosing and treating patients absent a face-to-face consultation was common in a number of circumstances. Physicians regularly order drugs for hospital patients based on diagnostic information received from hospital employees. Regulators and health care institutions have imposed guidelines and limitations on these practices as well. For example, hospital and nursing home licensing laws often require written confirmation of oral orders for therapies, including drugs, in a relatively short time frame. Further, in some jurisdictions, narcotics may only be administered in an emergency situation in those settings.⁸¹ Regulators, however, generally condemn marketing drugs on the Internet and prescribing to consumers who were wholly unknown to the prescribing provider prior to the Internet communication.

79. For example, in Illinois, an advanced practice nurse ("APN"), licensed under the Nursing and Advanced Practice Nursing Act, who has in place a written agreement with a collaborating physician, licensed in Illinois and providing ongoing professional oversight of the APN, may have limited authority to prescribe and dispense drugs including controlled substances. 25 ILL. COMP. STAT. §§ 65/15-5 - 65/15-55 (West 2000); American Nurses Association, 2000 Prescriptive Chart, *available at* <http://nursingworld.org/gova/charts/dea.htm> (last visited Mar. 21, 2001) (indicating that every U.S. jurisdiction, except for Georgia, Guam and Pennsylvania, provides at least limited prescriptive authority to one or more categories of advanced practice nurses).

80. Posner, *supra* note 27.

81. See, e.g., 28 PA. STAT. ANN. § 211.3. Pennsylvania long-term care licensing standards require that a physician's telephone and oral orders for medications be dated and countersigned by the prescribing practitioner within 48 hours and that oral orders for Schedule II drugs are only valid in the case of an emergency. *Id.*

When examining this question in connection with the efficacy of Internet prescribing, the FSMB's Report of its Special Committee on Professional Conduct and Ethics (the "FSMB Report") should be considered.⁸² The FSMB Report, adopted during the FSMB annual meeting in April, 2000, includes recommendations to strengthen state medical board authority over Internet prescribing.⁸³ More detailed guidelines on the topic are currently being developed for presentation at FSMB's 2001 annual meeting. Recommendations contained in the FSMB Report include the following:

State medical boards should consider it unprofessional conduct for a physician to provide treatment and consultation recommendations, including issuing a prescription, via electronic or other means, unless the physician has obtained a history and *physical evaluation of the patient* adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment recommended/provided. Exceptions should be defined to include: (1) an emergency, as defined by the state medical board; (2) treatment provided in consultation with another physician who has an ongoing relationship with the patient and who has agreed to supervise the patient's treatment, including use of any prescribed medications; or (3) on-call or cross-coverage situations in which the physician has access to patient records.⁸⁴

The FSMB Report asserts that "[p]rescribing of medications by physicians based solely on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct."⁸⁵ This assertion is premised on the fact that "[a]ccepted standards of medical practice must be upheld regardless of means of communication or delivery of health care services."⁸⁶ The FSMB Report identifies the following health risks which are posed by Internet prescrip-

82. Clarke Russ, et al., Federation of State Medical Boards Report of the Special Committee on Professional Conduct and Ethics, *available at* <http://www.fsmb.org/profconductpd.htm>. (Aug. 29, 2000). The FSMB does not have regulatory authority over health care practices. As an association of state medical boards, however, it has substantial influence over medical regulatory affairs. *Id.*

83. *Id.*

84. *Id.* (emphasis added). The FSMB Report also recommended that state medical boards require physicians who practice medicine via the Internet, including prescribing, to clearly disclose on the web site physician identifying information, including name, practice location, all states in which licensure is held, and financial interests in any products prescribed or recommended. *Id.*

85. *Id.*

86. *Id.*

tions without “adequate evaluation by a physician: (1) adverse drug reactions and/or interactions (2) misdiagnosis or delay in diagnosis and (3) failure to identify complicating conditions.”⁸⁷

The FSMB Report, along with the FSMB’s other efforts to define appropriate Internet prescribing policy, are just some examples of the exceptional level of interstate collaboration on this issue. The FSMB has played an active role in facilitating communication among the state medical boards and in assisting the boards with information about activities in other states and at the federal level. One component of this facilitator role is the FSMB establishment of an Internet clearinghouse to monitor and report entities offering online drug prescriptions based solely on filling out a questionnaire.⁸⁸ This clearinghouse program will continue through the Fall of 2002 assuming a determination to continue has been made after the first year of its operation. In the program, FSMB will target Internet sites where no physician evaluation is made nor is there much regard for licensing and prescribing laws and standards.⁸⁹

According to the AMA, a health care practitioner who offers a prescription for a patient they have never seen before, based solely on an online questionnaire, generally does not meet the appropriate medical standard of care.⁹⁰ John O’Bannon III, MD, a member of the AMA’s Council on Ethical and Judicial Affairs, has stated that, while there is nothing wrong with Internet prescribing per se, “any prescribing on the Internet or

87. *Id.*

88. See FSMB Press Release (September 15, 2000) (on file with author).

89. Telephone interview with Jeanne Hoferer, Federation of State Medical Boards representative (May 9, 2001) (notes on file with author).

90. The AMA House of Delegates, at their June 1999 meeting, adopted a resolution proclaiming: (1) to develop principles describing appropriate use of the Internet in prescribing medications; (2) to support the use of the Internet as a mechanism to prescribe medications with appropriate safeguards to ensure that the standards for high quality medical care are fulfilled; (3) to work with state medical societies in urging state medical boards to ensure high quality medical care by investigating and, when appropriate, taking necessary action against physicians who fail to meet the local standards of medical care when issuing prescriptions through Internet web sites that dispense prescription medications; (4) to work with the FSMB and others in endorsing or developing model state legislation to establish limitations on Internet prescribing; (5) to continue to work with the NABP and support its VIPPS program so that physicians and patients can easily identify legitimate Internet pharmacy practice sites; and (6) to work with federal and state regulatory bodies to close down Internet web sites of companies that are illegally promoting and distributing (selling) prescription drug products in the United States.

otherwise is wrong, illegal, and unethical if it occurs outside the context of a valid patient-physician relationship."⁹¹

Another group working on the regulatory oversight of Internet drug sales is the National Association of Attorneys General. This group has established the Online Sales of Drugs Working Group to address issues related to Internet pharmacies.⁹² This consortium, established under the leadership of Attorney General for the State of Kansas Carla Stovall, conducts monthly teleconferences to discuss state and federal regulatory actions overseeing Internet prescribing practices including policy statements, enforcement actions and legislative initiatives.⁹³ While the level of regulatory action among the states may be dynamically different, most state regulators participating in the group dialogues have expressed an intent to limit or abolish Internet prescribing practices in its current form.⁹⁴

Vermont, Maine, New Hampshire, and New York provide another example of a collaborative state effort to regulate the physician/patient relationship. These states have jointly issued a brief "statement of principle," providing, with limited "consultation" exceptions,⁹⁵ a provision that any medical service to a patient requires professional licensure in the state in which the patient encounter will occur.⁹⁶

Acting individually, a number of states, including Oklahoma, Maryland, Alabama, Ohio, and Texas have adopted policies, guidelines or statements clarifying standards for online drug prescribing and distribution. Some states, such as California, Il-

91. Charles Marwick, *Several Groups Attempting Regulation of Internet Rx*, 281 JAMA Medical News and Perspectives 11 (March 17, 1999).

92. See Kansas Attorney General Carla J. Stovall, Testimony before the United States House of Representatives Committee on Commerce, Subcommittee on Oversight and Investigations, May 25, 2000, available at <http://www.naag.org/legislation/may/stovall.online.pharm.cfm>.

93. *Id.*

94. National Association of Attorneys General, Resolution in Support of Legislation Encouraging Cooperative Federalism to Protect Consumers on the Internet (adopted Spring meeting, March 22-24, 2000, Washington, D.C.), available at http://www.naag.org/legislation/may/NAAG_resolution.pdf.

95. This exception is a principle that has been carved out under telemedicine law. State consultation exceptions, which permit out-of-state physicians to consult on patient cases provided that such physician works in tandem with or provides services at the request of a doctor licensed in the state where the patient is located, are premised on the infrequency of the consultations or the retention of final medical decision making by the in-state physician. Martin L. Keidan, *Not So Fast, It's Regulated: Some Warnings for the E-Health Biz*, BUS. L. TODAY, Sept./Oct. 2000, at 10-14.

96. Statement of Principle of the NE Region State Medical Boards, *Medical Practice Across State Lines* (Sept. 24, 1999) (on file with author).

linois and Oregon, have taken action against physicians who have prescribe drugs in violation of the standards governing Internet communications.⁹⁷ Furthermore, in states such as Arizona, California, and Virginia, legislation has been adopted to establish practice standards for prescribing medications over the Internet. In addition, Internet prescribing legislation has been introduced in Michigan, New York, and Delaware.⁹⁸ These types of administrative and legislative actions on the part of state medical boards are expected to continue and accelerate as more boards experience successful regulation efforts.⁹⁹

1. State Policy Statements

Medical board policies, or position statements, are interpretive statements that attempt to define or explain the meaning of laws or rules that govern the practice of physicians in a particular state. Such policies usually relate to professional discipline. The policies also set forth criteria or guidelines used by a medical board's staff in the investigation and prosecution of disciplinary cases. Typically, the guidelines are not intended to be comprehensive or exhaustive. Therefore, a position statement's absence or silence on certain matters should not be construed as lacking an enforceable standard. Further, the existence of a position statement should not necessarily be taken as an indication of a medical board's enforcement priorities. Many states have developed policies on Internet prescribing.

Notwithstanding the novelty of the Internet medium, and the numerous actions taken to set forth more well-defined statutes

97. Statement of James Winn, M.D., Executive Vice President, Federation of State Medical Boards, at <http://www.insideboulder.com/healthfitness/stories/1025fit.html> (last visited Mar. 21, 2001). The FDA, in its report *Buying Medical Products Online* reports that fourteen states (Arizona, California, Colorado, Connecticut, Illinois, Michigan, Kansas, Nevada, New Jersey, Ohio, Texas, Washington, Wisconsin, and Wyoming) have taken some action against physicians prescribing on the Internet. *Buying Medical Products Online*, *supra* note 18; see also *Patients Demand Cyber Interaction*, SelfhelpMagazine.com, July 29, 1999, at www.shpm.com/newsfeed/JulyNews.html. For example, in March 2000, the Oregon Board of Medical Examiners sanctioned Dr. Steven Moos for prescribing Viagra over the Internet. See http://www.courtstv.com/national/2000/0331/doctor_ap.html. In fining him \$5,000 and placing him on probation for ten years, the Oregon medical board found that Dr. Moos had acted in an unprofessional and dishonorable way in violation of professional licensure laws. *Id.*

98. See H.B. 5824, 90th Leg., Reg. Sess. (Mich. 2000); S.B. 7760, 1999 Leg., 223rd Leg. Sess. (N.Y. 2000); H.B. 642, 1999 Leg., 140th Gen. Assem. (Del. 2000).

99. Hearing on E-Drugs: Who Regulates Internet Pharmacies?: Before the Senate Comm. On Health, Education, Labor and Pensions (2000) (statement of the Fed. of St. Med. Boards, presented by Bruce A. Levy, Exec. Director, Tex. St. Board of Med. Examiners).

and rules to regulate Internet drug sales, state medical boards are well-equipped to define Internet prescribing policies. The development of telemedicine¹⁰⁰ policies developed by many states provides state regulators some experience in the area of Internet drug prescribing. For example, the Minnesota Board of Medical Practice has issued policy statements about telemedicine and prescribing guidelines.¹⁰¹ These policy statements provide a potential basis for the appropriate review of Internet prescribing practices. The prescribing guidelines suggest a methodology for managing the administration of drug therapies.¹⁰² These guidelines provide that, in prescribing drug therapies, a physician should document: (i) the drug or other therapy's proper method of use; (ii) the patient's response to the therapy; and (iii) the rationale for continuing or modifying therapy.¹⁰³ The guidelines also discuss the following specific items: (i) the necessity of a history and physical, including appropriate diagnostic test; (ii) development of a plan of care; (iii) review of the patient's prescription records and potential for chemical dependency, if prescribing a controlled substance; and (iv) obtaining informed consent and on-going monitoring of the patient's condition.¹⁰⁴

In another set of guidelines, *Practice by Physicians Not Licensed in Minnesota*, the Minnesota board concluded that if a patient resides in Minnesota, the treating physician must hold a valid Minnesota license.¹⁰⁵ As an annotation to the guidelines, the agency noted that determining the relationship between state licensure laws, the regional nature of the economics and de-

100. Telemedicine can be broadly defined as medical diagnosis and treatment via telecommunications. In a situation where telemedicine is employed the doctor and patient are physically separated and use a non-human conduit to exchange information. Kathleen M. Vyborny, *Legal and Political Issues Facing Telemedicine*, 5 ANNALS OF HEALTH LAW 61, 71 (1996).

101. Minnesota Board of Medical Practice, *Management of Prescribing*, MINNESOTA BOARD OF MEDICAL PRACTICE UPDATE NEWSLETTER, Fall 1990, available at <http://www.bmp.state.MN.US/Articles-prescribing.htm> (Oct. 24, 2000).

102. *Id.*

103. *Id.*

104. *Id.*

105. Minnesota Board of Medical Practice, *Practice by Physicians Not Licensed in Minnesota*, MINNESOTA BOARD OF MEDICAL PRACTICE UPDATE NEWSLETTER, Spring 1995, available at <http://www.bmp.state.MN.US/Articles-border-not-licensed.htm> (last visited Oct. 24, 2000).

livery system for health care, and interstate aspects of telemedicine, required more work, research, and legislation.¹⁰⁶

In Virginia, the state medical board has written guidelines for the maintenance of a patient medical record - an essential part of a valid physician/patient relationship.¹⁰⁷ Such guidelines, while drafted partly in contemplation of Internet drug prescription practices, are not specific to that practice.¹⁰⁸ The guidelines require medical records to include the following content: (i) an appropriate history and physical examination (if pain is present and controlled substances prescribed, the assessment of pain, substance abuse history, and co-existing diseases or conditions should be recorded); (ii) diagnostic tests when indicated; (iii) a working diagnosis; (iv) treatment plan; and (v) dated documentation of all written prescriptions including the medication's name, strength, dosage, quantity and number of refills.¹⁰⁹ The North Carolina Medical Board has instituted a similar policy to demonstrate the existence of a *bona fide* physician/patient relationship.¹¹⁰

In addition, North Carolina's medical board has also adopted a position statement specifically aimed at the practice of Internet prescribing.¹¹¹ The policy statement provides that, with certain exceptions, prescribing drugs to an individual unexamined by the prescriber is inappropriate.¹¹² The statement provides,

[b]efore prescribing a drug, a physician should make an informed medical judgment based on the circumstances of the situation and on his or her training and experience. Ordinarily, this will require that the physician personally perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan, a part of which might be a prescription.¹¹³

106. Virginia Board of Medicine, *Law, Regulation, and Healthcare Practice*, BOARD BRIEFS, Summer 2000, available at http://www.dhp.state.va.us/medicine/medicine_newsletters.htm (last modified Feb. 7, 2001).

107. *Id.*

108. *Id.*

109. *Id.*

110. Position Statement of the N.C. Medical Board, *Documentation of the Physician Patient Relationship*, available at <http://www.docboard.org/nc/pos2.htm> (May 1996).

111. Position Statement of the N.C. Medical Board, *Contact with Patients Before Prescribing*, available at <http://www.docboard.org/nc/pos2.htm> (Nov. 1999).

112. *Id.*

113. *Id.*

Cited exceptions to this general rule include admission orders for a newly hospitalized patient, prescribing for a patient of another physician for whom the prescriber is taking call, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment.¹¹⁴ The statement specifically provides, "[p]rescribing drugs to individuals the physician has never met based solely on answers to a set of questions, as is common in Internet or toll-free telephone prescribing, is inappropriate and unprofessional."¹¹⁵

In Ohio, the medical board promulgated Rule 4731-11-09, "Prescribing to Persons Not Seen by the Physician."¹¹⁶ The Ohio board adopted this rule to address Internet prescribing. However, because prescribing drugs via the Internet is illegal under drug trafficking laws, Ohio has promulgated the regulation, apparently, only to clarify state law. Additionally, the Ohio board has indicated that, where an out-of-state physician prescribes drugs over the Internet to an Ohio resident, the State could charge that physician with practicing medicine without a license. Such a charge could subject the physician to censure and possibly license revocation; the physician would also be subject to criminal drug trafficking laws.

The Alabama Board of Medical Examiners has adopted a policy that makes it inappropriate and unprofessional to prescribe drugs based solely on answers to questionnaires—a practice common in Internet or toll-free telephone prescribing.¹¹⁷ Yet, the Alabama Board of Medical Examiners does recognize certain circumstances where treatment plans prescribing drugs may be appropriate absent a face-to-face evaluation.¹¹⁸ Similar to the examples provided in North Carolina, the Alabama board also provides examples where face-to-face evaluations may not be necessary: (i) admission orders for a patient newly admitted to a hospital, (ii) short-term prescribing for a patient of another physician for whom the prescribing physician is covering, and (iii) continuing medication on a short-term basis for a new pa-

114. *Id.*

115. *Id.*

116. Ohio State Medical Board, ADMINISTRATIVE RULE 4733-11-09(A), *Prescribing to Persons Not Seen by the Physician*, available at <http://www.state.oh.us/med/rules/11-09.htm>.

117. ALA. ADMIN. CODE r. 540-X-9-.11 (2000). The basis for this policy, which became effective on April 21, 2000, is that it is difficult for a physician to make an informed medical judgment based on the circumstances of the situation without a personal face-to-face consultation.

118. *Id.*

tient prior to the patient's first appointment.¹¹⁹ Further, the Alabama Medical Board recognizes that established patients may not require a new history and physical examination for each new prescription.¹²⁰ In assessing the necessity of a face-to-face evaluation, it is interesting to consider whether the use of video-conferencing technology to provide video imaging of the patient to the health care provider would satisfy the examination requirement, at least in limited cases. Currently, the technology is not widely available, so it is not a legitimate consideration today but may be in the near future.

In Florida, the medical board takes the position that patients should not be prescribed drugs absent the following: (i) a patient diagnosis established through appropriate personal examination; (ii) a discussion of treatment alternatives; (iii) a reliable medical history accessible to the physician; (iv) the maintenance of a medical record; (v) a discussion with the patient of the benefits and risks of prescribed medications; and (vi) a patient follow up, when necessary, to assess the therapeutic outcome.¹²¹

The Texas Board of Medical Examiners has also established an Internet prescribing policy.¹²² This policy notes that section 3.08(4) of the Texas Medical Practice Act¹²³ authorizes the medical board to discipline a Texas physician for unprofessional conduct likely to deceive, defraud, or injure the public.¹²⁴ Texas' medical practice statute defines "unprofessional conduct" to include "prescribing or administering a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed."¹²⁵ Such conduct also includes prescribing, administering or dispensing dangerous drugs in a manner not consistent with public health and welfare.¹²⁶ Under Texas statute, conduct by a licensed Texas physician that violates the physician's professional duty to practice medicine in an acceptable manner consistent with public health and welfare, may be punishable by the medical board.¹²⁷

119. *Id.*

120. *Id.*

121. Department of Health, Florida Board of Medicine, Meeting Minutes, February 3-5, 2000.

122. Position Statement of the Texas Board of Medical Examiners, *Internet Prescribing Policy*, available at <http://www.tsbme.state.tx.us/policy/ipp.htm> (Dec. 1999).

123. *Id.*

124. *Id.*

125. *Id.*

126. TEX. HEALTH & SAFETY CODE ANN. § 483 (Vernon 2000).

127. *Id.*

Based on its interpretation of the above sections, the Texas board has determined that it is "unprofessional conduct for a physician to initially prescribe any dangerous drugs or controlled substances without first establishing a proper physician-patient relationship."¹²⁸ The Board has established four minimum criteria to determine whether a proper relationship has been established. A physician must: (i) verify that the person requesting the medication is in fact who he or she claims to be; (ii) establish a diagnosis through the use of accepted medical practices such as a patient history, mental status exam, physical examination and appropriate diagnostic and laboratory testing; (iii) discuss with the patient the diagnosis, its evidence, and the risks and benefits of various treatment options with the patient; and (iv) insure the availability of the physician or coverage for appropriate follow-up care.¹²⁹ Based on these criteria, the Texas Medical Board determined that "an online or telephonic evaluation by questionnaire is inadequate."¹³⁰

2. Enforcement Actions

The policing of Internet prescribing activities currently takes place through the enforcement of state medical practice acts. In large part, enforcement actions to date have been based on existing professional practice laws and regulations. In prosecuting physicians involved in Internet drug sales, regulators rely on the unethical or unprofessional conduct provisions of physician practice statutes. Such provisions and statutes allow a considerable degree of discretion in sanctioning a licensed provider.¹³¹ Such censure includes probation, temporary suspension, and license revocation. In addition to these conduct statutes, some enforcement agencies are also relying on consumer fraud act statutes to take enforcement action against rogue websites.

128. Position Statement of the Texas Board of Medical Examiners, *supra* note 122.

129. *Id.*

130. *Id.*

131. Note that most enforcement actions have involved the prosecution of physicians and pharmacy operators. If, however, no health care professional with prescribing authority is involved in an online consultation that is the basis for a prescription, the individual prescribing the drug could be subject to sanction for the unauthorized practice of medicine. Further, drug trafficking laws can also, in some instances, be used to prosecute licensed and non-licensed Internet "prescribers." Additionally, if a physician inappropriately delegates his prescriptive authority, improper delegation of medical tasks is usually a separate basis for licensure sanction. See, e.g., TEXAS OCC. CODE ANN. §§ 157.001-157.002, 164.001 (Vernon 2000).

Two actions against physicians for Internet prescribing preceded the modification of the Arizona physician licensing statute. In 1999, the first action, which involved Internet prescribing, was brought to the attention of the Arizona State Board of Medical Examiners ("BOMEX") by the State of Kansas Board of Healing Arts. The action was brought against Dr. William Clemans, a physician who offered Internet consultations for Viagra. On May 12, 2000, BOMEX imposed disciplinary action against another Arizona physician relating to Internet prescribing.¹³² BOMEX issued an interim order prohibiting Dr. Darryl Mohr from prescribing and dispensing drugs using the Internet as a communication device.¹³³

On August 7, 2000, four individuals and a pharmaceutical supply firm were indicted for illegally offering prescription drugs over the Internet to consumers.¹³⁴ The charges against the parties alleged conspiracy, mail fraud, FDCA violations, obstruction of justice and conspiracy to commit money laundering.¹³⁵ The indictment charged that the purpose of the conspiracy was to collect fees for non-existent medical consultations and to sell prescription drugs, including Viagra, Xenical, Celebrex, Propecia, and Claritin, to consumers who did not have valid prescriptions written by a licensed medical practitioner.¹³⁶

In another case, the Ohio State Medical Board took action against a physician who prescribed drugs over the Internet.¹³⁷ Dr. Lee Thompson of Dublin, Ohio operated an Internet pre-

132. In the Matter of Darryl Joseph Mohr, M.D., Board Case No. 13420 (Az. Board of Med. Examiners, May 12, 2000), *available at* <http://www.bomex.org/docimages/11224-20000512.pdf> (last viewed on Feb. 23, 2001).

133. *Id.* at 4. The order stated:

[Dr. Mohr] is restricted from prescribing or dispensing prescription medications or prescription only devices for any individuals and/or patients, in this or any other jurisdiction or locale, unless [Dr. Mohr] has conducted a personal physical examination of the patient. The aforementioned restriction includes, but is not limited to, [Dr. Mohr] using a computer or other electronic device to communicate with any individual in any jurisdiction or locale via the internet (or other electronic medium of communication) for the purpose of prescribing and/or dispensing any medication, drug, controlled substance or prescription only device.

Id.

134. Press Release, U.S. Dept. of Justice, *Indictment in Internet Sale of Prescription Drugs* (Aug. 7, 2000), *available at* <http://www.usdoj.gov/opa/pr/2000/August/460civ.htm>.

135. *Id.*

136. *Id.*

137. Tim Doulin & Mark D. Somerson, *Doctor Indicted in Web Drug Case*, COLUMBUS DISPATCH, July 10, 1999, at 1A.

scribing site, an activity that resulted in a drug trafficking indictment.¹³⁸ The offense, chargeable as a felony, was reduced to a misdemeanor in exchange for the relinquishment of his license to practice medicine in Ohio.¹³⁹

Under Illinois law, prosecution of Internet prescribing under the Medical Practice Act, is possible if determined that no *bona fide* physician/patient relationship had been established prior to prescribing and dispensing a prescription medication.¹⁴⁰ The Illinois Board of Medicine has not issued a formal policy statement against prescribing via the Internet. However, it has sanctioned a physician for such activities.¹⁴¹ In an Illinois action in 1999, Dr. Robert Filice was sanctioned by the Illinois Department of Professional Regulation ("IDPR") in connection with an alleged Viagra death.¹⁴² Over the Internet, Dr. Felice had prescribed Viagra to the now deceased patient based solely on a one-page health form.¹⁴³ No examination of, or discussion with, the patient occurred.¹⁴⁴

In 2000, the IDPR also took disciplinary actions against other licensees providing therapeutic advice and issuing prescriptions without a face-to-face consultation.¹⁴⁵ In one case, Dr. David Mayer was sanctioned in connection with his operation of a telephone advice service.¹⁴⁶ Dr. Mayer was reprimanded and fined by the IDPR for allowing his father, a board certified physician licensed in Michigan at the time of the incident, to answer the medical questions of an Illinois resident who called 1-800-ASK-ADOC.¹⁴⁷ Additionally, in February 2000, Dr. Avner Kaufman of Palos Heights, Illinois was suspended for prescribing medica-

138. *Id.*

139. State of Ohio v. Thompson, No. 99-cr-3644; *see also* Doulin & Somerson, *supra* note 137.

140. 225 ILL. COMP. STAT. ANN. 60/1-49 (West 2000). An Illinois physician dispensing drugs to individuals other than his *bona fide* patients would also be subject to prosecution under the Illinois Pharmacy Practice Act of 1987. 225 ILL. COMP. STAT. 85/1-40 (West 2000). This act requires the physician to register at a pharmacy if engages in drug dispensing activities. *Id.* The exception to this is if the physician meets the limited exceptions provided for a physician who is dispensing prescriptions to his *bona fide* patients. 225 ILL. COMP. STAT. 85/1-4 (West 2000).

141. Press Release, Naperville Physician's License Temporarily Suspended for Prescribing Viagra On-Line (May 5, 1999), available at <http://www.state.il.us/dpr>.

142. *Id.*

143. *Id.*

144. *Id.*

145. Illinois Department of Professional Regulation, Monthly Disciplinary Report, July 2000, available at <http://www.dpr.state.il.us/news/discipln/> (2000).

146. *Id.*

147. *Id.*

tions to patients he never examined and for asserting that he had no intention of altering his practice.¹⁴⁸

In October 1999, Illinois Attorney General Jim Ryan filed four lawsuits against Web-based pharmacies and out-of-state physicians.¹⁴⁹ The grounds for these suits stated that the physicians and pharmacies involved in the Internet business were engaging in consumer fraud and were not licensed in the State of Illinois.¹⁵⁰ In commenting on the actions at a press conference, the Attorney General asserted that "Internet [drug] sales in and of themselves are not illegal. But you can't use the Internet to sell prescription drugs if you're not a licensed doctor or you're not a registered pharmacy. That is illegal."¹⁵¹ One might infer that the Attorney General meant to emphasize that while some Internet transactions would be assessed on a case-by-case basis, those not involving licensed professionals would be considered *per se* illegal.

Some of the jurisdictional issues involved in regulating Internet conduct raise constitutional questions. This is particularly true when determining the treating health care provider's state of licensure vis-a-vis the patient's state of residence. In connection with Internet prescribing activities, the Oklahoma has reviewed the authority of one of its professional licensure board's to regulate a physician located and licensed outside of Oklahoma based on that out-of-state physician's treatment of an Oklahoma resident.¹⁵² This issue was analyzed in light of the limitations placed on the states by the Commerce Clause of the United States Constitution.¹⁵³ In an advisory opinion, the Oklahoma Attorney General analyzed the whether the Oklahoma Board of Dentistry could regulate dental services provided to an Oklahoma resident via the Internet.¹⁵⁴ The case involved an Oklahoma resident who suffered an allergic reaction to antibiotics which were prescribed over the Internet based

148. Illinois Department of Professional Regulation, Monthly Disciplinary Report for Feb. 2000, *available at* <http://www.dpr.state.il.us/news/discpln/> (2000).

149. *Illinois v. ExpressMed*, No. 99-ch-452 (Sangamon Cir. Ct., Springfield, Ill. Oct. 21, 1999).

150. Douglas Holt, *State Sues Out-of-State Internet Drug Dispensers*, CHI. TRIB., Oct. 22, 1999, §2, at 1.

151. *Id.*

152. Op. Okla. Att'y Gen. 00-041 (Aug. 30, 2000), *available at* <http://www.oklegal.onenet.net/oklegal-cgi/isearch> (2000) (on file with author).

153. U.S. CONST. art. I, § 8.

154. Op. Okla. Att'y Gen., *supra* note 152.

on the resident's online description of her dental problems.¹⁵⁵ The Attorney General held that Oklahoma may assert jurisdiction over out-of-state parties who affect Oklahoma residents via the Internet, in the same manner as the state's dental practice act is applied to in-state parties.¹⁵⁶ The test cited for determining jurisdiction is: (i) whether the actor purposefully directed his or her activity in a substantial way toward Oklahoma residents; and (ii) whether the actor knew, or should have known, that the resulting harm was likely to be suffered in Oklahoma by his or her actions.¹⁵⁷

3. Legislative Actions

Arizona was one of the first states to amend its physician practice statute to specifically address Internet prescribing.¹⁵⁸ Passed in April 2000, Arizona's statute now provides that a physician's prescription order via the Internet constitutes *unprofessional conduct*.¹⁵⁹ Although the provision does not specifically address Internet prescribing, it was proposed and enacted to address such practices.

In California, the legislature passed Senate Bill 1828, effective January 1, 2001, which amends California's physician practice statute.¹⁶⁰ This bill stipulates that it is unprofessional conduct for a physician to prescribe, dispense, or furnish dangerous drugs or dangerous devices on the Internet without a good faith

155. *Id.*

156. *Id.* The Attorney General qualified this finding stating "whether jurisdiction exists will depend on the unique facts of each case and the extent to which the out-of-state actor avails himself or herself to the privilege of doing business with people residing in Oklahoma." *Id.*

157. *Id.* An inquiry to the Oklahoma Board of Dentistry revealed that while the question presented to its Attorney General was based on authentic complaint, the Board of Dentistry has not taken any action against the provider involved in the matter. Soon after the Attorney General Opinion was issued the Oklahoma Board of Medical Licensure and Supervision began working on a policy on Internet prescribing. See also *Police Web Prescribing*, AMERICAN MEDICAL NEWS (July 26, 1999), at http://www.ama-assn.org/sci-pubs/amnews/amn_99/edit0726.htm.

158. See H.B. 2145, 44th Leg., 2d. Reg. Sess. (Az. 2000). House Bill 2145 signed by the Governor on April 10, 2000, amends the definition of "unprofessional conduct" in the physician practice statute to include: "Prescribing, dispensing or furnishing a prescription medication or a prescription-only device as defined in section 32-1901 to a person unless the licensee first conducts a *physical examination* of that person or has previously established a *doctor-patient relationship*." *Id.* (emphasis added). The general prohibition does not apply to: (i) a physician who provides temporary patient supervision on behalf of the patient's regular treating physician; or (ii) in emergency situations. *Id.*

159. *Id.*

160. S.B. 1828, 1999.00 Reg. Sess. (Cal. 2000).

prior examination and medical indication for the drug or device.¹⁶¹ The bill also provides a penalty of up to \$25,000 per occurrence; and it requires reporting a physician licensed outside of California to that physician's professional licensing authority.¹⁶² The California legislation also provides a similar regulatory framework for discipline under the pharmacy practice statute for improper dispensing activities carried out on the Internet.¹⁶³

The State of Virginia requires that a *bona fide* physician/patient relationship exist prior to prescribing any drug therapy.¹⁶⁴ Virginia has specifically reviewed whether a *bona fide* physician/patient relationship can exist when the practitioner writes a prescription to a patient whom he has "examined" via a questionnaire completed online.¹⁶⁵ Prior to enactment of HB 1437 there were no specific laws or regulations governing or defining such a relationship. However, Virginia House Joint Resolution 759 charged the Virginia Board of Medicine, in consultation with the Board of Pharmacy, to examine the sale of prescription drugs over the Internet.¹⁶⁶ In this resolution, lawmakers expressed several concerns, which included, (i) consumers' ability to purchase powerful drugs through the Internet without ever seeing a doctor; (ii) fear that patients in Virginia could be harmed; and (iii) the illegal prescribing practices of out-of-state physicians not licensed to practice in Virginia.¹⁶⁷

In returning its report to the legislature, the committee summarized problems with the current practices of many of the Internet drug sites as follows: (i) no physical examination of the patient; (ii) no evaluation of the patient to determine if the drug might cause direct or indirect—by way of side effects—harm to the patient; (iii) no follow-up with the patient or continuity of care; (iv) no prospective drug utilization review by an online pharmacy to detect possible drug interactions or contraindications; (v) the concern that a patient would not likely report the use of a drug ordered online to a pharmacist conducting a drug utilization review for another prescription so drug interaction would go undetected; and (vi) the elusiveness of the sites—if

161. *Id.*162. *Id.*163. *Id.*

164. H.B. 1437, Va. 2000 Sess. (Va. 2000).

165. *Id.*

166. H.J.R. 759, Va. 1999. Sess. (Va. 1999).

167. *Id.*

investigated, they are quickly closed down and reopened under another name.¹⁶⁸

The committee specifically noted that the presence of an adequate medical record is an essential part of a valid physician/patient relationship. An adequate medical record should contain the following components: (i) an appropriate history and physical examination (if pain is present and controlled substances prescribed, the assessment of pain, substance abuse history, and co-existing diseases or conditions should be recorded); (ii) diagnostic tests when indicated; (iii) a working diagnosis; (iv) a treatment plan; and (v) dated, written documentation of all prescriptions including the medication's name, strength, dosage, quantity and number of refills.¹⁶⁹

Based on the study recommendations, the State of Virginia enacted House Bill 1437.¹⁷⁰ This legislation expands the definition of a "*bona fide* practitioner/patient relationship" to mean that the practitioner, prior to prescribing a drug, has (i) obtained or has access to a readily available medical and drug history, (ii) communicated the benefits and risks of the drug being prescribed, (iii) performed an appropriate examination of the patient, and (iv) initiated additional interventions and follow-up, if needed.¹⁷¹ The legislation also prohibits out-of-state pharmacists from dispensing any drugs to patients in Virginia that do not result from a *bona fide* practitioner/patient relationship.¹⁷² Further, no prescription is to be filled by such pharmacists unless there is a *bona fide* practitioner-patient-pharmacist relationship.¹⁷³

The entities participating on the task force include Virginia's Board of Pharmacy, its Board of Medicine, health care associations, employer groups and business groups.¹⁷⁴ The task force is charged with (i) reviewing current rules and statutes potentially affecting Internet prescribing and health care; (ii) reviewing other states' regulatory schemes, along with the federal regulatory scheme, for regulating Internet health care activity; (iii) discussing security and privacy issues; and (iv) making

168. *Id.*

169. *Id.*

170. H.B. 1437, Va. 2000 Sess. (Va. 2000).

171. *Id.*

172. *Id.*

173. *Id.*

174. *Id.*

recommendations for agency rules and/or statutory changes to address Internet health care delivery.¹⁷⁵

Moreover, other states, such as Iowa¹⁷⁶ and Michigan,¹⁷⁷ have established working groups to study Internet drug sales. In January 2000, the State of Michigan appointed a Task Force on Internet Pharmacies and Prescribing to its Bureau of Health Services.¹⁷⁸ Other states are relying on their existing agency governing bodies to formulate a regulatory position and enforcement strategy. As enforcement opportunities arise, other regulatory agencies may also become involved as they field complaints about their licensees.

As the agencies regulating Internet drug continue to enforce laws and rules restricting the operation of Internet websites selling prescription drugs, one might expect the availability of this service to decline. However, in the meantime, consumers are gaining more awareness of the uses of a variety of prescription drugs while pharmaceutical companies are successfully developing an abundance of new drugs.¹⁷⁹ It seems likely in this environment, one in which direct-to-consumer advertising continues on a broad scale basis,¹⁸⁰ that patients will and (assuming that the drugs the FDA approves are safe and effective) should seek alternative means for procuring those drugs with greater ease than can be accomplished through traditional means of prescription drug procurement. In considering what alternative means might be available, one can consider the policy objectives in regulating drugs articulated by the FDA.

175. *Id.*

176. Iowa, 78th General Assembly, House Concurrent Resolution 124; Senate Concurrent Resolution 120.

177. Michigan Bureau of Health Services, *Task Force on Internet Pharmacy and Prescribing*, available at <http://www.cis.state.mi.us/bhser/itf.home.htm> (Oct. 2000).

178. *Id.*

179. From 1992 through July 2000, the FDA approved 277 new drugs (about 33 per year), compared to 189 from 1984 to 1991 (about 24 per year). See Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Profession, Report to Congress, *The Pharmacist Workforce: A Study of Supply and Demand for Pharmacists*, Dec. 12, 2000.

180. See Timothy Pratt & John Kuckelman, *The Learned Intermediary Doctrine and Direct-to-Consumer Advertising of Prescription Drugs*, 51 FED'N INS. & CORP. COUNSEL Q 17 (2000).

III. EXPANDING CONSUMER ACCESS TO PRESCRIPTION DRUGS THROUGH PHARMACISTS

As drug therapy becomes an even more significant component of modern medicine—resulting in cures for fatal diseases, treatment of acute conditions and management of chronic conditions which have made it possible for people to live longer, more productive lives¹⁸¹—it is reasonable to consider the further expansion of the role of pharmacists beyond their traditional role. Historically, pharmacists been dependent on physician prescribing. Pharmacists are, however, becoming more frequently involved in independent activities, such as mandated and voluntary patient counseling, monitoring of disease outcomes, and other aspects of patient care.

In addition, regulators are gradually expanding the role of pharmacists by granting them limited prescriptive authority, a function which many other health care professionals already enjoy. The concept of pharmacists prescribing is not entirely new but its implementation is substantially novel. Limited prescriptive authority for pharmacists was recommended following an interdisciplinary Conference on Pharmacy Manpower co-sponsored by the University of California School of Pharmacy and the National Center for Health Services Research and Development in September of 1970.¹⁸² A pharmacist's prescriptive authority under protocols has existed in the Indian Health Service since the early 1970s.¹⁸³ Currently, about half of the states currently permit pharmacists some type of prescriptive authority.¹⁸⁴ Idaho, Louisiana, Nebraska, Ohio, and Tennessee, as well as the U.S. territory of Guam, join the growing number of jurisdictions that permit their pharmacists to develop collaborative practice agreements with prescribers.¹⁸⁵ Such agreements generally allow

181. Wayne Anderson, *Pharmacists in the Health Care System*, available at <http://pharmacy.buffalo.edu/about/paper.shtml> (last visited May 20, 2001).

182. See <http://www.powerpak.com/CE/PharmLaw/lesson.cfm>.

183. Indian Health Manual, 3, Chapter 7, Pharmacy, Section 3-7.3D(2a)(vi); see also Indian Health Service, Department of Health and Human Services Program Memorandum, Oct. 18, 1996 (regarding Designation of Pharmacists as Primary Care Providers with Prescriptive Authority).

184. See Kathy Riley, *Collaborative Prescribing Authority for Pharmacists Gains Momentum*, THE CONSULTANT PHARMACIST, Vol. 1, No. 9 (September 1996).

185. North Carolina Board of Pharmacy, *Twenty-Four States Allow Collaborative Practice Agreements*, Newsletters on the Web (January 1999), available at <http://www.ncbop.org/jan99-4.asp>.

pharmacists to initiate and/or modify patients' medication regimens pursuant to an approved protocol.¹⁸⁶

Federal law establishes whether a drug requires a prescription, but does not dictate who may prescribe.¹⁸⁷ This came about as a result of the Durham-Humphrey Amendment of 1951.¹⁸⁸ Ordinarily, prescriptive authority is explicitly given to physicians. For example, the New York State Medical Practice Act defines the practice of the profession of medicine as "diagnosing, treating, operating, or prescribing for any human disease, pain, injury, deformity, or physical condition"¹⁸⁹ The authority to prescribe drugs, however, is not exclusively vested with physicians. For example, under the Dependency Producing Drugs Act, Connecticut defines a prescribing practitioner as a "physician, dentist, veterinarian, podiatrist, osteopath, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, or to administer a controlled substance in the course of professional practice."¹⁹⁰ Pharmacy practice acts do not ordinarily authorize pharmacist prescribing, but rather identify the other familiar aspects of pharmacy practice.¹⁹¹ The National Association of Boards of Pharmacy, for example, suggests model language for the definition of pharmacy practice:

"The "practice of pharmacy" means the interpretation, evaluation, and implementation of medical orders; the dispensing of prescription drug orders; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care in all areas of patient care including primary care; and the responsibility for compounding and labeling of drugs and devices (except labeling by a manufacturer, repackager, or distributor of non-prescription drugs and commercially packaged legend drugs and devices), proper and safe storage of drugs and devices, and maintenance of proper records for them."¹⁹²

186. *Id.*

187. William Hoffman, *Hubert Humphrey: Retrospective of a Living Room Shoot-Out*, THE DORIC COLUMN (April 3, 2001), available at <http://mbbnet.umn.edu/doric/humphrey.html>.

188. 21 U.S.C. §333 (West 2000).

189. N.Y. EDUC. LAW §6521 (McKinney 2000).

190. CONN. GEN. STAT. §21a-240(43) (2000).

191. See, e.g., Illinois Pharmacy Practice Act, 225 ILL. COMP. STAT. 85/3.

192. National Association of Boards of Pharmacy, Model State Pharmacy Act §104.

In this definition, prescribing is not one of the activities encompassed within the definition of the practice of pharmacy. The broad definition of pharmaceutical care under the Model Act leaves open the possibility that pharmacy activities may be expanded under appropriate legal authority. Specifically, the Model Act states: "the provision of drug therapy and other patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process. . . ." ¹⁹³ This broad definition provides state boards substantial autonomy in the adoption of implementing rules.

On April 1, 2001, rules became effective in North Carolina which govern clinical pharmacist practitioners. A clinical pharmacist practitioner ("CPP") is a licensed pharmacist who is approved to provide drug therapy management under the direction and supervision of a licensed physician who has provided written instructions for a patient and disease-specific drug therapy that may include ordering, changing, or substituting therapies or ordering tests. CPPs must be approved by the state boards of pharmacy and medicine, must have an unrestricted license and must meet specific training and education qualifications. The supervising physician who has a signed collaboration agreement with the CPP must be readily available for consultation with the CPP and must review and countersign each order written by the CPP within seven days. ¹⁹⁴

Florida has enacted a program which permits pharmacists a limited degree of autonomy in ordering drugs. Pharmacists may order and dispense certain drugs from a formulary created by a committee comprised of Board Members from pharmacy, medicine, and osteopathy. The pharmacist may order a quantity of drug not to exceed the "standard course of treatment" and patients must be advised to seek the advice of an appropriate health care provider if the complaint does not improve upon completion of the drug regimen. Patient profiles must be maintained for patients for whom the pharmacist orders and dispenses drugs. The profile must contain specific information, including the patient's chief complaint, and a statement regarding the patient's medical history. Other restrictions also apply. For example, the dosage may not exceed the manufacturer's rec-

193. *Id.*

194. 21 N.C. ADMIN. CODE 46.3101.

ommendations and drugs cannot be ordered for a pregnant or nursing patient.¹⁹⁵

A protocol program such as the one in Florida creates, in effect, a third class of drugs. Drugs that are transitional or intermediate between requiring a physician's order and unrestricted OTC sale. Drugs in this class under such a regulatory scheme would be available directly to consumers, but only if sold by a pharmacist.

Under a planned regulatory scheme providing limited prescriptive authority to pharmacists, there are still a number of barriers to access. Significantly, in December 2000 as a result of a congressional mandate, the Bureau of Health Professions of the Health Resources and Services Administration issued a report reviewing the extent of the supply shortage of qualified pharmacists in the United States. This study concluded that there have been sharp increases in the demand for pharmacy services and that a shortage of pharmacists is emerging. Under either independent or collaborative prescribing schemes, there is an expectation that the services provided by pharmacists will be expanded. There may not, however, be adequate reimbursement for such enhanced services. At the same time, because of increases in the complexity of medications, polypharmacy and the growing geriatric population, patient pharmaceutical counseling becomes more important than ever. Further, the typical drug store setting does not provide physical privacy that patients should be able to expect in a health care counseling setting. Some have cited certain logistical problems with the traditional pharmacy setting as a basis for moving toward Internet dispensing of drugs.¹⁹⁶ None of these items, however, individually or together, present inherent barriers to improving access to prescription drugs through the expansion of pharmacists' scope of practice. On the other hand, there is currently no feasible solution to the primary problem identified in connection Internet prescribing (*i.e.*, the absence of a face-to-face encounter). A recent report of patient and provider satisfaction with pharmacist prescribing reviewed the success of the pilot program currently underway in Washington State where a pharmacist, pursuant to a collaborative agreement with a physician may prescribe emer-

195. FLA. STAT. ANN. § 465.186 (2) (West 1996); Florida Rule 64B16-27.220.

196. See, *e.g.*, Megan Flaherty, *Drugs and the Internet: Online Pharmacists Serve the Electronic Neighborhood*, available at <http://healthcare.monster.co.uk/articles/onlinepharmacists/> (last visited May 20, 2001).

gency contraception pills.¹⁹⁷ It concluded that pharmacists, prescribers and consumers expressed overall satisfaction with and favorable opinions about the program and encouraged the expansion of the program to other states.¹⁹⁸

CONCLUSION

As discussed in Part II of this article, there is currently a patchwork of state laws addressing Internet prescribing. Regulators must collaborate on this issue and address it further at a federal level which, likely, will only clarify the regulatory bias against the practice. On the other hand, to enhance access to medically necessary drug therapies, each state government that has not done so should develop a comprehensive policy to address prescription drug access issues. Many of the recent current events relating to issues such as Internet prescribing, prescription drug coverage initiatives, direct-to-consumer drug advertising, OTC status controversies, dietary supplements and medication errors should help to fuel the debate over the appropriate delivery system for drug therapies. In conclusion of this review, I cannot delve into a discussion of the role of the patient and his responsibility to be a conscientious and accountable health care consumer. The patient's responsibilities (along with rights), however, should also be weighed and closely considered as lobbyists push toward enhancement of drug therapies and services, because, along with greater access to health care services, comes the debate over who pays for such access.¹⁹⁹

197. Sunshine D. Sommers, et al., *The Emergency Contraception Collaborative Prescribing Experience in Washington State*, 41 J AM. PHARM. ASSOC. 60, 2001.

198. *Id.*

199. And, lest we not forget, this ruckus over Internet prescribing really started over that mischievous little, blue pill that, arguably, could not be credited with saving a single life but that certainly has made more than a few people happy and more satisfied! But that topic is something to think about on another day.