Pharmaceutical Dispensing in the "Wild West": Advancing Health Care and Protecting Consumers Through the Regulation of Online Pharmacies

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NOTES

PHARMACEUTICAL DISPENSING IN THE "WILD WEST": ADVANCING HEALTH CARE AND PROTECTING CONSUMERS THROUGH THE REGULATION OF ONLINE PHARMACIES

The "explosion"\(^1\) of Internet pharmacies\(^2\) on the World Wide Web has created a wealth of opportunities for improvements in the provision of health care.\(^3\) Unfortunately, the Internet's inherent characteristics that enable these positive developments also provide fertile soil for modern day "snake oil salesmen"\(^4\) and "unscrupulous marketers."\(^5\) Problems such as assuring the quality of medical care, guaranteeing the accuracy of exchanged information, fraud, and abuse have rapidly become evident.\(^6\) While pharmaceutical dispensing through traditional pharmacies is highly regulated, guidance concerning the regulation of dispensing on the Internet is lacking. The market's swift emergence, the unique jurisdictional elements of its operation, and the diversity of involved governing bodies have regulators struggling to devise the ideal mechanism to address the challenge.\(^7\)

2. Pharmacies that offer services on the World Wide Web are referred to by many names, including: Internet pharmacies, online pharmacies, e-pharmacies, and cyber-pharmacies. For the purposes of this Note, these terms will be used interchangeably.
3. See infra notes 46-53 and accompanying text.
6. See infra notes 67-99 and accompanying text.
Historically, pharmaceutical services have been governed predominantly by the states. In this respect, a number of states' attorneys general and state licensing boards have prosecuted online pharmacy offenders under existing state pharmacy, consumer protection, and unprofessional conduct regulations.\textsuperscript{8} Alternatively, a few states have passed new laws dealing explicitly with online pharmacies.\textsuperscript{9} On the prosecutorial side, the Food and Drug Administration (FDA) has also joined the states in a limited role as provided by the Food, Drug, and Cosmetic (FD&C) Act.\textsuperscript{10} In addition, the American Medical Association (AMA) and the National Association of Boards of Pharmacy (NABP) have taken an active role by respectively formulating recommendations and instituting a certification program for online pharmacies.\textsuperscript{11} Concomitantly, Congress has requested information and heard testimony concerning online pharmacies.\textsuperscript{12} As a result, Congress is currently considering the implementation of the Internet Pharmacy Consumer Protection Act as an amendment to the FD&C Act to provide minimum standards for online pharmacy websites.\textsuperscript{13}

This Note explores the regulatory challenges of providing pharmaceutical products via the Internet in the United States. It begins with a review of the existing regulatory scheme for prescription drugs in the United States as well as the development of online pharmacies. It then examines the unique jurisdictional, public safety, and abuse issues associated with Internet dispensing, and reviews the applicable legislative history to provide a grounded understanding of the subject. Following a discussion of the actions of state and federal regulators, legislators, and health care professionals, the Note analyzes their respective approaches. Finally, it recommends a collaborative approach, describing specific steps for each interested party, that attempts to protect the rights of legitimate providers while reducing the risks posed by disreputable operators.

\textsuperscript{8} See infra notes 193-207 and accompanying text.
\textsuperscript{9} See infra notes 213-18 and accompanying text.
\textsuperscript{11} See infra notes 225-41 and accompanying text.
\textsuperscript{12} See infra notes 122-46 and accompanying text.
\textsuperscript{13} See infra notes 156-62 and accompanying text.
The Pre-E Era

Traditionally, the states have regulated the dispensing of prescription drugs.\(^{14}\) In addition to the practical regulations regarding dispensing,\(^{15}\) state pharmacy and medical boards regulate the licensing\(^{16}\) and professional standards\(^{17}\) of health care practitioners. The decision to defer responsibility for pharmacy regulation to the states stems from principles elucidated in the Constitution.\(^ {18}\) In particular, the Tenth Amendment preserves the power of the states to regulate what is not directly regulated by the federal government.\(^ {19}\) The states, however, are not the sole arbiters of pharmaceutical law.

The Commerce Clause of the Constitution enables Congress to regulate commerce among the states.\(^ {20}\) With this in mind, the Federal FD&C Act was enacted in 1938 to control the sale of drugs and authorize only those that are safe and effective.\(^ {21}\) These provisions were devised well before the advent of the Internet, although their purpose was akin to the desires of current


\(^{15}\) See, e.g., N.J. STAT. ANN. § 45:14-4.4 (West Supp. 2000) (prohibiting pharmacists from filling a prescription not issued on a New Jersey prescription blank or lacking required prescriber/facility information); VA. CODE ANN. § 54.1-3410 (Michie 1998) (describing requirements for a licensed pharmacist to legally sell and dispense a drug).

\(^{16}\) See, e.g., N.J. STAT. ANN. §§ 45:9-6 (requiring a license to practice medicine or surgery), 14-6 (requiring pharmacists be registered to practice) (West 1995); VA. CODE ANN. §§ 54.1-2900 to -2910.1, -2929 to -2957.3, -3304, -3304.1, -3310 to -3319 (Michie 1998 & Supp. 2000) (presenting general and specific provisions dealing with various aspects of licensing health care professionals, including pharmacists and physicians).

\(^{17}\) See, e.g., VA. CODE ANN. §§ 54.1-2914, -3315 (Michie 1998) (describing actions deemed unprofessional conduct).

\(^{18}\) See U.S. CONST. amend. X.

\(^{19}\) "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." Id.

\(^{20}\) "The Congress shall have Power . . . [t]o regulate Commerce . . . among the several States . . . ." U.S. CONST. art. I, § 8, cl. 3.

regulators: "to protect patients from injuries resulting from unsafe and counterfeit drugs and from illicit practice of medicine and pharmacy." While there may be an inherent assumption, given its name, that the FDA is the sole authority for the enforcement of food and drug issues, at least two other agencies wield significant influence in this arena. The Drug Enforcement Administration (DEA) regulates narcotic substances via the Controlled Substances Act, and the Federal Trade Commission (FTC) governs the advertising of over-the-counter medications. The requirements of this integrated system of regulations and authorities at the state and federal level have provided "an effective safety net to protect the U.S. public from harmful or ineffective drugs, as well as improper prescribing or dispensing of pharmaceuticals." The development of online pharmacies, however, has torn a significant hole in this net.

The Internet & Online Pharmacies

The Internet has evolved into a remarkable tool for acquiring information (including health care information) and conducting business. A recent Harris Poll indicated that of the 97 million people using the Internet, 74% view health information. While such access is a hallmark of the Internet and has the obvious

25. Henney, supra note 22, at 861.
27. See Online Health: Number of Users Continues to Grow, AM. HEALTH LINE, Aug. 5, 1999, available in LEXIS, News Library, Medical and Health Materials Combined. Additionally, the number of Americans using the Internet for health information, roughly 70 million, increased 16% over seven months. See id.
advantage of empowering its users, the lack of quality control standards and the fact that practically anyone can post information renders the quality of this information particularly suspect. As the editors of the Journal of the American Medical Association described, "[t]he problem is not too little information but too much, vast chunks of it incomplete, misleading, or inaccurate." Although the dangers of incomplete, misleading, or inaccurate information are not only applicable to online pharmacies, the impact of such information is increasingly pronounced, given the recent surge of online pharmacies.

According to Carmen Catizone, Executive Director of the NABP, online pharmacies were among the first e-commerce children of the New Year, born in earnest following the performances of online giants such as Amazon.com during the December 1998 holiday season. At that time approximately twenty-six online pharmacies were identified. This number skyrocketed to over 400 by August

28. Brody remarks about two cases of individuals finding legitimate solutions to individual health ailments that had gone previously uncured. See Brody, supra note 5; see also Jeanne Lee, The Internet Can Save Your Life; . . . If it Doesn't Scare You, Mislead You or Rip You Off First: Here's How to Get the Best Health Info on the Web, MONEY, Mar. 2000, at 118, 122 (describing one patient's use of the Internet, including professional search companies, to aid in the diagnosis and treatment of her rapidly deteriorating eyesight).


30. Brody, supra note 5.


33. See William Glanz, FDA Warns Against Cyber-drugs: Agency Vows to More Closely Scrutinize On-line Pharmacies, WASH. TIMES, July 31, 1999, at C7; Online Pharmacies: Feds Push For More Regulation, AM. HEALTH LINE, Aug. 2, 1999, available in LEXIS, News Library, Medical and Health Materials [hereinafter Online Pharmacies]. Soma.com, taken from the Greek "for the body," was perhaps the first Internet pharmacy appearing in the middle of January 1999. Soma.com is 'Dedicated to Improving Patients' Health,' CHAIN DRUG REV., Apr. 26, 1999, at 46, LEXIS, News Library, Medical and Health Materials Combined. In the process Soma.com marketed itself as "a retail pharmacy first and foremost," attempting to distinguish itself by offering only health care products, avoiding cosmetics and beauty aids, and attempting to establish a respected reputation as a retail pharmacy, thus foreshadowing the concerns of patients, practitioners, and regulators. Id. At that time planetRx.com and Drugstore.com had also announced plans to launch before the end of
1999.\(^{34}\) Given the potential financial stakes\(^{35}\) in this emerging market, one author remarked, "the battle for customers could make the online bookstore competition look like a playground scuffle."\(^{36}\)

While Peter Neupert, the CEO of drugstore.com, doubts that online pharmacies signal the end for traditional drugstores, he predicts that within five years they will capture 20% to 25% of the pharmaceutical market.\(^{37}\) Many of the traditional "brick and mortar"\(^{38}\) chain drugstores have launched or invested in existing

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^{35}\) See Online Pharmacies, supra note 33; Roan, supra note 32.

^{36}\) While approximately $165 billion was spent on pharmaceuticals in 1998, including prescriptions, over-the-counter products, personal care items, vitamins, "wellness' products," beauty aids, and cosmetics, see Tedeschi, supra note 33, Forrester Research anticipates that Internet prescription sales will exceed 15 billion dollars by 2004; see Steve Tarter, *Pharmacies Must Change to Adjust to New Internet Customers*, J. STAR (Peoria, IL), Mar. 21, 2000, available in 2000 WL 16487878. If Wall Street is any indicator, however, all of the existing online pharmacies may not be around in 2004 to enjoy the potential financial rewards. See Associated Press, *Tough Times for Online Drug Stores*, June 24, 2000, available at http://www.nytimes.com (hypothesizing that planetRx.com's financial woes are due in part to its lack of affiliation with a traditional "brick and mortar" provider, and describing the precipitous drop in stock prices experienced by planetRx.com and Drugstore.com); Sam Howe Verhovek, *Dot-Com Leaders Await a Shakeout of Losers*, N.Y. TIMES, Apr. 23, 2000, at A12 (describing drugstore.com's focus on customer retention as the company anticipates a market shakeout that “will separate the men from the boys”).

^{37}\) Tedeschi, supra note 33. Americans spent roughly five times the amount of money on prescriptions compared to the U.S. book market. Depending on the source, the number ranges from $90 billion to $120 billion. Compare Susan Ferraro, *Pharmacy Futures, Our Online Drugstore Test-Drive Found Them Virtually Useless—For Now*, DAILY NEWS, Apr. 11, 1999, at 16 (indicating the expenditure was $102 billion), with Tedeschi, supra note 33 (indicating the expenditure for prescriptions alone was $90 billion). See also Herman, supra note 4 (noting predictions by health industry professionals that Internet pharmacy sales may compare with the success of Internet music and book sales).

^{38}\) See Rubin, supra note 14. It is unclear, however, if such predictions are the chicken or the egg. In other words, have the potential financial gains in online pharmacy enticed the entry of the traditional chain drugstore leaders, or is their current presence in the online market the reason why online industry executives such as Neupert are making such predictions? Cf. Online Pharmacies Convene Summit, *Vow to Stop Fraudulent Pharmacy Web Sites*, BNA HEALTH L. REP., Nov. 18, 1999, at 1829, available in LEXIS, Area of Law-By Topic, Healthcare & Medical (citing a Corporate Research Group report predicting online pharmacies will obtain one to two percent of the market by 2001).

online pharmaceutical services.\textsuperscript{39} While some are unconvinced of the financial rewards of online services,\textsuperscript{40} many participants have forged real alliances in the virtual world in an effort to gain access to pharmacy benefit plan members\textsuperscript{41} and a broad range of insurance

\textsuperscript{39} CVS purchased Soma.com in May 1999 for $30 million, and Rite Aid is a significant investor in Drugstore.com. See Brandon Copple, \textit{The Reluctant Webster}, \textit{Forbes}, Oct. 18, 1999, at 78. Others such as Drug Emporium and AARP Pharmacy Service also offer online prescription services. See \textit{The Ins and Outs of Online Drugstores}, \textit{Consumer Rep.}, Oct. 1999, at 42.

\textsuperscript{40} A large factor in Walgreen's success is convenience, and not the type offered in a cyberpharmacy. Perhaps considerations such as this caused Walgreen's Chairman, Daniel Jorndt to remark, "We're not sure dot.com pharmacies will ever make money." Copple, supra note 39; see also \textit{Finding the Proper Balance Between Stores and the Net}, \textit{Chain Drug Rev.}, Aug. 30, 1999, at RX70, \textit{available in LEXIS}, News Library, Medical and Health Materials Combined (highlighting a Jupiter Communications Report predicting that online purchasing will produce only an incremental business of roughly four percent by 2002). In other words, traditional brick and mortar pharmacies need to be more concerned with preventing the loss of customers to online providers than with increasing revenues through Internet sales.

\textsuperscript{41} "The real key to the rise of online drug stores will be the participation of pharmacy benefits managers who handle about 85 percent of the prescription medication consumed by the nation's insured." Tarter, supra note 35 (quoting a Forrester Research analyst). Merck & Co., the nation's largest pharmacy benefit manager, and CVS, the nation's second largest retail pharmacy chain, agreed to connect their Internet sites. See Robert Berner, \textit{Merck, CVS Agree to Link Internet Sites}, \textit{Wall St. J.}, Oct. 6, 1999, at A3. As a result, CVS agreed to sell the roughly 7000 over-the-counter products that it offers on its own website on an Internet site run by Merck-Medco and Merck-Medco will permit its members to obtain prescriptions via CVS's website. See id. Online pharmacies experienced problems when the pharmacy benefit managers (PBM) they contracted with began canceling their contracts. As a result, many became allied with major retail chain pharmacies or PBMs. See Burson, supra note 1. A component of the partnership between Rite Aid's purchase of twenty-five percent of drugstore.com was drugstore.com's access to the participants in Rite Aid's pharmacy benefit management business. See Nancy Tarleton Landis, \textit{Express Scripts, PlanetRx.com Forge Agreement}, 56 \textit{Am. J. Health-Sys. Pharmacy} 1918 (1999); Berner, supra at A3. Until recently Rite Aid was the parent company of PCS, the second largest pharmacy benefit manager in the U.S. See Landis, supra at 1918. However, Rite Aid agreed to sell PCS to Advance Paradigm Inc. for $1 billion. See Lorraine Mirabella, \textit{Rite Aid Reports Wider Losses}, \textit{Baltimore Sun}, Oct. 11, 2000, at Business, 1C, \textit{available in LEXIS}, News Library, News Group File. PlanetRx.com and Express Scripts, the third largest pharmacy benefit manager in the United States, reached an agreement identifying planetRx.com as the sole Internet pharmacy to provide prescription and nonprescription products to Express Scripts members. See id. This agreement was later restructured making planetRx.com the "preferred, but not exclusive, on line pharmacy" for Express Scripts. \textit{News Briefs}, 57 \textit{Am. J. Health-Sys. Pharmacy} 1479 (2000). As a result of the aforementioned agreements, the three largest pharmacy benefit managers have secured agreements to provide their customers with online pharmaceutical services accounting for approximately 137 million Americans. See id. (referring to 36 million members); Berner, supra, at A3 (referring to links with nearly 51 million Americans); PCS Health Systems, Information Center, Facts and Figures, at
providers.\textsuperscript{42} Even with the trepidation of some large chain pharmacies, however, some smaller family-owned pharmacies that have been on the decline in recent years\textsuperscript{43} view the online pharmacy as an opportunity to expand and compete more effectively.\textsuperscript{44} An improved ability to compete may be crucial in an environment in which perhaps the only thing declining faster than the number of independent pharmacies is the rate of reimbursement offered by third-party payors.\textsuperscript{45} Although the experts disagree whether online pharmacies will be a boon for independents, it will likely be beneficial for consumers.\textsuperscript{46} The nature of the Internet clearly offers some distinct advantages, including additional opportunities for convenient, discrete, quality, cost-effective pharmaceutical services.\textsuperscript{47}

The beneficial potential of online pharmacies is significant. Consider the ability to provide information and products to individuals whose access to conventional pharmacies is restricted because of chronic disease or geography.\textsuperscript{48} Similarly, legitimate

\textsuperscript{42}“These alliances give the online pharmacies access to almost every major insurance plan.” Burson, \textit{supra} note 1. For example, Soma.com went from having 300 participating insurance plans to nearly 9000 after aligning with CVS. \textit{See id.} While the startup electronic pharmacies are attempting to obtain contracts with insurance providers, the existing traditional chain pharmacies have benefited from not having to acquire, but merely extend, their current insurance contracts to address online sales. \textit{See Roan, supra note 32; see also Ferraro, \textit{supra} note 36} (discussing some of the “glitches” associated with using an online pharmacy, including problems associated with insurance coverage).

\textsuperscript{43} \textit{But see} Mike Vogel, \textit{Independent Pharmacies Rebound}, \textit{CHAIN DRUG REV.}, Nov. 22, 1999, at 3, \textit{available in LEXIS, News Library, Medical and Health Materials Combined} (emphasizing that although borderline independent pharmacies are gone, the remaining independents are benefitting from increasing prescription volume and sales).

\textsuperscript{44} Mom-and-pop drugstores like Giannotti’s Pharmacy have established their own web pages. \textit{See Rubin, supra note 37}. In addition, CornerDrugstore.com has registered over 1000 independent pharmacies in the United States for patients to obtain online pharmaceutical services. \textit{See id.} However, not all of the experts agree that online dispensing will benefit independent pharmacists. The loss of impulse buying may have a detrimental effect. \textit{See id.}


\textsuperscript{46} \textit{See Roan, supra note 32}.

\textsuperscript{47} \textit{See id.} Additionally, cyberpharmacies often provide such incentives as access to volumes of reputable health information, such as that offered on the website originated by former Surgeon General Dr. C. Everett Koop, drkoop.com. They also provide twenty-four-hour online consultation, and email reminders for refills. \textit{See id.}

\textsuperscript{48} \textit{See Woodcock, supra note 26}.
options include online prescription transmission, electronic refills, and electronic consults within narrowly defined circumstances. Essentially, online pharmacies, when coupled with legitimate practices, "are just another channel of distribution that some people will find more convenient," according to Dr. John L. Colaizzi, Dean of Rutgers College of Pharmacy. Such benefits are not limited to online pharmacies; technology is also arriving that will improve health care delivery between diverse health care providers and information systems.


50. See Aetna, supra note 49.

51. Such circumstances may occur when the physician has the patient's medical history and physical information, has seen the patient recently, and the patient is under the physician's care. See id.; cf. AMA Promotes E-Mail in Physician-Patient Communications with Suggested Guidelines, BNA HEALTH L. REP., June 22, 2000, at 956, available in LEXIS, Area of Law-By-Topic, Healthcare & Medical (discussing the adoption of email guidelines for patient communication and the adoption of a proposal recommending reimbursement for such electronic communications).

52. Robert Cohen, Regulation of Drugs on the Web: Authorities Struggle to Rein in Business, STAR-LEDGER (Newark, N.J.), July 6, 1999, at 1. (describing legitimate practices as the existence of "a physician-patient relationship," meeting of "ethical considerations," and the following of "standard practices").

The potential advantages of online pharmacies, however, do not exist in a vacuum. They are accompanied by a longer, and potentially more detrimental, list of disadvantages, including: concerns about privacy and the transmission of confidential health information;\(^{54}\) difficulties with insurance coverage;\(^{55}\) length of time associated with the process;\(^{56}\) added costs;\(^{57}\) lack of opportunities for personal uniform contact\(^{58}\) and counseling;\(^{59}\) opportunities for fraud and abuse;\(^{60}\) and the added competition from traditional pharmacies implementing more modern conveniences.\(^{61}\) Additionally, a particular challenge may rest in certain patients themselves. Although older individuals are typically the largest users of

54. See Cassie M. Chew, *Industry Asks: Can HHS Rule Protect Privacy, Promote E-Commerce?*, BNA HEALTH L. REP. Mar. 30, 2000, at 486 (expressing the concern of the Department of Health and Human Services that the "risk of improper uses and disclosures has increased as the health care industry has begun to move from primarily paper-based information systems to systems that operate in various electronic forms"). Such concerns may be addressed by services such as the online credentialing of physicians, recently announced by Intel Corp. and the American Medical Association. See Ann Carrns, *Intel and AMA Form Service to Improve Security of Online Medical Information*, WALLST. J., Oct. 12, 1999, at B6.

55. See Sharon Bernstein, *Ordering Drugs Online Can Still Be a Headache*, L.A. TIMES, Sept. 30, 1999, at C9 (stating that online pharmacies are grappling with "the clunky process of taking orders, verifying insurance and prescription authenticity and delivering the product").

56. Patients may expect standard delivery in five to ten days, and some deliveries deemed "overnight" may take two or three days. See *The Ins and Outs of Online Drugstores*, supra note 39. These limits may be due in part to the fact that some orders are not processed on weekends or holidays. See id.

57. Fees may range from free shipping for first-class mail to twenty dollars for overnight delivery depending upon weight. See id.

58. In a recent survey, 72% of physicians and 76% of pharmacists surveyed believed that Internet pharmacies would provide additional strain on the pharmacist-patient relationship. See Val Cardinale, *Report Predicts Bright On-line Pharmacy Future*, DRUG TOPICS, June 5, 2000, at 27, available in LEXIS, News Library, Medical and Health Materials Combined. But see id. (indicating that most consumers did not believe Internet pharmacies would affect pharmacist-patient relationships).

59. In an era when "pharmaceutical care" is the professional buzzword and pharmacists are encouraged to develop significant patient relationships, the Internet may provide communication advantages and new challenges.

60. See *infra* notes 67-99 and accompanying text.

61. Traditional chain drugstores are implementing new systems such as automated telephone refills, drive-through pick-ups, and continuing with ordinary, customer-friendly services, such as home delivery.
prescription drugs in the United States,\textsuperscript{62} and consequently account for a substantial pool of potential online pharmacy customers, they also represent a segment of the population less likely to have Internet access.\textsuperscript{63} This level of access, however, may already be changing.\textsuperscript{64}

In another aspect of the consumer realm, the FDA and pharmaceutical manufacturers are struggling with regulatory\textsuperscript{65} and liability\textsuperscript{66} concerns surrounding the direct-to-consumer promotion and advertising of pharmaceuticals on the Internet. Even with all of these considerations, a concern that underlies all Internet pharmacy transactions, beyond the mere adequacy of information and accuracy of dispensed products, is the reputability of the entities’ practices. Reputable behavior, or its more troubling

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  \item \textsuperscript{62} "The elderly are the largest consumers of prescription medications . . . because they have the lion’s share of chronic diseases and symptoms." Ronald B. Stewart, \textit{Drug Use in the Elderly, in THERAPEUTICS IN THE ELDERLY} 174 (Jeffrey C. Delafuente & Ronald B. Stewart eds., 2d ed. 1995).
  \item \textsuperscript{63} See Rubin, \textit{supra} note 37. The high incidence of chronic disease in the elderly results in their significant use of maintenance medications. See Stewart, \textit{supra} note 62, at 174. As a result, the regularity and long-term therapy associated with maintenance medications makes the elderly particularly well suited for online prescribing.
  \item \textsuperscript{64} The ability of online pharmacies to capture this potential market is not without hope as those over fifty represent the most rapidly growing subgroup in cyberspace. See Rubin, \textit{supra} note 37.
  \item \textsuperscript{66} PlanetRx.com and drugstore.com have established separate facilities for their prescription and nonprescription inventory in part to avoid potential errors in filling patients orders. See Tedeschi, \textit{supra} note 33. Notably, the New Jersey Supreme Court’s holding in \textit{Perez v. Wyeth Labs Inc.} marked a shift in manufacturers’ potential liability and the importance of the learned intermediary doctrine. \textit{734 A.2d 1245, 1256 (N.J. 1999)} (holding that the “learned intermediary” defense is not available to manufacturers who participate in direct marketing of drugs to consumers). The significance of this holding should not be taken lightly, especially considering the significant number of pharmaceutical companies that reside in New Jersey. New Jersey has been referred to as “the nation’s medicine chest.” See Edward R. Silverman, \textit{Drug Firms Boost New Jersey’s Economy by More than $8 Billion}, \textit{STAR-LEDGER} (Newark, N.J.), Dec. 14, 1997, available in LEXIS, News Library, News Group File. In addition, it remains to be determined, in light of the New Jersey Supreme Court’s holding, the impact rogue Internet pharmacies’ dispensing of products may have on pharmaceutical manufacturers. Pfizer, the maker of sildenafil citrate, known under the trade name Viagra®, filed a complaint with the FTC to prohibit the online dispensing of Viagra® without adequate protection. See Roan, \textit{supra} note 32.
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absence, is at the heart of the debate about online pharmacy regulations.

Internet Prescribing and Safety

Functionally speaking, reputable online pharmacies do not operate much differently from their "brick and mortar"\textsuperscript{67} brothers or mail-order\textsuperscript{68} sisters. Patients contact the pharmacy via the Internet, and after providing the necessary registration and payment information (e.g., name, address, drug allergies, current medications being used, etc.), the pharmacy dispenses a medication from a prescription provided via mail, e-mail, phone, or fax, depending upon the given state’s regulations.\textsuperscript{69} Depending upon the online pharmacy’s parent, the patient may then pick up the prescription at a locally convenient retail site or have the prescription delivered via standard or overnight delivery.\textsuperscript{70} These legitimate sites, while introducing new practical concerns for regulators, are not the predominant problem.

The most dangerous and worrisome sites are those rogue pharmacies that provide patients with prescription medications over the Internet via online doctors’ services with essentially no examination or physician contact.\textsuperscript{71} Consumer demand for these services is being met by a waiting list of physicians, lured by the

\textsuperscript{67} Fleming, supra note 38, at 51.

\textsuperscript{68} Although Merck-Medco is attempting to distinguish its mail order component from online pharmacies, it has conceded that it possesses common dispensing interests, and as such a similar functional framework. See \textit{id}. Additionally, insurance providers such as Blue Cross and Blue Shield’s Federal Employee Program, which insures 3.7 million patients, are cautious about the potential impact of online pharmacies on exclusive mail order coverage options. See Tedeschi, supra note 33.

\textsuperscript{69} Some states viewed online pharmacies similarly with mail-order ones and licensed them to dispense in their state. See Burson, \textit{supra} note 1. Roughly half of the states permit the electronic transfer of prescriptions. See \textit{id.}; see also Theodore R. LeBlang, E-mail Scripts Seen As Analogous To Phone-Ins, \textit{AM. DRUGGIST}, Apr. 1, 1999, at 54-55 (describing Walgreen Co. \textit{v. Wisconsin Pharmacy Examining Bd.}, 577 N.W.2d 387 (Wis. Ct. App. 1998), in which the Wisconsin Court of Appeals noted the benefits of electronic prescribing, indicated the similarities to traditional methods, and affirmed the circuit court’s ruling in favor of Walgreen’s use of an electronic prescribing test system).

\textsuperscript{70} See The Ins and Outs of Online Drugstores, \textit{supra} note 39.

prospect of easy money, writing prescriptions for existing sites,\textsuperscript{72} or by physicians starting their own online dispensary.\textsuperscript{73} Lack of adequate physician-patient interaction is only the first problem.

The process of obtaining a prescription through a domestic rogue online pharmacy illustrates some significant health safety concerns. Perhaps a telling aspect of the motivation behind these sites is often the first question they require online patients to answer: Will that be Visa or American Express?\textsuperscript{74} Although profitability is an obvious goal of these sites, consumer safety is the target of regulators.\textsuperscript{75} Many sites do not list the credentials of health professionals, if any, who are involved in the process.\textsuperscript{76} There is often no way, therefore, to determine the credentials, identity, or even if a pharmacist or physician is involved. Equally disturbing are the health questionnaires that such sites often use in lieu of a traditional physician exam.\textsuperscript{77} The problems of this pseudo-exam are subsequently aggravated by the inability for follow-up.\textsuperscript{78} Overall, these sites do the absolute minimum in a veiled attempt to comply with state

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\textsuperscript{72} See Stolberg, supra note 7. Struggling physicians, like Dr. Leandro Pasos, sign up with companies like Performance Drugs to review electronic health forms of potential Viagra\textsuperscript{®} patients for $5,000 per month. See id. Additionally, Bill Stallknecht, pharmacist and co-owner of ThePillbox.com, has stated, "I probably have 5,000 names of doctors who want to participate." Id.

\textsuperscript{73} See id. According to Eric Thom, Vice President of Confmed.com, the site was founded by an obstetrician-gynecologist after he hired a website designer, "called his pharmaceutical representative, gave them his American Express number, ordered about 200 pills and started listing his site on some search engines." Id.

\textsuperscript{74} See Bernard S. Bloom & Ronald C. Iannacone, Internet Availability of Prescription Pharmaceuticals to the Public, 131 ANAALSOF INTERNAL MED. 830, 832 (1999). This, however, is not necessarily different from a patient's experience in a traditional health care setting. See id. (indicating that most hospitals and physicians' offices request payment information before medical information).

\textsuperscript{75} Carmen Catizone, Executive Director of NABP stated, "We are not concerned about the economics, but about patient safety." Lisa Napoli, Dispensing of Drugs on Internet Stirs Debate, N.Y. TIMES, Apr. 6, 1999, at F6.

\textsuperscript{76} Dr. Bloom and Mr. Iannacone's study determined that although 21.4% of sites surveyed provided information on how physicians become consultants, at least 80.4% of the sites surveyed did not provide physicians' names, specialties, locations, or qualifications. See Bloom & Iannacone, supra note 74, at 831-32.

\textsuperscript{77} See Randolph D. Smoak, Jr., Internet Prescribing, Report of the Board of Trustees of the American Medical Association #35-A-99, at http://www.ama-assn.org/meetings/public/annual99/reports/onsite/bo/rtf/bot35.rtf (last visited Oct. 23, 2000) (discussing the dangers and inadequacies of the minimal information exchanged via rogue online pharmacy questionnaires, including a sample questionnaire for Viagra\textsuperscript{®}).

\textsuperscript{78} See id.

\end{footnotesize}
examination and dispensing requirements.\textsuperscript{79} These operational mechanisms, coupled with FDA approvals in recent years of a number of "lifestyle"\textsuperscript{80} drugs like Viagra\textsuperscript{81}, have provided illegitimate sites with a potentially profitable but flagrantly dangerous niche market.\textsuperscript{81} This market often preys on the fears, desires, and wallets of "cyberchondriacs."\textsuperscript{82}

As if rogue domestic sites were not dangerous enough, foreign sites present their own unique and dangerous concerns. The problem of patients ordering prescription drugs from foreign countries is not new. According to Bill Hubbard, acting deputy commissioner for policy with the FDA, "'[w]e've always had these catalogues where people could buy from overseas, but it was a very small market.... The Internet takes it up a big notch.'"\textsuperscript{83} Although pharmaceutical companies may not market unapproved drugs in the United States, and U.S. Customs or Postal authorities may seize these products in the mail, individuals may order these drugs as long as they are for their own use.\textsuperscript{84} Although Hubbard is correct, "big" is probably an insufficient term to describe the magnitude of the Internet's impact and the plethora of resulting problems. As Representative Ron Klink (D-Pa.) described, "'[i]t is strictly the Wild West of drug dealing via the Internet.'"\textsuperscript{85} The Internet is often praised for the accessibility it offers to legitimate products and information; however, the same access enables patients to order

\textsuperscript{79} See, e.g., Stolberg, supra note 7 (describing the procedures of a Texas online pharmacy owner who accepts prescriptions only from Texas physicians to reduce the "chance of running afoul of regulators in another state").

\textsuperscript{80} Examples of "lifestyle" agents include: sildenafil citrate [(Viagra\textsuperscript{81})], for erectile dysfunction, finasteride [(Propecia\textsuperscript{81})] for hair loss, orlistat [(Xenical\textsuperscript{81})] for obesity, levonorgestrel and ethinyl estradiol [(Preven\textsuperscript{81})] for emergency contraception, bupropion hydrochloride [(Zyban\textsuperscript{81})] for smoking cessation. See Roan, supra note 32.

\textsuperscript{81} See infra notes 74-97 and accompanying text.

\textsuperscript{82} See id.; see also 21 U.S.C. § 956 (1994) (indicating the personal use exemption for controlled substances).

\textsuperscript{83} Herman, supra note 4.

\textsuperscript{84} See id.; see also 21 U.S.C. § 956 (1994) (indicating the personal use exemption for controlled substances).

\textsuperscript{85} Stolberg, supra note 7. But see Sarah E. Taylor & Harold J. Feld, Promoting Functional Foods and Neutraceuticals on the Internet, 54 FOOD & DRUG L.J. 423, 432 (1999) (commenting that "law applicable in real space is equally applicable in cyberspace, although the Internet may create challenges for implementation").
oxycodone from Spain, or Xenical® from the British Channel Islands.

Equally troubling is the anonymity that cyberspace provides and the resulting ability of patients to mistakenly or deliberately falsify information in order to obtain the approved and unapproved products they desire. A number of journalists have spotlighted the dangers in their own purchasing exploits, and at least one news station obtained Viagra® for two pets, a deceased person, and a man with cardiac disease. Inherent in this acquisition is the ability of patients to obtain medications “without so much as talking to a doctor.” Federal regulations are designed to provide safe and

86. See Napoli, supra note 75 (describing oxycodone as an analgesic classified as a controlled substance in the United States).
87. See Herman, supra note 4.
88. See Bloom & Iannacone, supra note 74, at 832 (explaining that default click selections facilitate patients’ provision of false information); Smoak, supra note 77 (theorizing that the medical history questionnaires used by rogue online pharmacies may contain medical terminology that is “likely to be beyond the level of understanding of a lay person”).
89. See Bloom & Iannacone, supra note 74, at 832. For example, there is little barrier to prevent a patient suffering from an eating disorder from ordering and receiving a weight loss product designed for the clinically obese. See Joshua Fischman, Drug Bazaar: Getting Medicine Off the Web is Easy, But Dangerous, U.S. NEWS & WORLD REP., June 21, 1999; Herman, supra note 4. Physicians and pharmacists participating in these rogue sites defend their practice by claiming that patients who are prepared to lie will get the drug whether online or in a traditional setting. See Herman, supra note 4; Napoli, supra note 75. One physician stated, “I have to assume you are telling the truth. Even if you come to my office, you can tell me anything.” Stolberg, supra note 7. But see Herman, supra note 4 (arguing that at least in person, “the doctor can see their approximate age, their obesity, listen to their heart, take a blood pressure reading”).
90. See Liz Brody, Prescription for Tragedy: Just Name the Rx Drug, and You Can Buy It Online; Online Rx Drugs a Deadly Threat, N.Y. POST, Mar. 12, 2000, at 6, available in LEXIS, News Library, News Group File (identifying the various products purchased without a prescription by the health editor of Glamour, including Xenical®, Prozac®, Ultram®, penicillin, Preven®, and Xylocaine®); Bernstein, supra note 55; Fischman, supra note 89; Corey Hann, Viagra Anyone?, U. WIRE (Syracuse), Mar. 30, 2000, available in LEXIS, News Library, News Group File; The Ins and Outs of Online Drugstores, supra note 39, at 42; Patti Waldmeir, E-health Practitioners Fell for My Online Deception: Patti Waldmeir on the Ethics of Web Sales As a Potentially Lethal Drug is Sent to a Fictional Character Whose Only Link with Reality Was Somebody Else’s Credit Card, FIN. TIMES (London), June 22, 2000, at 11, available in LEXIS, News Library, News Group File; Today: Discussion with Janice Liberman (NBC television broadcast, Mar. 20, 2000), transcript available in LEXIS, News Library, News Group File.
92. Fischman, supra note 89.
efficacious products manufactured under strict quality control guidelines, but there are no such guarantees with products obtained through rogue foreign online pharmacies. In fact, there is no guarantee that the product ordered is the one the patient actually requested. Additionally, the lack of adequate physical exams and consultations may increase the risk of potentially life-threatening drug interactions or harmful adverse events.

Beyond the problems resulting from online providers, now regulators have to contend with electronic bulletin boards enabling an online "flea market," where patients are offering to sell their leftover drugs to other patients. The significance of the problems with online pharmacies was highlighted by Bloom and Iannacone's recent study. The importance of their results was manifested in the decision of the editor of the Annals of Internal Medicine to post the study on its website months before the article was scheduled for publication. As health professionals and probing journalists expose the intrinsic health related problems of these disreputable sites, the legislators, regulators, and professional organizations are also developing a heightened awareness of the thorny jurisdictional problems inherent in these electronic transactions.

93. See id.
94. See Woodcock, supra note 26.
95. In one instance, a fifty-two-year-old man with a history of cardiac disease died from a heart attack after purchasing Viagra from an Internet provider that required only the completion of a questionnaire before shipping the product. Although the drug has not been linked to his death, the FDA has emphasized that a physician's direct examination could have prevented the event. See GOOD QUESTION, How Safe is It to Buy Prescription Drugs Online?, FLA. TIMES-UNION (Jacksonville), May 7, 2000, at H-5; see also Fischman, supra note 89 (discussing the risks of purchasing drugs online); Andrew Jacobs, 4 New Jersey Prep Schoolers Fall Ill After Buying Drug on eBay, N.Y. TIMES, May 26, 2000, at B1 (describing the hospitalization of four seventeen-year-old students after overdosing on dextromethorphan purchased online); Smoak, supra note 77 (indicating that although Viagra is beneficial to many men, it also has been linked to 100 deaths); The Doctor is Online, supra note 71 (noting that Propecia (for hair loss) may cause birth defects if a pregnant woman touches the product).
96. Napoli, supra note 75.
97. See id.
98. See Bloom & Iannacone, supra note 74.
99. See id; see also Denise Grady, Drug Buying On the Web? Be Careful, Study Says, N.Y. TIMES, Oct. 5, 1999, at F7. This early release is an ideal example of the accessibility and reliability of information that the Internet can provide.
The problem facing regulators is that a patient may sit at their home personal computer in one state, deal with an online site in another state, have a prescription issued by a physician in a third, and then have a pharmacy in a fourth state dispense the product. This intricate web of connections has left lawmakers puzzled, wondering where to start. The FDA has the authority to act under the auspices of the FD&C Act. Additionally, other federal agencies, such as the FTC, DEA, U.S. Customs Service, and the Postal Service, have related authority. Furthermore, the states regulate the licensing of pharmacists, pharmacies, and other health professionals. Although the states lacked explicit regulations or laws on e-prescribing at the end of 1998, some states' attorneys general have filed claims using existing state licensing and consumer protection laws. Finally, professional organizations such as the AMA and the NABP provide licensing and professional standards. Although each group is an important member of the enforcement team, their roles and interactions remain inadequately defined. As James Winn, Executive Vice
President of the Federation of State Medical Boards (FSMB), stated, the difficulties inherent in this regulatory scheme are like "'trying to nail Jell-O to the wall.'"\textsuperscript{110}

The process of bringing an online site or provider to justice is complicated from the first step, identifying them. Many of the disreputable sites do not maintain information about their location or providers, often requiring law enforcement personnel to "'sort through multiple shell corporations, addresses that turn[] out to be mail drops, and overlapping physical and Internet addresses shared by different entities.'"\textsuperscript{111} Once identified, the enormity of the Web allows providers to close up shop and re-appear at another site a short time later.\textsuperscript{112} The FDA has made efforts both alone and with the help of Internet Service Providers\textsuperscript{113} (ISPs) to act against these sites, but it is a formidable task, requiring additional resources.\textsuperscript{114}

Although the domestic jurisdictional issues are particularly daunting, the problem of bringing action against a foreign site is even more frustrating because jurisdiction is limited.\textsuperscript{115} According to Carmen Catizone, Executive Director of the NABP, "'[t]he foreign-based sites are going to be almost impossible to monitor.'"\textsuperscript{116} Given this difficulty, the FDA is working with the World Health Organization (WHO)\textsuperscript{117} and cooperating with other nations\textsuperscript{118} in an

\begin{thebibliography}{118}
\bibitem{rubin} Rita Rubin, \textit{On-line Viagra Worries Medical Boards}, USA TODAY, Jan. 21, 1999, at 1D.
\bibitem{schwartz} See Schwartz, supra note 91, at 11.
\bibitem{woodcock} See Woodcock, supra note 26 (describing the FDA's requests for voluntary cooperation of website managers to remove illegal sites and ads).
\bibitem{minutes} See Minutes, supra note 100 (noting the FDA's lack of sufficient resources to combat the problem on its own).
\bibitem{hear} See Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce, 106th Cong. (2000) (statement of William K. Hubbard, Senior Associate Commissioner for Policy, Planning, and Legislation, FDA) [hereinafter Hubbard], at http://www.fda.gov/ola/2000/internetsales.html (May 25, 2000) (lamenting that although the FDA has jurisdiction over foreign residents who violate the FD&C Act by selling to U.S. residents, practical issues prevent enforcement); Woodcock, supra note 26 (highlighting the limited jurisdiction possessed by federal agencies to deal with foreign online providers).
\bibitem{roan} Roan, supra note 32.
\bibitem{minutes2} See Minutes, supra note 100.
\bibitem{hubbard} See Hubbard, supra note 115 (stating that the FDA Office of Criminal Investigations maintains relationships with Belgium, Brazil, Canada, Germany, Ireland, the Netherlands, Singapore, Spain, and the United Kingdom, as well as other nations).
\end{thebibliography}
attempt to address the problem, but a formalized international approach does not yet exist. One reason may be the various standards for prescription medications throughout the world. In the meantime, the WHO has stressed cooperation among member nations to enforce particular national standards and prohibit illegal international sales. An increasing awareness of the problems found in a global electronic pharmaceutical market led lawmakers abroad and at home to call for action.

**Viagra® E-mail and Legislative Impetus**

The legislative process officially began in March 1999, when Democratic members of the House asked the Comptroller General to conduct a formal review of the "exploding trend of online pharmacies." Ironically, only a few days later, Dennis P. Fitzgibbons, minority deputy staff director for the House Commerce Committee, received e-mail messages promoting a website where consumers could purchase Viagra® without a physician's visit. In their letter, the House members expressed concern that these pharmacies "may be outpacing formal state and federal controls," and requested an

119. See Herman, supra note 4.
120. See id.
121. See Kevin O'Sullivan, *Medicines Board Supports US Move on Illegal Web Pharmacies*, IRISH TIMES, Dec. 31, 1999, at 4, available in 1999 WL 24436659 (indicating that the Irish Medicines Board has called for an EU-wide initiative to address online pharmacy issues); see also Hubbard, supra note 115 (describing an Italian proposal that all of Europe address the issue); Adam Creed, *New Zealand Looks to Close Internet Medicines Loophole*, NEWSBYTES, Jan. 21, 2000, available in 2000 WL 2272221 (relating efforts by the New Zealand Ministry of Health to eliminate a legal loophole enabling pharmacists to provide prescription drugs to foreign patients without a prescription); Alex Hannaford, *No Prescription Needed: The Internet Drugs Scam*, EVENING STANDARD (London), Mar. 14, 2000, at 60, available in 2000 WL 6858833 (elaborating on a government investigation in the UK focusing on online pharmacies, particularly Direct Response Marketing, located in the British Channel Islands).
123. Although Fitzgibbons did not purchase the medication, the plethora of disclaimers and liability releases, as well as the speed of the process and limited information exchanged, suggested to him that "[the] virtual physician [was] a virtual quack." Suzanne M. Smalley, *Drugs Online: Virus or Cure?*, NAT'L J., June 12, 1999, at 1606.
124. Dingell, supra note 122.
analysis of five primary issues. Shortly after submitting this letter to the Comptroller, the members also requested the input of Dr. Jane Henney, Commissioner of the FDA. In their letter to Dr. Henney, the members requested the FDA's opinion or knowledge on six primary issues. In response, the FDA addressed the members' concerns first in written form, and later in testimony before the Subcommittee on Oversight and Investigations.

In its letter, the FDA specifically responded to the members' six points in the following ways. First, although the FDA was aware of the authority of various federal regulatory agencies and states regarding online pharmacies, it was unaware of any single agency that functioned as the "primary regulator." Second, while the states traditionally regulate dispensing, the FDA's Center for Drug Evaluation and Research (CDER) reviews and acts against "violative" sites. Additionally, the FDA's limited authority (especially regarding foreign sites) and resources necessitate the surveillance and assistance of multiple federal agencies, state

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125. See id. These issues were: (1) "How pervasive is the online pharmaceutical industry? ... "; (2) "[D]etermine the differences between [existing] online pharmacies ... "; (3) "Determine how these firms are or are not being regulated ... "; (4) "[H]ow issues of health safety and privacy are being addressed"; and (5) "What quality issues pertain to the methods used to ship these ... products?" Id.


127. See id. These issues were: (1) "What agency ... [should be] the primary regulator of Internet pharmacies?"; (2) "What specific activities or functions does FDA believe it is responsible for ... ?"; (3) Are the existing laws and accompanying regulatory structure adequate?; (4) "[T]he differences between existing online pharmacies."; (5) How issues of health, safety, and privacy are being addressed; and (6) "What quality issues ... relate to the methods used to ship [these] ... products, and does [the] FDA believe it has jurisdiction in this area?" Id.


129. See Woodcock, supra note 26.

130. See Plaisier, supra note 128.

131. See id. The FDA's acts have included: sending warning letters to sites promoting unapproved agents, sending warning letters to foreign sites with copies to their respective home governments, posting import alerts on illegal foreign items available via the Internet, working with Web managers to remove infringing sites, and acting against promotional claims that violate the FD&C Act. See id.
boards, and professional organizations. To this end, the FDA was developing draft guidance and assessing its human resources. Third, the FDA's internal working group was planning to meet to address the adequacy of existing regulations and regulatory design. Fourth, the FDA expressed concern over the "geographic diffusion and other unique characteristics of the Internet," and stated that new regulations must deftly balance the concerns of legitimate e-commerce with the need to protect public health. Fifth, the FDA was unable to assess potential problems with privacy and the potential for adverse events. Furthermore, the FDA had no evidence at the moment to indicate that online pharmacies were more susceptible to fraud than other pharmacies that lack direct patient contact. Finally, the FDA asserted that quality standards apply "to all drugs sold in commerce in the United States, regardless of whether the order is placed in person, online or by the mail."

In contrast to this initial correspondence, the FDA's subsequent legislative testimony was not designed to answer provided questions. Instead, the agency focused on the benefits and risks associated with online pharmacies, framing its initiatives as a governmental hands-off approach consistent with the Administration's Framework for Global Electronic Commerce. Additionally, this initial testimony, and the subsequent hearing

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132. See id.
133. See id.
134. See id.
135. Id.
136. See id.
137. See id.
138. See id.
139. Id.
140. See Woodcock, supra note 26. The five principles of the Framework for Global Electronic Commerce are:

1. The private sector should lead. 2. Governments should avoid undue restrictions on electronic commerce. 3. Where governmental involvement is needed, its aim should be to support and enforce a predictable, minimalist, consistent and simple legal environment for commerce. 4. Governments should recognize the unique qualities of the Internet. 5. Electronic Commerce over the Internet should be facilitated on a global basis.

Id.
141. See id.
held roughly one year later, informed the Subcommittee about the FDA's continuing progress in cyberspace.

The FDA was joined by professional organizations such as the AMA in this democratic process. AMA physician Herman I. Abromowitz's testimony focused on the physician's professional perspective toward online prescribing. In particular, Dr. Abromowitz highlighted the AMA's opinion on the minimum standards for proper medical care, the AMA's desire to work collaboratively with other organizations to facilitate acceptable electronic prescribing practices, and the opportunities for legitimate online prescribing.

INITIAL RESPONSES TO THE ONLINE PHARMACY PHENOMENON

Federal Enforcement

FDA

The FDA, through its Office of Regulatory Affairs and Center for Drug Evaluation and Compliance, has actively confronted the problem of illegal online pharmaceutical sales. It initially identified over sixty cases potentially linked to such illegal sales. Dr. Woodcock, Director of the FDA's CDER, identified some prime examples in her testimony before Congress. These included: (1)

142. See Hubbard, supra note 115.
143. See Abromowitz, supra note 49.
144. These minimum standards include: (1) "an examination of the patient to determine a specific diagnosis and whether there actually is a medical problem;" (2) "a dialogue between the physician and patient to discuss treatment alternatives and determine the best course of treatment;" (3) "the physician must establish or have ready access to a reliable medical history;" (4) "provid[ing] information to the patient about the benefits and risks of the prescribed medication;" and (5) "physician . . . follow-up . . . to assess the therapeutic outcome." Id.
145. See id. (expressing the AMA's desire to work with state medical societies, state and federal regulatory bodies, the Federation of State Medical Boards, and others).
146. See id. (identifying three areas that the AMA considers legitimate uses of online prescribing: "Computer order entry and on-line transmission of prescriptions"; "ordering refills—either patient to pharmacy or physician to pharmacy"; and "electronic consults between physician and patient where the outcome is an ordered prescription.").
147. See Woodcock, supra note 26.
148. See id.
the first FDA conviction for wire fraud based on the online sale of an unapproved HIV home test kit;\footnote{149} (2) the identification of a Canadian website that provided GHB prep kits to an Illinois man who was later convicted of possession of a controlled substance;\footnote{150} (3) the seizure by the FDA’s Office of Criminal Investigations (OCI) of multiple steroid shipments from foreign manufacturers to the operator of a U.S. website that purported to function as a “buyers club”\footnote{151}, and (4) multiple efforts against a South American lab, marketing via its company website, abortion kits containing drugs unapproved in the United States.\footnote{152} Since these initial actions, the FDA implemented an Internet Drug Sales Action Plan\footnote{153} and continues to engage in civil\footnote{154} and criminal\footnote{155} enforcement activities. Spurred by the testimony of Dr. Woodcock and others, the Democratic members of the House, led by Representative Ron Klink (D-Pa.), introduced legislation to assist in this fight.

\footnote{149} See id.
\footnote{150} See id.; see also Guy Gugliotta, House Votes to Put GHB On List of Illegal Drugs: Diet Supplement Linked to Deaths, 'Date Rape', WASH. POST, Feb. 1, 2000, at A8 (describing that, although the FDA banned GHB in 1991, chemical precursors of GHB have been legally sold as “diet supplements,” and indicating that this vote closed the loop hole, thus categorizing the drug as an illegal controlled substance).
\footnote{151} See Woodcock, supra note 26.
\footnote{152} See id.
\footnote{153} See Hubbard, supra note 115. The plan includes the following components: public outreach, professional outreach, coordination with states and other federal agencies, international cooperation, and refining/broadening enforcement activity. See id.
\footnote{154} Most notably, after considering thousands of sites, the FDA reviewed over 400 drug-related Internet sites for potential civil or criminal action. See id. As of May 25, 2000, the Office of Compliance sent 38 warning letters to domestic Internet pharmacies alerting them of potential “administrative and/or regulatory enforcement action” if the sites failed to remedy “products, practices, processes or other activities” that the FDA considered violative of the FD&C Act or other statute. Id. Similarly, 17 “cyber letters” (warning letters sent online) were sent to foreign sites. See id. In addition, the FDA, working with the Department of Justice (DOJ), obtained two preliminary injunctions prohibiting the sale of illegal items, garnered 12 product seizures, 11 product recalls, the voluntary destruction of 18 products, and issued 17 import alerts. See id.
\footnote{155} The FDA’s Office of Criminal Investigations (OCI), in cooperation with various federal and state agencies, had 86 criminal investigations open and 46 preliminary investigations occurring as of May 25, 2000. See id.
Elevators, Escalators, and Hair Stylists

The Internet Pharmacy Consumer Protection Act (Act) was introduced as an amendment to section 503 of the FD&C Act. The Act proposes Web-based notification requirements for online providers in an attempt to protect public health and safety, and was prompted in part by Congressman Klink's observation that current laws required "elevators, escalators and hair stylists ... to display more licensing information than websites selling potentially lethal drugs." Essentially the Act has two components. The first explains minimum identification requirements for online pharmacy websites, and the second addresses enforcement authority. Regarding identification, the Act requires the site to list the name and state of licensure of every professional working with the site (e.g., dispensing physicians, consulting physicians, and pharmacists), as well as the licenses held by practitioners that conduct patient consultations designed to provide a prescription. Regarding enforcement, the Act leaves the authority with the state if the state has provisions no less stringent than those proposed in the Act. Currently, the Act remains in committee in the House.

U.S. Customs Service

The essentially exponential growth of online pharmacies in 1999 was reflected in a 450% increase in the quantity of pharmaceuticals seized by the United States Customs Service from 1998 to 1999.

159. See H.R. 2763.
160. See id.
161. See id.
162. See id.
Although this growth presents an increasing burden upon the Customs Service's limited resources, the Service continues to work separately and in cooperation with other federal agencies to limit the influx of illegal foreign pharmaceuticals. Additionally, in testimony before Congress, the Service emphasized the need for an approach employing cooperation, communication, and additional resources as well the specific need for the U.S. Postal Service to implement an automated manifest information system. The Customs Service's recommendations and actions have not been confined, however, to domestic tactics. For example, in 1999 Customs officials worked with authorities in Thailand, a prime source of illegal foreign drugs, to seize 2.5 million pharmaceutical dosage units, arrest twenty-two Thai citizens, and demonstrate the Customs Service's continued commitment to protect America's borders from illegal activities, both electronic and tangible.

Department of Justice

The Department of Justice (DOJ) has also become increasingly involved with Internet dispensing by: (1) outlining avenues that exist for prosecuting online pharmacies through existing laws

164. The Customs Service utilizes fewer than 220 people at fourteen international mail facilities nationwide. See id. Although the Postal Service must present all international mail to Customs, the volume of daily shipments and the manual nature of the selection and inspection process prevents all mail from being inspected. See id.

165. The Customs Service utilizes its CyberSmuggling Center to address the challenges of illegal activity facilitated by electronic commerce. See id. Additionally, Customs created a Cyber Crimes Unit to address a number of issues including locating and identifying foreign operators selling illegal pharmaceuticals via the Internet. See id.

166. The Customs Service actively cooperates with the FDA, the DEA, and the U.S. Postal Service via an informal working group and is involved with the FDA's Office of Criminal Investigations on a number of continuing investigations. See id.

167. While Express Consignment Operations like FedEx and UPS must keep detailed shipping and transaction records for Customs' examination, the Postal Service is not so obligated and only maintains individual manifests for roughly five percent of international mail. See id. Although the Postal Service does not possess such detailed automated technology, it is attempting to develop a system that would provide Customs with information comparable to that provided by Express Consignment Operators. See id. Similarly, although Express Consignment Operators must reimburse Customs for the costs associated with processing their packages, the Customs Service is not reimbursed by the Postal Service for inspecting incoming foreign mail. See id.

168. See id.
regulated by the FDA, the DEA, and the FTC; (2) enforcing these laws; (3) engaging in training and education of law enforcement personnel; (4) cooperating with domestic and foreign enforcement agencies; and (5) supporting the Internet Prescription Drug Sales Act of 2000, with the proposal that the bill be amended to provide a mechanism for injunctive relief.

169. The DOJ identified the possibility of utilizing 21 U.S.C. § 353(b) to pursue violators who dispense pharmaceuticals via an online questionnaire or without a prescription. See Prepared Testimony of Ethan M. Posner, Deputy Attorney General, Before Subcomm. on Oversight and Investigations of the House Comm. on Commerce, 106th Cong. (2000) [hereinafter Posner], available in LEXIS, News Library, New Group File (elaborating that § 353(b) would consider pharmaceuticals "misbranded" if dispensed without a prescription and highlighting that the use of a questionnaire may not meet the requirement that prescriptions be dispensed pursuant to a valid prescription). The DOJ also noted that drugs dispensed without a prescription and thus "misbranded" would violate 21 U.S.C. § 331(a) when introduced or distributed into interstate commerce. See id.

170. See id. (highlighting 21 U.S.C. §§ 822, 829 and 841 because the definition of a "prescription" under the Controlled Substances Act may not include those drugs dispensed via an online questionnaire). A Maryland grand jury indicted a physician for dispensing controlled substances applying these sections of the Controlled Substances Act. See id.

171. The FTC's authority to prohibit "unfair or deceptive acts or practices" could be utilized via 15 U.S.C. § 45. See 15 U.S.C. § 45(a)(1) (1994); see Posner, supra note 169. For example, a number of online pharmacies settled charges raised by the FTC, including that the website claimed it was a "full service clinic" and "network[ed] with an organization of physicians throughout the United States and Internationally" when allegedly no clinic existed and only one physician was a part of the "network." See Online Pharmacies Settle FTC Charges, M2 PRESSWIRE, July 13, 2000, available in LEXIS, News Library, News Group File; see also Posner, supra note 169 (noting the potential utility of other charges via federal mail fraud and wire fraud theories).

172. The DOJ specifically identified ten recently filed cases ranging from charges against a physician for dispensing controlled substances using only patients' e-mail requests to a federal grand jury indictment against BONGMART.com for selling nitrous oxide. See id.

173. The Office of Legal Education for the DOJ presented a number of seminars including a how-to presentation on Internet Prescription Sales highlighting mechanisms for prosecutors to investigate, analyze, and charge an online pharmacy case. See id.

174. DOJ officials have met with officials from twelve other federal and state agencies as a member of the Drugs and Medical Products Interagency Working Group. See id. Additionally, officials have met with various state authorities such as state medical and pharmacy board representatives, and each state's Attorney General. See id.

175. See id. (noting U.S. support for the Council of Europe's drafting of a cybercrime convention as well as the cooperation of the G-8 by facilitating the investigation and prosecution of cybercrime).

176. See id.
Presidential Proposal

The President also joined the political chorus of concern in the final days of the last millennium by submitting a proposal to address online pharmacies as part of the 2001 budget. The Clinton proposal requires online pharmacies to obtain federal certification through the FDA, and creates civil penalties of up to $500,000 for each incident of dispensing prescription drugs without a valid prescription. Additionally, the proposal grants the FDA administrative subpoena power designed to compel cyberpharmacies to provide records to federal officials. The President, moreover, hopes to improve the FDA's ability to examine online pharmacies by providing an additional $10 million to increase staffing by 100 and upgrade the FDA's computer capabilities.

In an effort to achieve these goals, the Administration, via Secretary of Health and Human Services Donna Shalala, introduced the Internet Prescription Drug Sales Act of 2000 to Congress on May 2, 2000. The bill would require online pharmacies to be licensed in each state where they practice and in each state to which they deliver prescription drugs. It would also mandate that all online pharmacies meet federal laws concerning the practice of pharmacy (i.e., storage, handling, and record-keeping requirements) and the completion of a pre-launch notice to all applicable state pharmacy boards, as well as the Secretary of Health and Human Services.

178. See New Initiative, supra note 177 (specifying that "[s]ites operating without first demonstrating FDA compliance [will] be subject to sanctions"); Pear, supra note 177.
179. See New Initiative, supra 177.
180. See id.
181. See id.; Pear, supra note 177.
182. See Hubbard, supra note 115.
183. See id.
Finally, the bill would provide both federal and state mechanisms for enforcement, including monetary civil penalties. The proposal, in general, and the bill, in particular, represent a reversal of the Administration's views on online pharmacy regulation. While the Administration may believe that Congress is willing to progress in this area, given its introduction of the Internet Pharmacy Consumer Protection Act, such optimism may be misplaced.

The presidential proposal has drawn limited, essentially courteous, approval from pharmacy professionals, who complimented the President for recognizing the benefits of online pharmacies as well as the need for strong penalties for rogue operators. Professional organizations, however, have voiced opposition to a proposal that expands FDA authority over online pharmacies. The reputable pharmaceutical players in this market prefer that the regulatory power remain where it has always existed, with the states. Meanwhile, as the President and Congress prepared to battle illegitimate online pharmacy services

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184. Specifically, the notice would need to contain "information required to be posted on the site and assurances of compliance with the requirements of the bill." Id. The bill would also call for the posting of a declaration on the website confirming compliance with the notice requirement and providing information that could be used to contact the pharmacy (i.e., the address and phone number of the pharmacy). See id.

185. The Secretary could prevent the site from posting its declaration of compliance after proper notice and opportunity provisions were met. See id. Sites that violated the proposed Act could incur fines and be the subject of state civil action. See id.

186. Clinton Proposes Greater FDA Authority Over Online Pharmacies; Reactions Skeptical [hereinafter Clinton], BNA HEALTH L. REP. Jan. 6, 2000, at 12, available in LEXIS, Area of Law-By Topic, Healthcare & Medical (noting that only a few months earlier, Justice Department Deputy Associate Attorney General Ivan Fong told the House Commerce Subcommittee on Oversight and Investigations that "more assistance for enforcement [was needed], not more laws").

187. See id.


189. A spokesman for House Commerce Committee Chairman Thomas Bliley, Jr. (R-Va.) indicated that the Chairman is concerned that such a proposal would be "a precedent for regulation of the Internet by politicians who not only do not understand the technology, but could not turn on a fax machine." Clinton, supra note 186.

190. See id.

191. Both the National Association of Chain Drugstores and the National Association of Boards of Pharmacy have indicated their disapproval of measures that would expand FDA authority. See id.

192. See id.
with the pen and the purse, states' Attorneys General began combating these practices with laws already on the books.

**Consumer Protection through Existing State Laws**

Although states lacked any explicit laws relating to online prescribing, they challenged pharmacies and providers with existing licensing and consumer protection regulations. Missouri Attorney General Jay Nixon provides a classic example. He obtained a temporary restraining order (TRO) followed by a permanent injunction against S&H Drug Mart, which uses the website www.ThePillbox.com, and William Stallknecht, its pharmacist-owner. Both were featured in a *New York Times* special report. The basis for the claim was that the San Antonio pharmacy was providing medications to Missouri citizens without a Missouri pharmacy license. The final order required that: (1) Stallknecht pay restitution to Missouri residents who made online

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193. See Smoak, supra note 77.

194. In addition to actions in Missouri and Kansas, state law enforcement officials have also launched offensives against online pharmacies and providers in Arizona, Florida, Illinois, Michigan, New Jersey, and Pennsylvania. See Online Pharmacies Charged with Consumer Protection Law Violations, BNA HEALTH L. REP., May 11, 2000, at 693 (explaining three suits in Pennsylvania involving violations of consumer protection laws by online pharmacies); State Files Consumer Fraud Charges Against Eight Online Pharmacies, BNA HEALTH L. REP., Apr. 6, 2000, at 503 (discussing New Jersey's efforts against illegitimate online pharmacies); State Files Consumer Fraud Lawsuit Against Online Pharmacy, Pharmacist, BNA HEALTH L. REP., July 20, 2000, at 1123 (describing two suits filed by the Arizona Attorney General's office); State Officials Form Internet Prescription Task Force to Review Current Laws, Security, BNA HEALTH L. REP., Jan. 20, 2000, at 92 (depicting the agreement often companies not to sell prescription pharmaceuticals to Michigan residents after Michigan's Attorney General threatened to sue); Sara Fritz, In U.S., No Easy Ex For Online Pharmacies, ST. PETERSBURG TIMES, Apr. 2, 2000, at 1A, available in 2000 WL 5605608 (indicating that, to date, Florida had only pursued one online pharmacy); On-Line Pharmacies: Illinois Sues Four Cos. For Fraud, AM. HEALTH LINE, Oct. 22, 1999, available in LEXIS, News Library, Medical and Health Materials; infra notes 195-207 and accompanying text.

195. See Nixon Obtains TRO to Stop Illegal Internet Sales of Drugs [hereinafter Nixon], at http://www.ago.state.mo.us/7899.htm (July 8, 1999).


197. See Stolberg, supra note 7.

198. See Nixon, supra note 195.
purchases from January 1 to June 30, 1999; (2) Stallknecht "pay $15,000 in penalties and costs to the state of Missouri;" (3) the website post a notice that prescription sales were not available to Missouri residents; and (4) violations of the injunction would result in a maximum penalty of $5,000.\textsuperscript{199} The claim was brought after two prescriptions were filled without verification during an investigation by the Attorney General's office.\textsuperscript{200} Although William Stallknecht, the pharmacist-owner of ThePillbox.com, indicated that he keeps detailed records and dispenses only prescriptions of Texas physicians to reduce potential suspicion in other states, he admitted his daily expectation that investigators will arrive at his store.\textsuperscript{201} In conjunction with the TRO, Nixon obtained an agreement with the Texas physician who wrote the unverified prescription that he would no longer treat Missourians or provide prescriptions for them using Internet services.\textsuperscript{202} Under similar circumstances, Nixon obtained a TRO against a Houston clinic, pharmacy, and physician.\textsuperscript{203}

Meanwhile, in Kansas, State Attorney General Carla Stovall filed a similar claim for offering medications without adequate patient evaluation and deceptive advertising,\textsuperscript{204} as well as five consumer protection suits\textsuperscript{205} against numerous companies, pharmacies, physicians, and other individuals. Stovall's claims arose initially

\begin{itemize}
\item \textsuperscript{199} Missouri Judge, supra note 196.
\item \textsuperscript{200} One prescription was for Propecia\textsuperscript{®} and was ordered by a pregnant investigator after providing a false name. See id.
\item \textsuperscript{201} See Stolberg, supra note 7.
\item \textsuperscript{202} See Nixon, supra note 195.
\item \textsuperscript{203} See Nixon Obtains TRO Against Online Clinic and Pharmacy to Stop Illegal Internet Prescribing and Sales of Drugs, at http://www.ago.state.mo.us/82699.htm (Aug. 26, 1999).
\item \textsuperscript{205} See Attorney General Files Lawsuits to Prohibit Internet Drug Sales, at http://www.ink.org/public/ksag/contents/news-releases/news99/internetdrugsales.htm (June 9, 1999) (describing three instances in which a minor, working with investigators, purchased Viagra\textsuperscript{®} and Meridia\textsuperscript{®}, a controlled substance, without an exam or consultation, using his real age and mother's credit card). Attorney General Stovall reached a settlement in one case, was requesting the court to enforce a settlement in a second case, and was negotiating settlements in the remainder of cases pending as of May 25, 2000. See Hearings Before the Subcomm. on Oversight and Investigations of the House Comm., 106th Cong. (2000) (statement of Carla J. Stovall, Kansas Attorney General)[ hereinafter Stovall], available in 2000 WL 726296.
\end{itemize}
from a suit filed by her office in November of 1998, on behalf of the Kansas Board of Pharmacy, against Dr. Leandro Pasos for violations of the Kansas Healing Arts Act. 206 Foreshadowing potential future problems for regulators, the Washington Medical Quality Assurance Commission cited Dr. Pasos for unprofessional conduct as a result of his online prescribing roughly six months after the Kansas Board named him in a suit. 207

In an effort to reduce such duplicative efforts, conserve resources, and promote effective law enforcement, the National Association of Attorneys General (NAAG) created an Online Pharmacy Working Group. 208 Although this collaborative effort has already demonstrated its utility, 209 State Attorneys General recognize that a successful approach will require federal cooperation. To that end, the NAAG adopted a resolution endorsing "cooperative federalism in addressing Internet issues." 210 More importantly, the NAAG set forth two concrete requests: First, that the states remain the "primary enforcers of laws relating to the health of their citizens," 211 and second, that the federal government provide "nationwide injunctive relief." 212 In doing so, the states actively defined their preferred role in this arena and offered a tangible example of how to reach this objective. Such suggestions, however, are not exhaustive. For example, as existing state laws have provided some recourse for authorities, a few states have begun a more targeted approach.

Creating New State Laws

In an effort to address some of the jurisdictional complications of online dispensing, one of the first of a new breed of laws addressing

207. See Stolberg, supra note 7.
208. See Stovall, supra note 205.
209. See id. (elaborating on the effective collaboration of Kansas and Washington against an online pharmacy and physician).
210. Id.
211. Id.
212. Id. The NAAG foresees a law similar to a federal telemarketing law permitting "[s]tates to obtain an injunction effective nationwide, and yet not prohibit any State from filing an action in its State court, based on State law." Id.
nonresident Internet pharmacies was passed in Indiana.\textsuperscript{213} Indiana's Internet pharmacy law requires providers to adhere to Indiana's generic drug laws as well as the law of their domicile.\textsuperscript{214} Similarly, Arkansas modified and expanded its existing nonresident pharmacy statute to address the growing concerns of Internet pharmacies. The law requires the out-of-state pharmacy to be licensed in Arkansas, to have a licensed Arkansas pharmacist, and to designate an Arkansas resident as an agent.\textsuperscript{215} In addition, if the pharmacy comes under scrutiny, it must appear before the Arkansas Board of Pharmacy.\textsuperscript{216}

In a related effort, Illinois legislators have required nonresident pharmacies to meet special registration requirements.\textsuperscript{217} Finally, a number of other states are reviewing potential legislative options to address the complexities of online dispensing.\textsuperscript{218} While states have begun enforcing existing laws and developing new laws, State Medical and Pharmacy Licensing Boards have been active partners in the enforcement of acceptable professional practice standards.

\textit{Licensing Boards}

With the primary objective of upholding the standards of professional practice, and perhaps the secondary motive of instilling in offenders the fear of prosecution, suspended licenses, and the inability to practice, state licensors have stepped in. For example, the Illinois Professional Regulation Department suspended the license of Dr. Robert Filice for writing Viagra\textsuperscript{a} prescriptions founded

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\item \textsuperscript{217} See \textit{Landis, supra} note 213, at 1174.
\item \textsuperscript{218} Legislation focusing on online pharmacies is pending in California, Kansas, Maine, New Hampshire, New York, and Rhode Island. See Chad Bowman, \textit{More Regulators Just Say No To Online Drug Prescriptions}, BNA \textit{Health L. Rep.} May 18, 2000, at 729, \textit{available in LEXIS}, Area of Law-By Topic, Healthcare & Medical. Similarly, Virginia instituted an evaluation of online pharmacy dispensing. \textit{See id.}
\end{itemize}
\end{footnotesize}
only on the information contained in a single page patient questionnaire and payment of an $85 consulting fee.219 His license was later reinstated with restrictions following a hearing.220 Similarly, eleven other state medical boards have acted against physicians for writing online prescriptions.221 A Nevada physician was warned that he could no longer continue online prescribing with Viagra.222 In Wisconsin, the board “summarily suspended” a physician, only to later reconsider the decision.223 In Colorado, the board chided a physician and warned of the future potential for disciplinary action.224 These actions have been welcomed by national professional organizations that possess the ability to make and recommend standards, as well as guide practitioners, but are limited in their authority to reprimand.

Professional Organizations

The AMA has expressed its almost sacred consideration for the physician-patient relationship and its concern at the potential for significant erosion of that relationship through improper, unregulated online prescribing.225 The organization has made it clear that the requirements226 a physician must satisfy to establish a physician-patient relationship in a traditional setting should apply equally to the Internet.227 As such, prescriptions offered "solely on the basis of a questionnaire would not suffice,"228 and

220. See Abromowitz, supra note 49.
221. See Bowman, supra note 218 (including California, Colorado, Florida, Hawaii, Michigan, Missouri, Nevada, Ohio, Washington, Wisconsin, and Wyoming). A minimum of eight additional medical boards have released statements concerning online prescribing. See id.
222. See Cheryl A. Thompson, Internet-based Prescribing and Dispensing Trouble Medical and Pharmacy Boards, 56 AM. J. HEALTH-SYS. PHARMACY 500, 500 (1999).
223. See id.
224. See id.
225. See Abromowitz, supra note 49 (expressing the AMA's "grave[] concern[] about current misuse of the Internet for prescribing purposes").
226. See supra note 144 and accompanying text.
227. See Smoak, supra note 77.
228. Id.
"fall[] well below a minimum standard of medical care."\textsuperscript{229} The AMA, however, has indicated its concern for the simultaneous protection and development of legitimate electronic prescribing opportunities.\textsuperscript{230} Promoting the optimal use of this developing technology while inhibiting its abuse is a delicate balance. To that end, the AMA Board of Trustees has recommended a six-point plan concerning its professional role in guiding the use of online prescribing and its cooperation with other organizations in cyberspace.\textsuperscript{231}

The AMA's first three recommendations express its opposition to online prescribing without adequate protections, its desire that state licensing boards act against improperly operating sites as well as practitioners, and its proposal that the AMA develop guidelines on the physician-patient relationship given the advancements in technology.\textsuperscript{232} The remaining three of the AMA's six recommendations deal with its cooperation with other organizations, the first being the FSMB.\textsuperscript{233} In this cooperative effort the AMA hopes to develop model laws on Internet prescribing at the state level.\textsuperscript{234}

The second collaborative partner identified by the AMA is the NABP.\textsuperscript{235} In particular, the AMA indicated its support of the NABP's Verified Internet Pharmacy Practice Sites (VIPPS) program.\textsuperscript{236} The NABP developed the program to address growing public concern about Internet pharmacy services,\textsuperscript{237} and the AMA supports the program because it provides a mechanism whereby "physicians and patients can easily identify legitimate Internet

\textsuperscript{229} Id.
\textsuperscript{230} See \textit{supra} note 146 and accompanying text.
\textsuperscript{231} See Smoak, \textit{supra} note 77.
\textsuperscript{232} See \textit{id}.
\textsuperscript{233} See \textit{id}.
\textsuperscript{234} The concerns of the AMA and the Federation of State Medical Boards on the subject seem well matched. In a February 1999 FDA meeting, the FSMB stressed the use of a collaborative approach and professional leadership. See \textit{Minutes, supra} note 100. The FSMB Committee on Professional Conduct and Ethics has also noted, "it would be unprofessional to issue a prescription or a recommendation to a patient without conducting an evaluation adequate enough to establish a diagnosis." Rubin, \textit{supra} note 110 (quoting James Winn, Executive Vice President of FSMB).
\textsuperscript{235} See Smoak, \textit{supra} note 77.
\textsuperscript{236} See \textit{id}.
pharmacy practice sites.\(^{238}\) The program requires VIPPS certified pharmacies to adhere to the "licensing and inspection requirements of their state and each state to which they dispense."\(^{239}\) The first certified pharmacies, Drugstore.com, Merck-Medco Managed Care L.L.C., and planetRx.com, bear the VIPPS certification hyperlink signifying that they meet the twenty-point pharmacy practice criteria.\(^{240}\) Finally, the AMA also proposed working with the FDA and other regulatory agencies to eliminate illegally operating online pharmacies.\(^{241}\)

WHOSE JOB IS IT ANYWAY?

**FDA Authority**

**Certification**

The FDA has deftly pursued violators and should be commended for its efforts. The FDA's initial intention to follow the Framework for Global Electronic Commerce, proposing that the private sector should lead along with the states is especially commendable.\(^{242}\) President Clinton's proposal to expand FDA authority, however, is troubling. The proposed federal certification will yield limited efficacy. Although federal certification may provide the FDA with a master list of online operators and consumers with additional information about their online provider, it seems likely that the predominant registrants will be reputable operators. Some rogue sites may shy away from the arena if the proposed stiff penalty for lack of certification is enforced, but many will likely continue to operate illicitly, moving from state to state until the states

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\(^{238}\) Smoak, supra note 77.

\(^{239}\) National Ass'n of Bd's. of Pharmacy, supra note 237.

\(^{240}\) See National Ass'n of Bd's. of Pharmacy, VIPPS Criteria, at http://www.nabp.net/vipps/consumer/criteria.asp (last modified Nov. 29, 1999). Since these first three sites were approved, the following sites also have received the VIPPS seal of approval: cvs.com, familymeds.com, healthscript.com, teldrug.com, eMD.com, accuratepharmacy.com, and clickpharmacy.com See National Ass'n of Bd's. of Pharmacy, List of Pharmacies, at http://www.nabp.net/vipps/consumer/listall.asp (last visited Oct. 23, 2000); National Ass'n of Bd's. of Pharmacy, What's New, at http://www.nabp.net (last visited Oct. 23, 2000).

\(^{241}\) See Smoak, supra note 77.

\(^{242}\) See Woodcock, supra note 26.
themselves have adopted sufficient, effective regulatory and enforcement mechanisms.

Certification will devastatingly blur the boundary between the states' and federal government's authority to regulate pharmacy practice. Mandatory federal certification would enable the federal government to regulate electronic pharmacies such as Eckerd online, but the FDA would continue to lack any authority to regulate traditional brick and mortar pharmacies such as a neighborhood Eckerd store. Consider those pharmacies, both large retail chains and local independents, that permit patients to electronically request their prescriptions and then to pick up the prescriptions at their neighborhood pharmacy. Would the electronic transmission of a prescription or refill request convert the traditional pharmacy into an online pharmacy subject to federal oversight? Where will the FDA's authority cease and the states' authority begin? Would such access then compel the need for brick and mortar access? The prospect of federal certification seems to generate more questions than it answers, possibly explaining why online pharmacy providers have expressed concern over the appropriateness and effectiveness of such a system. As a result, certification may unnecessarily restrict the electronic options that pharmacies offer their patients and essentially inhibit a core tenet of the Internet—access. It is likely that such an outcome would most significantly impact independent pharmacies, perhaps driving them out of pharmaceutical e-commerce and eliminating a valuable tool for competing with the mammoth chains.

243. If answered affirmatively, the FDA would go from having no authority to regulate pharmacies to having the authority to regulate both online and traditional sites. If answered negatively, regulators could not effectively monitor the entire prescriptive process at a federal level. Would this compel the need for brick and mortar access? If the FDA is being stopped at the pharmacy's front door, would the agency examine alternative ways to get behind the pharmacy counter, perhaps entering through the telephone lines?

244. Consider patients that use the Internet sometimes and brick and mortar pharmacies at other times. Will this allow the government access to each brick and mortar pharmacy where the patient has received a prescription and also used online services? What about patients who simply have a question answered online but have all of their prescriptions filled nonelectronically?

245. As one online pharmacy CEO stated, the proposed FDA subpoena authority and accompanying legislation "must be narrowly tailored . . . to avoid creating problems for the legitimate online pharmacies." Clinton, supra note 186.
Penalties

Although the certification system appears problematic, the need for increased penalties associated with violations is obvious. Without severe and enforceable penalties, there will be little incentive for operators to follow the law or officials to enforce the law. Current federal law makes the dispensing of a prescription medication without a valid prescription illegal. Such existing laws, as identified by the DOJ, could be expanded monetarily, and legislative terms could be modified to define online prescribing effectuated via a short questionnaire as failing to meet the definition of a valid prescription. As such, individual prescribers or websites could be held responsible for such actions. Although effective enforcement of such penalties may depend on the assistance of state regulators, the FDA could likely enact such penalties without the kind of drastic expansion of authority inherent in online certification.

Administrative Subpoena Power

The Administration's proposal fails to address the limits of the Administration's new-found subpoena power. In particular, various potential patient privacy concerns arise. Once again, the concept generates a multitude of questions. How would such power be brought to bear in the case of a provider that offers only online services or the potentially more problematic situation in which a consumer uses both online and traditional components of his pharmacy? Will the FDA be sending investigators to the corner drugstore to obtain the files they desire? Will these investigators be privy to confidential patient information? To what extent will the FDA seek to prosecute individuals receiving dangerous or unapproved agents as opposed to the websites offering such products? Health care providers, pharmacists especially, are faced with numerous existing barriers to effective patient communi-

247. See supra notes 169-76 and accompanying text.
Such power may potentially inhibit patients' willingness to address openly their medication concerns and may dangerously inhibit daily provision of effective pharmaceutical care.

Foreign Sites

Regulating the electronic border-crossing of foreign sites into the United States admittedly may be the most problematic aspect of online pharmacies. The absence of any suggestions within the President's proposal, however, represents a lost opportunity to introduce a comprehensive plan. The inherent limits of federal authority to penalize foreign online pharmacies from offering products in the United States significantly limit regulators' options. Given the FDA's national authority to approve pharmaceutical agents for sale in the United States, as well as its international reputation, the FDA is most suitably positioned to address the global market. Consequently, it would provide a unified national voice to foreign online pharmacies, Internet service providers, and governments. The agency's electronic warnings to foreign cyberpharmacies are a valuable first step. Similarly, the formation of a comprehensive Internet Drug Sales Action Plan and a desire to maintain existing relationships with foreign agencies should be applauded.

A laudable goal would be the creation of an international panel coordinated under the auspices of the WHO. The panel could be established to develop uniform mechanisms for nations to inform one another of rogue sites operating within their borders and

248. Such barriers include high pharmacy counters creating an actual obstruction between pharmacists and patients, noisy practice environments (i.e., constantly ringing phones), lack of a private consultation area, and reduced time to spend with patients due to excessive dispensing demands.

249. This may be especially true if patients perceive FDA oversight as a potential limit on their use of nontraditional products, such as herbal agents, which have experienced a recent surge in popularity. Patients may be more apt to forego consultation with the pharmacist, risking potentially life-threatening drug interactions or disease contraindications.


251. See supra note 153 and accompanying text.

252. See supra note 118 and accompanying text.
outline a series of steps for dealing with such providers.\(^{253}\) As with existing efforts, the FDA could participate in such an effort through its OCI. Similarly, professional organizations with an international membership, such as the NABP, could assist in bridging these regulatory gaps by expanding professional guidelines and commenting upon proposed enforcement or legislative actions.\(^{254}\)

**FDA as a Centralized Resource**

The administration's proposal is not entirely flawed. The FDA may serve as an exceptionally useful centralized resource for the states, and the President's proposal to increase funding to assist the FDA in countering rogue online pharmacies is an excellent step in the right direction. Additionally, the measures taken to educate consumers and practitioners through the FDA's new website\(^{255}\) and the intended "Potentials & Perils" campaign\(^{256}\) are also meritorious. The FDA should continue to search, investigate, and prosecute online pharmacy offenders, using its OCI as a key player in this process. Similarly, the Administration should be encouraged to retain its active links with other agencies (foreign and domestic), professional organizations, and practitioners to remain abreast of pharmacologic trends and technologic developments within the online pharmacy arena. For instance, the laudable efforts of the U.S. Customs Service and DOJ dovetail nicely with the FDA's approach. Their separate and collaborative efforts should continue to advance. Also, the FDA may be uniquely situated to function as

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253. Such steps could include notifying the foreign online pharmacy of its alleged infraction, and then sending a copy of the notification to the foreign nation's representative, and a representative of the ISP. If the pharmacy failed to remedy the situation in a certain period of time, the host nation could impose a standard sanction (e.g., minimum fine) and, perhaps by predetermined agreement with the ISP provider, terminate service to the offending site.


256. See **Clinton, supra note 186**.
a national clearinghouse of information from the states regarding offenders.

Some states are implementing online lists of health care professionals that have been subject to discipline to provide consumers with greater information regarding the practitioner they select.\(^{257}\) Similarly, the FDA could receive and publish on its website a master list of those sites that the states have reported as violating state provisions. Alternatively, if the states independently developed such sites, the FDA could create a master site with links to each of the state sites.

The FDA should also be encouraged to establish partnerships with private and academic sectors to increase its breadth of available technological resources.

*Legislative Responsibilities and the Internet Pharmacy Consumer Protection Act*

The Internet Pharmacy Consumer Protection Act (Act) has been called a "first step" by one of its developers, and it appears to be a good one.\(^{258}\) By providing minimum standards for identification of Internet pharmacy providers and then leaving the enforcement of the issue to the states, Congress has demonstrated an appropriate balance for the regulation. The Act suffers, however, from some of the same deficiencies found in the Administration's proposal because, with minimum identification standards, like mandatory certification, an assumption is made that providers will comply. Again, the reputable sites likely will comply; given the ability of providers to hide in cyberspace, however, it will be extremely difficult to identify and enforce penalties against those who do not. If sites do not comply, how can they be identified? Unfortunately, neither the President's proposal nor the Act under review addresses this issue.

\(^{257}\) See Jeff Houck, *Web Site Puts Patients On Line to Probe Doctor Lawsuits*, PALM BEACH POST, July 16, 1999, at 1B, available in 1999 WL 21272140 (describing Florida's Department of Health website that provides information on doctors' academic credentials, state disciplinary actions, and malpractice judgments over $5,000).

\(^{258}\) See Ron Kink, *Safety System Challenged By Drug Sales on Internet*, available in LEXIS, News Library, Roll Call File (Feb. 21, 2000).
Congress may fulfill its legislative responsibility by first doing its best to provide additional funding for the FDA, as requested by the President, and for other collaborating agencies in need of additional resources such as the U.S. Customs Service. The legislators may also promote the development of advanced technologies to assist the FDA and the states in their identification and enforcement efforts. This might be accomplished by establishing federally funded research grants targeted at the academic sector, or tax incentives for private companies to develop more advanced Web searching technology. While creating such incentives, legislators must also be mindful of the desire not to inhibit unreasonably online commerce and communication.

The States

The predominant state laws that exist to counter the current situation are clearly inadequate. States' Attorneys General are forced to tackle twenty-first-century problems with twentieth-century laws designed without adequate consideration for the Internet. These provisions are ineffective deterrents because they lack significant penalties. Additionally, the nature of the Internet makes it relatively easy for offenders to jump from one state to another state where policing may be less rigorous, or where the laws are even less useful to prosecutors. Even with these difficulties, a number of diligent States' Attorneys General pursued commendable and successful claims against rogue operators in 1999. Amidst the morass of inadequate traditional laws, a few state legislatures have been successful in developing new laws in an attempt to deal with this problem. In doing so, they have begun to forge a new legislative path for dealing with these sites. These new state laws may represent one of the best future tools because of their focused approach and consideration of developing

259. This inadequacy is exemplified by the fact that nineteen states will likely evaluate bills dealing with the regulation of online pharmacies next year. See Clinton, supra note 186.
260. See Pear, supra note 177 (describing federal officials frustration that most fines were limited to $1000 for a violation).
261. See supra notes 195-207 and accompanying text.
262. See supra notes 213-18 and accompanying text.
technology. The success of such laws, however, depends on the coexistence of stringent penalties, effective tools for identification, and diligent enforcement. All of these elements must be supported by a foundation of cooperation among the states, between the states and federal government, and between the states and professional organizations. The NAAG's suggestion of nationwide injunctive relief in the exercise of "cooperative federalism" is a sensible example of how this spirit of cooperation may enhance regulatory efforts and should be implemented.

Professional Organizations

To date, professional organizations have adequately fulfilled their advisory duties by providing information and guidance to government regulators. In order to realize their potential, these organizations must fulfill their developing commitments to produce revised practice standards for their practitioners. Organizations such as the AMA and NABP serve a crucial link between government regulators and the professionals they represent, because such organizations generally have a more accurate knowledge of their constituents' concerns and capabilities, making them well suited to tailor narrow but effective revised practice standards. It seems innately more likely that professionals will prefer regulations generated from associations or organizations within which they have a stake than from the federal or state government. Alternatively, it also seems more likely that effective, appropriately tailored state and federal regulations will result from a cooperative effort between the government and professional organizations. Although plans are being made in this regard, professional organizations also have the ability to make significant contributions in an advisory capacity to the state and federal government concerning proposed legislation. Essential to the effectiveness of these standards will be their association with well-defined and enforced penalties for violations. Additionally, the development and introduction of the VIPPS Certification Program by the NABP is a premier example of

263. See Abromowitz, supra note 49; Smoak, supra note 77; Stovall, supra note 205.
the type of forward-thinking, precisely defined tool that will benefit both practitioners and patients. Although the program has been criticized for being voluntary, and as such will likely fail to motivate rogue operators to meet its standards, it is precisely this type of professional leadership that the FDA depended upon when affirming the Framework Global Electronic Commerce. Because a program of this type is voluntary, it will provide added incentive for reputable providers to meet its rigid standards in order to market themselves as a leader in the field.

Finally, for programs such as VIPPS and revised practice guidelines to be effective, an educational campaign must accompany such efforts. The campaign should be two-pronged, targeting both professionals and the public. After updating professionals' knowledge of the field, these newly educated professionals may then help directly educate their own patients. In this manner the professionals may help reinforce the public messages conveyed via professional organizations' websites and traditional advertising. These organizations may seek to enlist student members of their respective bodies to assist in this public outreach.

CONCLUSION

The initial shockwave that followed the cyberpharmacy explosion left unsuspecting regulators dazed. As the dust begins to clear, it appears that the states, partnered with professional organizations and the federal government, are best positioned to address the unique issues associated with electronic pharmacies on the front line. Although apparently no more prepared than any of their regulatory counterparts, the states' historic function as regulators of pharmaceutical dispensing and licensure in the traditional (Pre-E) sense, has enabled them to regain their legislative and prosecutorial footing and establish a presence in this emerging electronic health care environment. The states, however, cannot police this arena alone. The inherent jurisdictional complexities require significant cooperation to adequately prohibit, identify, and prosecute offenders. With this in mind, a comprehensive mechanism is necessary. An approach that includes revised practice standards, Internet-focused state promulgated regulations, stiffer
penalties for violators, and enhanced identification tools is essential. The utilization of the FDA as a centralized tracking and enforcement resource at home and as a unified voice of authority to deal with foreign violators, coupled with the education of professionals and the public will also be crucial. In this respect, the FDA's initial efforts, via its Internet Drug Sales Action Plan, appear well targeted. Similarly, the continued attention, innovation, collaboration, and labor of professional organizations and other federal agencies are necessary. The implementation of such an organizationally broad, but narrowly focused, approach will enable the government to develop guidelines that protect the safety of U.S. citizens, while having the least restrictive impact on Internet commerce and the exchange of information.

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