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CAVEAT EMPTOR: REGULATING THE ON-LINE MEDICINE MAN IN THE NEW FRONTIER

*Patricia Stolfti**

The explosion of technology and universal access to the Internet over the past decade has created a global on-line marketplace at every person's fingertips.¹ The Internet has become "a sprawling mall offering goods and services"² to even the most alienated in our society. Everyday, Internet businesses are redefining and restructuring the distribution of goods and services by finding creative ways to harness competition, sell products, render services, disseminate information and gain access to new consumers.³ In a society where time is precious and convenience is essential, electronic commerce (e-commerce) is impacting all facets of life – our economy, our relationships, our workplaces, our health, and our

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1. ABA, *Achieving Legal and Business Order in Cyberspace: A Report on Global Jurisdiction Issues Created by the Internet* (forthcoming 2000).

In recent years, the number of computers and users connected to the Internet has skyrocketed as well. The number of computers hooked up to the Internet globally in 1992 totaled only 1.3 million whereas currently there are more than 68 million worldwide. Today, there are nearly 260 million users internationally with Internet access, and forecasts project there will be over 765 million users by 2005. The number of Internet users in the United States equaled 110 million at the end of 1999.

2. *ACLU v. Reno*, 521 U.S. 844, 853 (1997).

3. See Nancy Toross, Comment, *Double Click on This: Keeping Pace with On-line Market Manipulation*, 32 *LOY. L.A. L. REV.* 1399 (1999); see also Brian K. Epps, *Maritz, Inc. v. Cybergold, Inc.: The Expansion of Personal Jurisdiction in the Modern Age of Internet Advertising*, 32 *GA. L. REV.* 237, 239 (1997) (quoting Louise Kehoe, *Surge of Business Interest*, *FIN. TIMES*, Mar. 1, 1995, at XVIII); see also *Economic Perspective: Quarterly Economic and Market Analysis, First Quarter 2000*, at <http://www.schroders.com> (last visited July 2000) (“[W]hile the Internet should result in a reduction in business costs it will also lead to increase in competition. New companies can enter industries more easily. One issue will be the extent to which people are prepared to trust the new businesses and execute the transactions on line.”).

legal system.⁴

The vastness and newness of Internet development is creating a rapidly evolving electronic medium in which it is difficult to ascertain distinct legal boundaries. Regulated industries that “go global”⁵ must recognize that they will reach numerous legal jurisdictions that may have different or even conflicting regulatory requirements.⁶ The most notable regulated-industry to proliferate onto the Internet is the on-line pharmacy business.⁷ A simple query on any web search engine will return hundreds of websites that sell prescription drugs. It is estimated that over 500 electronic businesses offer prescription drugs over the Internet.⁸ “The on-line pharmaceutical market is expected to grow from \$11 million in 1998 to \$890 million in 2002, making it one of the fastest-growing e-commerce industries.”⁹

This growth of “cyber-drugstores”¹⁰ has created grave concern within the medical and legal communities regarding the safety and quality of prescription drugs dispensed over the Internet. Public health officials are “concerned about the Internet pharmacies that do not adhere to state licensing requirements and standards and enable consumers to obtain prescription drugs without a prescription and adequate physician supervision.”¹¹ While proponents of cyber-drugstores espouse the convenience and cost effectiveness of ordering prescription drugs from a personal computer in the comfort of one’s home, critics point out the ease of access to prescription and illegal drugs over the Internet.¹² The risks include receiving outdated, contaminated or inferior drugs, the possibility of dangerous drug interactions, and children gaining access to dangerous

4. See *The Impact of the Internet on the Mission of the Attorneys General: Legal Challenges to Civil and Criminal Law Enforcement and Recommendations for Action*, at <http://www.naag.org/features/legis.html> (last visited Oct. 17, 2000).

5. Richard Raysman & Peter Brown, *On-line Advertising and Marketing*, N.Y. L.J., Sept. 14, 1999, at 7.

6. See *id.* at 3.

7. See *id.*

8. F-D-C Reports, Inc., *The Pink Sheet: FTC Surf Days Turn Up 500 Fraudulent Sites; Prescribing Sites Raise Concerns*, 61(22) at 24 (May 31, 1999).

9. Christiane Truelove, *The New Frontier*, MED AD NEWS 18 (10) at 1 (Oct. 1, 1999).

10. Raysman, *supra* note 5, at 7.

11. U.S. GENERAL ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL REQUESTERS, INTERNET PHARMACIES ADDING DISCLOSURE REQUIREMENTS WOULD AID STATE AND FEDERAL OVERSIGHT, GAO-01-69 (Oct. 2000) [hereinafter GAO REPORT].

12. See Raysman, *supra* note 5, at 3.

or inappropriate drugs, such as Viagra.¹³

These concerns are creating a jurisdictional and regulatory quagmire that has ignited a debate over how to regulate the distribution and purchase of prescription drugs over the Internet.¹⁴ Intrinsic in the on-line pharmacy regulatory debate is the growing tension between the roles of the federal and state governments as regulatory and enforcement entities.¹⁵

Traditionally, pharmacies operate in community settings subject to state regulatory control boards.¹⁶ However, e-commerce is changing the way pharmacies do business. In the contemporary electronic marketplace, state laws regulating pharmacy practice run the risk of having an extraterritorial effect on Internet companies outside a state's legal jurisdiction. Through the Internet marketplace individuals can easily access and order drugs from pharmacies unlicensed in a particular state and receive the drugs across state borders through the mail. The federal government's role in regulating pharmacy practice has remained limited to the Food and Drug Administration's (FDA) role of ensuring that prescription drug products are safe and effective for consumption by consumers.¹⁷

The use of the Internet to sell and distribute drugs has created a jurisdictional struggle between the authority of the federal government, through the FDA, to regulate the quality and effectiveness of drugs and the state's right to regulate and license pharmacy practice. Both the states and the federal government are grappling with the challenge of balancing the benefits of on-line pharmacies with the health and safety concerns of the products dispensed to consumers. Unfortunately, ambiguity remains as to what level of government has the authority to regulate entities selling drugs over the Internet.

The current state-based system of regulation has established safeguards

13. See Jane E. Henney, *Internet Purchase of Prescription Drugs: Buyer Beware*, 131 ANNALS OF INTERNAL MED. 861-62 (1999) (explaining that Viagra is a popular drug for impotence, which if used incorrectly, can lead to severe health consequences).

14. See generally *Drugstores on the Net: The Benefits and Risks of On-line Pharmacies*; *Hearing Before the Subcomm. on Oversight & Investigations on Commerce of the House Committee on Commerce*, 106th Cong. (1999) [hereinafter *House Hearing*].

15. See *id.*

16. See Raysman, *supra* note 5, at 7.

17. See Federal Food Drug and Cosmetic Act of 1938 § 353(b)(1), as codified 21 U.S.C. § 503(b)(1) (1994).

to ensure proper oversight and distribution of prescription drugs.¹⁸ However, the Internet easily bypasses these safeguards because it creates ambiguous legal boundaries¹⁹ and allows pharmacies and physicians to anonymously reach across state borders to prescribe, sell, and dispense prescription drugs without complying with state regulations.²⁰ Regulators find themselves in a quandary over how to balance the current state-based system of regulation while maintaining safety and professional standards that allow consumers the flexibility and convenience of purchasing prescription drugs on-line.²¹

This Comment addresses how federal and state interests should be balanced to meet the demands of pharmacy regulation in a technological society. Part I presents a backdrop for the current regulatory debate by providing an overview of the evolution of the current structure of federal and state regulation of prescription drugs. Part II categorizes the mechanisms of purchasing drugs on-line, with an emphasis on the benefits and risks associated with the on-line purchasing of drugs. Part III analyzes the federalism issues related to the regulation of the Internet and in particular, on-line pharmacy licensing. Part IV examines the current efforts by the pharmaceutical industry, the states and the federal government to work within the existing legal boundaries to regulate on-line pharmacies and suggests that a partnership between the federal and state governments must be formed. Finally, this Comment culminates with a proposal to uphold the original intent of Congress and the FDA to create a pharmacy regulatory system to protect the consumer, while still allowing federalism to flourish.

I. THE DEVELOPMENT OF DRUG REGULATION IN THE UNITED STATES

In the last century, governments at all levels - federal, state, and local - collaborated with the medical and pharmaceutical professions to create a "risk-management system"²² that ensures patient and consumer protections, and medical quality by both doctors and apothecaries.²³ This risk-management regulatory system allows state and federal governments

18. See Henney, *supra* note 13.

19. See *id.*

20. See GAO REPORT, *supra* note 11.

21. See *Issue Brief No. 752, Physician Connectivity: Electronic Prescribing* (National Health Policy Forum, The George Washington University) (2000).

22. PETER TEMIN, *TAKING YOUR MEDICINE-DRUG REGULATION IN THE UNITED STATES* 48-50 (1980).

23. *Id.*

to maintain separate and distinct roles with reference to licensing, drug approval, and enforcement.²⁴

A. Federal Role in Pharmacy Regulation

Federal regulation of prescription drug distribution is controlled primarily by the Food, Drug and Cosmetic Act (FDCA)²⁵ and the Controlled Substance Act (CSA).²⁶ Currently, several federal agencies have concurrent jurisdiction over drug distribution in the United States.²⁷ This comment will primarily focus on the background pertinent to prescription drug distribution and the role of the FDA and the FDCA.

The FDCA, approved by Congress in 1938, provided a latticework for the current infrastructure that regulates the prescribing, dispensing, and distribution of prescription drugs in the United States.²⁸ The FDCA led to the development of the FDA and regulations that have evolved into the government-regulated system of prescription drug distribution that we have today. The United States Congress, the FDA, and the states have moved from self-regulation by the consumer toward government-based protection and regulation.²⁹ The FDA was created to guarantee the effectiveness and safety of all available drugs.³⁰ Congress assumed that consumers could not understand the implications of a list of ingredients and would not follow directions for proper use.³¹ The FDCA was not intended to deprive the consumer and medical profession of potent but valuable drugs.³² Instead, the purpose of the FDCA and the FDA is to ensure proper monitoring of prescription drugs by licensed doctors and safe distribution into the hands of consumers by licensed pharmacists.³³ This system created assurances of safety to the public, that any drug on

24. See Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 (1994); see also TEMIN, *supra* note 22, at 48-50.

25. Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301.

26. Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 801 (1994).

27. The Food and Drug Administration (FDA), the Department of Justice (DOJ), the Federal Trade Commission (FTC), the Drug Enforcement Agency (DEA), the Customs Service and the Postal Service are the federal agencies that have a role in the regulation of drugs.

28. See TEMIN, *supra* note 22, at 43.

29. See *id.*

30. *Id.*

31. *Id.*

32. See *id.* at 48-50.

33. See *id.*

the market could be taken in reasonable quantities without harm.³⁴

In 1948, the Supreme Court also approved FDA oversight of the drug regulatory system in *United States v. Sullivan*.³⁵ Between 1951 and 1971, the drug regulatory system evolved through congressional amendments providing increased regulation and oversight by the FDA.³⁶

These changes gave the FDA additional authority to approve the introduction of new drugs into the market.³⁷ Congress granted physicians and pharmacists the ability to protect their patients from knowingly or accidentally misusing medicines that are either toxic or have the potential for causing harm.³⁸ Accordingly, under the FDCA, prescription drugs may now be distributed only with a valid prescription under the professional supervision of a physician.³⁹ A prescription drug is misbranded if it is not dispensed pursuant to a valid prescription in accordance with 21 U.S.C. § 353(b).⁴⁰

Violators of the FDCA can be charged either civilly or criminally.⁴¹ For a felony conviction, the government must establish that the defendant acted with intent to defraud or mislead either the consumer or the government, or that the defendant is a repeat offender.⁴² Civil cases do not require proof of intent to defraud.⁴³

Congress also expanded the agency's authority by allowing it to create and enforce standards of good manufacturing practices⁴⁴ for pharmaceutical manufacturers and to enforce labeling laws.⁴⁵ It also extended the agency's administrative authority to withdraw approval that it had previously granted to drugs for several reasons, such as safety

34. *See id.*

35. *U.S. v. Sullivan*, 332 U.S. 689, 694 (1948).

36. Congress made changes to the FDCA and the regulation and safety of drugs through the Durham Humphrey Amendment, the 1962 Drug Amendments, and additional regulatory actions by the FDA; TEMIN, *supra* note 22.

37. *See* TEMIN, *supra* note 22, at 48-50.

38. *See House Hearing*, *supra* note 14 (statement of Ivan K. Fong, Deputy Assistant Att'y Gen., U.S. DOJ).

39. *See* Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 353 (b)(1).

40. Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 353 (b).

41. *See House Hearing*, *supra* note 14 (statement of Ivan K. Fong, Deputy Assistant Att'y Gen., U.S. DOJ).

42. *Id.*

43. *Id.*

44. *See* Pub. L. No. 87-781 (1962); *see also* TEMIN, *supra* note 22, at 48-50.

45. *See id.*

concerns.⁴⁶ However, the agency could not interfere with a doctor's right to prescribe approved drugs for patients.

Currently, the FDCA⁴⁷ requires that

- (1) A drug intended for use by man which
 - (A) is a habit-forming drug to which 352(d) of this title applies;
or
 - (B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
 - (C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug.⁴⁸

The drug shall be dispensed only by prescription or authorized prescription refill.⁴⁹

In addition to classifying and authorizing the sale of prescription drugs, the FDA has the authority to allow drugs to be sold without a prescription; these are known as over-the-counter drugs.⁵⁰ Moreover, the FDA statutorily regulates pharmaceutical importation, the sale or distribution of an adulterated or misbranded drug, the sale or distribution of an unapproved drug, the illegal promotion of a drug, the sale or dispensing of a prescription drug without a valid prescription, and counterfeit drugs.⁵¹

The duties of the FDA, as outlined above, define the extent of the FDA's current authority over the distribution of drugs. The FDA establishes which drugs are obtainable over-the-counter and which drugs require a prescription from a licensed professional.⁵² However, the FDA has never obtained any regulatory control over the licensure of pharmacists or doctors. Throughout the entire regulatory debate these responsibilities remained with the states. As a result, the states maintain their rights to regulate, monitor, and license the professionals who have dispensing and prescribing privileges.

46. *See id.*

47. Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 353 (1994).

48. Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 503(b)(1) (1994).

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.*

B. Current State Role in Prescription Drug Regulation

State boards or commissions of pharmacy are responsible for the oversight and licensing of pharmacies and pharmacists.⁵³ State medical boards within each state license and regulate how physicians and prescribers write prescriptions.⁵⁴ These roles of the state boards of pharmacy and medicine are analogous to the legal profession's state bar and ethics requirements. In order to be licensed to practice in a state, pharmacists and doctors must meet that state's licensing requirements. All fifty states and the District of Columbia have a state medical board or commission of pharmacy responsible for licensing and regulating all pharmacies doing business within a state.

Most states also require pharmacies that operate out of state, but that ship products to consumers within their state, to be licensed by their state board or commission.⁵⁵ This may include Internet and mail service pharmacies.

Many states have enacted statutes to regulate mail-order delivery of drugs. Forty states currently have codified mail-order pharmacy requirements, which require a pharmacy to be licensed wherever its headquarters is physically located and wherever the patients it serves reside.⁵⁶ Therefore, mail-order pharmacies must meet each state's requirements to service customers in more than one state. However, eleven states have chosen not to enact licensing requirements for out-of-state mail order pharmacies.⁵⁷

For example, in the Connecticut statute, a "Non Resident Pharmacy" is defined as any pharmacy located outside the state of Connecticut which ships, mails or delivers, in any manner, devices or drugs into Connecticut pursuant to a prescription order.⁵⁸ The statute requires registration of the pharmacy with the state, outlines four criteria that must be met to deliver drugs into the state and mandates the use of a business hour telephone number that must be affixed to every prescription drug container

53. See *Issue Brief No. 752*, *supra* note 21.

54. See *House Hearing*, *supra* note 14 (statement of Carla Stovall, Att'y Gen., State of Kansas).

55. See *House Hearing*, *supra* note 14.

56. *Id.* (stating that forty states currently require pharmacies to be licensed wherever its headquarters are physically located and wherever the patients it serves reside. This process is somewhat similar to the procedure mail-order pharmacies undergo to service customers in several states).

57. See, e.g., GAO REPORT, *supra* note 11 (Mass. and W.Va.).

58. CONN. GEN. STAT. § 20-627(a) (1999).

dispensed.⁵⁹ Other states, such as Alabama, mandate that any nonresident pharmacy that ships, mails or delivers prescription drugs or devices to a patient in the state of Alabama shall designate a resident agent in Alabama for service of process.⁶⁰ If a resident agent is not designated, the designee automatically becomes the Secretary of State of Alabama.⁶¹

Furthermore, all states statutorily provide that entities illegally obtaining or supplying drugs by fraud, deceit, misrepresentation, subterfuge or forgery will face revocation of license, prosecution or another type of penalty.⁶² States enacted these laws to protect their respective citizens from black-market pharmacies and to ensure consumer trust, safety and protection by licensed professionals.

Throughout the debate surrounding the creation of the FDCA, Congress recognized that a state-based pharmacy licensing regulatory system, as described above, was the best approach.⁶³ The rationale behind Congress' decision was that this responsibility fell within the state's police powers to regulate the health, safety, and welfare of its citizens. Congress acknowledged that the drug system needed to change from a market driven arrangement, where consumers were making their own choices, to a hierarchical structure, where pharmacies and pharmacists controlled distribution of potentially dangerous pharmaceuticals through prescriptions.⁶⁴

In the current evolving marketplace, numerous cyber-drugstores are easily circumventing the current scheme of regulations. The Internet is creating a market or consumer driven system remarkably similar to that existing prior to the enactment of the FDCA. This similarity exists because consumers now have direct access to drug manufacturers and drug information through the World Wide Web, which circumvents the prescriber and the pharmacist. Thus, much of the debate that occurred during the creation of the current state-based system of pharmacy regulation is being revisited. The same dangers from which Congress tried to protect consumers at the inception of the regulatory system are being revived with current trends. Prescription drug advertisements targeting consumers and the growth in Internet use are causing the federal and state governments to re-evaluate the balance of regulatory

59. CONN. GEN. STAT. § 20-627 (b)(1)-(4),(c).

60. ALA. CODE § 34-23-92 (1990).

61. *Id.*

62. *See, e.g.*, CONN. GEN. STAT. § 20-627(a) (1999).

63. *See TEMIN, supra* note 22, at 55.

64. *See id.*

authority.⁶⁵

II. THE NEW PHARMACEUTICAL LANDSCAPE

Like traditional community pharmacies, Internet pharmacies allow consumers to order new prescriptions and refill existing prescriptions, to obtain important information regarding their medication, to receive prescription refill reminders, and to access their complete medication profile.⁶⁶ Internet pharmacy sites represent an alternative electronic medium for ordering prescriptions, comparable to a fax or telephone.⁶⁷ For example, just as a “patient takes a prescription to a pharmacy, a physician calls in a prescription, or the patient calls in a refill,”⁶⁸ patients can now access the World Wide Web via the Internet to order prescription medications on-line.⁶⁹ The orders can then be delivered by mail to the consumer or picked up from a local pharmacy. Many on-line pharmacies are subsidiaries of traditional community or chain drugstore pharmacies.⁷⁰ However, new on-line pharmacies have begun to spring up because corporations not previously engaged in pharmaceutical distribution have recognized the potential of the growing market. As a result, several different business forms have emerged. E-pharmacies can be strictly on-line or they can form partnerships with more traditional healthcare entities, including community pharmacies, chain drugstores, pharmacy benefit managers (PBMs), insurance companies or Health Maintenance Organizations.⁷¹

Regardless of the form of the relationship, pharmacies and pharmacists must be licensed by state boards of pharmacy, and must comply with a comprehensive set of laws and regulations. Federal and state regulators are becoming concerned with questionable and unethical pharmaceutical practices, including prescribing and dispensing drugs through some

65. See *House Hearing*, *supra* note 14.

66. See NATIONAL ASSOCIATION OF CHAIN DRUG STORES ISSUE BRIEF: INTERNET PHARMACEUTICAL SERVICES (Aug. 2, 1999) at www.nacds.org/news/release/nr080299brief.html.

67. *Id.*

68. *Id.*

69. *Id.*; see generally *House Hearing*, *supra* note 14.

70. See <http://www.cvs.com> (last visited Nov. 8, 2000); <http://www.riteaid.com> (last visited Nov. 8, 2000).

71. See Larry Stevens, *E-pharmacies A Slow Go – Marketing Prescriptions On The Web Still Seen As A Big Headache*, INTERNETWEEK, Feb. 28, 2000, at <http://www.internetweek.com> (last visited Mar. 2000).

Internet pharmacy sites.⁷² These sites, labeled “rogue” sites by the FDA, legislatures, and regulators, may be providing unsafe products or allowing customers to obtain prescription drugs illegally.⁷³ These sites provide opportunities for irresponsible marketers to prey on ill consumers, with potentially serious consequences.⁷⁴

There are several ways in which the sale and distribution of pharmaceutical products over the Internet can be categorized. Traditional “click and mortar”⁷⁵ online pharmacies require consumers to obtain a prescription from a licensed physician before ordering the drug.⁷⁶ A valid prescription must be submitted, either by the prescriber or consumer, to the on-line pharmacy by fax, e-mail or phone. The on-line pharmacy then verifies the prescription with the prescribing physician. Finally, prescription drugs are either delivered by mail to the consumer or picked up at a community drugstore that has partnered with the cyber-drugstore.⁷⁷ An example of a traditional site is drugstore.com,⁷⁸ a site that is run like the corner drugstore or mail service pharmacy. This site complies with all current laws of the fifty states and with the federal law regarding the distribution of pharmaceuticals.⁷⁹ The only difference between the community drugstore and drugstore.com is the manner in which the company communicates with its customers.⁸⁰ Most state and federal governmental officials believe that on-line drugstores functioning in the same manner as traditional pharmacies are legitimate, safe, and can effectively and conveniently distribute prescription drugs to consumers.⁸¹

A second category of on-line pharmacies offers the services of a doctor or other prescriber to diagnose and prescribe medication for a patient on-

72. See generally *House Hearing*, *supra* note 14.

73. See *id.*

74. See *House Hearing*, *supra* note 14 (statement of Jody Bernstein, Director, Bureau of Consumer Protection, FTC).

75. *Steven*, *supra* note 71.

76. See <http://www.drugstore.com> (last visited Oct. 4, 2000); *E-Drugs-Who Regulates Internet Pharmacies? Hearing Before the Senate Committee on Health, Education, Labor, and Pensions*, 106th Cong. (2000) [hereinafter *Senate Hearing*] (statement of Peter M. Neupert, President and CEO, Drugstore.com); *House Hearing*, *supra* note 14.

77. See *id.*

78. <http://www.drugstore.com> (last visited Dec. 17, 2000).

79. See *Senate Hearing*, *supra* note 76 (statement of Peter M. Neupert, President and CEO, drugstore.com).

80. *Id.*

81. *Id.* (statements by Sen. Jeffords, Sen. Kennedy, Sen. Dodd, and Kansas Att’y Gen. Carla J. Stovall).

line.⁸² The website pharmacy then distributes the medication without a physician ever physically seeing the patient.⁸³ Typically these on-line doctor/pharmacies use an on-line medical questionnaire which asks for the patient's medical history and a list of current medications.⁸⁴ Based on the answers to these questionnaires, the doctor gives his diagnosis and prescribes a medication.⁸⁵ The lack of patient-physician contact, the ease by which these drugs can be obtained by fraud or unethical review of medical history, and the potential for people to be harmed by receiving drugs that may not be suitable or necessary to treat the patients condition, all raise serious health concerns.⁸⁶ For example, some pharmacy sites focus solely on the prescribing and dispensing of certain lifestyle enhancing drugs.⁸⁷ These medications are often provided without the benefit of complete patient medical information. Moreover, the dispensing pharmacy may not even be licensed.⁸⁸ Children, women, elderly patients with heart conditions, and even household pets are receiving incorrect or inappropriate medication, such as Viagra, from on-line ordering despite the fact that the patient accurately and honestly completed the on-line form.⁸⁹ "The ease with which these drugs, especially the controlled substances, [are] distributed without an exam, without even a conversation with the recipient, is shocking and should be terrifying to those invested in public health."⁹⁰ These websites do not meet the requirements established by most states for the ethical and legal practice of dispensing medical advice and prescription drugs.

Illicit on-line pharmacies are a third type of pharmacy site. These sites allow consumers to purchase prescription drugs without a prescription.⁹¹ Alarming, these sites even sell narcotics and other equally dangerous drugs to consumers without any type of authorization from a health professional.⁹² Sites that allow prescription drugs to be sold without any

82. See *House Hearing*, *supra* note 14.

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

87. See *House Hearing*, *supra* note 14; for other sites that offer lifestyle drugs, see <http://www.quest.com> (last visited Dec. 17, 2000).

88. See *House Hearing*, *supra* note 14.

89. See *Senate Hearing*, *supra* note 76.

90. *Id.* (statement of Carla Stovall, Kansas Att'y Gen.).

91. See *id.* (statement of Ivan K. Fong, Deputy Associate Att'y Gen., U.S. DOJ).

92. See *Senate Hearing*, *supra* note 76.

pretense of a prescription are clearly violating the FDCA, the FDA regulatory rules, the CSA, and the laws of all fifty states.

The final category and the hardest for FDA to regulate are "offshore foreign-based sites."⁹³ These sites allow foreign-based entities to reach across international borders to provide medications, which may or may not be obtained with a prescription, to United States consumers.⁹⁴ These sites often provide consumers with experimental treatments not available in the United States or with drugs not approved by the FDA. Foreign sites may allow pharmaceutical products to be ordered without a prescription, and import the products into the United States via mail.⁹⁵

The problem with these sites is that every country has a different approval process for prescription drugs. Many countries have less stringent drug approval processes than the United States. The Internet allows residents of the United States to access a website of an entity selling pharmaceuticals in another country that may not meet domestic health requirements or vice versa.⁹⁶ These situations raise legitimate concerns about the quality and safety of prescribing and dispensing prescription drugs through Internet drugstores. Consumers are at risk when pharmacy sites either offer prescription drugs or unapproved fantasy cures that could be dangerous to their health.⁹⁷

III. GEOGRAPHIC VAGUENESS OF THE INTERNET

The Internet obscures geographic and legal barriers and creates a drug marketplace without defined borders.⁹⁸ Because of the global nature of e-commerce, it is doubtful whether any individual legal entity can regulate the Internet. This issue is further complicated by the fact that domain names, web addresses, location of consumers, and the situs of entities selling drugs cannot accurately be identified.⁹⁹ Congress and state legislatures want to pass laws protecting consumers from the dangers of

93. *Id.*

94. *Id.*

95. See *House Hearing*, *supra* note 14; for other sites that offer lifestyle drugs, see <http://www.quest.com> (last visited Dec. 17, 2000).

96. A simple example: the U.S. FDA has approved the sale of some strengths of hydrocortisone without a prescription. England and Ireland on the other hand, prohibit the over-the counter sale of this drug. Interview with Louise Kingston, Irish Attorney and Ph.D candidate, in Washington, D.C. (Jan. 20, 2000).

97. See *House Hearing*, *supra* note 14.

98. *ACLU v. Reno*, 521 U.S. 844, 853 (1997).

99. *Id.*; see *Toross*, *supra* note 3; *Impact of the Internet*, *supra* note 4; *House Hearing*, *supra* note 14.

rogue pharmacy websites. However, the inability of regulators to accurately determine the location of a website and to stop someone from visiting a site, makes it difficult to do so.¹⁰⁰ Furthermore, because no boundaries exist, conflicts are created over what legal entity actually has legal authority to proscribe laws.¹⁰¹ Aside from the vast problems created in the international market and by the transference of data, the borderless nature of the Internet has also sparked a federalism debate within the United States.

A. Will Federalism Thrive in the New Frontier?

Since the Constitutional Convention in 1776, two competing Constitutional theories have emerged within our legal system. The first theory interprets the Constitution as creating a strong uniform federal government. The other interpretation reserves certain powers to the states. "These simple truths of power bestowed and power withheld under the Constitution have never been more relevant in this day, when accretion, if not actual accession, of power to the federal government seems not only unavoidable, but even expedient,"¹⁰² especially in light of the creation of the Internet. However, as President Woodrow Wilson observed, "[t]he question of the relation of the states to the federal government is the cardinal question of our constitutional system. At every turn of our national development we have been brought face to face with it."¹⁰³

In the wake of the Internet revolution, the federalist division of power in the United States has the potential to be undermined and seriously diminished. Many legal scholars believe that the federal government is the only governmental entity that has authority to regulate activity occurring over the Internet in the United States.¹⁰⁴ This theory is based on the Commerce Clause¹⁰⁵ and the interstate nature of e-commerce. However, others follow the theory that the Constitution and legal precedent have established traditional state roles of regulation, such as the state police powers,¹⁰⁶ that may be thwarted by technology.

100. See *Reno*, 521 U.S. at 853.

101. *Id.*

102. *Brzonkala v. Va. Polytechnic Inst.*, 169 F.3d 820, 826 (4th Cir. 1999).

103. Raymond C. Scheppach & Frank Shafroth, *GOVERNANCE IN THE NEW ECONOMY*, NATIONAL GOVERNOR'S ASSOCIATION 20 (2000).

104. See generally Steven R. Salibu, *Who Should Govern the Internet?: Monitoring and Supporting A New Frontier*, 11 HAR. J. L. & TECH 429 (1998).

105. See U.S. CONST. art. I, § 8 cl. 3.

106. See generally *United States v. Lopez*, 514 U.S. 549 (1995).

Thus once again, policy makers are re-examining the allocation of regulatory power within the federalist system of government. "Sometimes, a greater reliance on federal standards will be the right policy choice. Other times, the right policy choice will be to devolve responsibilities to state and local governments, rather than centralize them at the federal level."¹⁰⁷ The growing federal and state regulatory debate surrounding on-line pharmacies is a prime example of the legal conflicts created by these two divergent theories regarding the regulation of Internet activity.

The Constitution of the United States recognizes the authority of the states, since the states preceded and ratified it and reserved to the states the authority to regulate the health, safety, and welfare of their citizens.¹⁰⁸ The licensing of pharmacies falls within these states rights. It is important to examine the reasons states were given the power to license and regulate pharmacies. Traditionally, most pharmacies were operated within the local communities and only dispensed drugs to citizens in one particular state or location. States were given the authority to ensure that pharmacies distributed drugs in a safe manner that protected the health of its citizens. As discussed earlier, states monitored drug distribution by enacting professional licensing safeguards. The federal government concurred with the state-based approach to regulating pharmacy practices. It was easier for citizens to seek relief through a local or state government entity rather than through a federal agency. States established licensing and certification processes to provide professional standards to ensure consumer safety in many professions outside of the healthcare area as well. Learned licensed professions, such as lawyers, doctors, teachers, and pharmacists, are exclusively regulated by each individual state.

The following cases illustrate the diverging views within the legal community in relation to federalism and regulation of the Internet. In 1997, the United States District Court for the Southern District of New York ruled in *American Libraries Association v. Pataki*¹⁰⁹ that the Internet "represents an instrument of interstate commerce"¹¹⁰ and that the "novelty of the technology should not obscure the fact that regulation of the Internet impels traditional Commerce Clause considerations."¹¹¹ The district court held that a state Internet Act could not survive Commerce

107. Scheppach & Shafroth, *supra* note 103.

108. See generally *Lopez*, 514 U.S. at 549.

109. *American Libraries Assn v. Pataki*, 969 F. Supp. 160 (S.D.N.Y. 1997).

110. *Id.* at 173.

111. *Id.*

Clause scrutiny, "because it places an undue burden on interstate traffic, whether that traffic be in goods, services or ideas."¹¹² The judge renounced all state regulation of the Internet and called for a "uniform national treatment [that] bars the states from enacting inconsistent regulatory schemes."¹¹³

Three days after *Pataki*, the Supreme Court of New York also addressed the jurisdictional issues of the Internet. In *New York v. Lipsitz*,¹¹⁴ the court took the position that traditional jurisdictional standards have proven efficient to resolve civil Internet jurisdictional issues to date.¹¹⁵ The court held that the New York State courts had jurisdiction over the respondent who sold magazine subscriptions under both unregistered and registered assumed business names in violation of existing state consumer fraud statutes.¹¹⁶ "The Internet medium is essentially irrelevant, for the focus is primarily upon the location of the messenger and whether the messenger delivered what was purchased."¹¹⁷ "Where a person . . . conducts a business within the forum state by being a subscriber to a local Internet service provider and selling a product through that provider, jurisdiction is proper."¹¹⁸ The New York State court focused on the transaction involved and not the venue or medium in which it was purchased.

The New York court distinguished *Pataki* from *Lipsitz* on two grounds. First, state consumer protection laws are applicable to the conduct of a local business and were not designed nor aimed at regulating conduct outside the state's borders.¹¹⁹ Second, the law at issue in *Lipsitz* was not designed to create an Internet regulatory scheme.¹²⁰ In dicta, the court stated that:

The claims are of local concern, as recognized by the nationwide system of state consumer protection laws. There is *no*

112. *Id.*

113. *Id.* at 184.

114. *N.Y. v. Lipsitz*, 663 N.Y.S.2d 468 (1997).

115. *See id.*

116. *See id.*

117. *Id.*

118. *Id.* at 473 (citing *CompuServe, Inc. v. Patterson*, 89 F.3d 1257 (6th Cir. 1996). For varying tests for tort and intellectual property claims, see *EDIAS Software Int'l. v. Basis Int'l.*, 947 F. Supp. 413 (D. Ariz. 1996), *CA Software v. Reliability Research*, 631 F. Supp. 1356 (D. Cal. 1986) and *Playboy Enters. v. Chuckleberry Publ'n*, 939 F. Supp. 1032 (S.D.N.Y. 1996).

119. *See Lipsitz*, 663 N.Y.S.2d at 468; *Pataki*, 969 F. Supp. at 160.

120. *See Lipsitz*, 663 N.Y.S.2d at 468.

compelling reason to find that local legal officials must take a “hands off” approach just because a crook or a con artist is technologically sophisticated enough to sell on the Internet. Invocation of “the Internet” is not the equivalent to a cry of “sanctuary” upon a criminal’s entry into a medieval church. It should be sufficient that the laws sought to be applied, even if they might tangentially implicate interstate commerce, are “media neutral” and otherwise pass constitutional muster.¹²¹

The distinction is that *Lipsitz* dealt with an existing state law being applied to the Internet, while *Pataki* tested a law targeted directly at the Internet.¹²² This same distinction would logically apply to regulation of prescription drugs over the Internet.

Just because there is now a new medium in which illegal acts can occur does not mean we throw out the baby with the bath water; in other words an otherwise illegal act does not become legal merely because it is committed using technology and the Internet.¹²³ A state does not become powerless to protect its citizens merely because a threat to the health and welfare of its citizens arises on-line rather than in person, by mail, or in some other traditional manner.¹²⁴ Therefore, states should be able to apply existing state licensing and consumer protection laws to on-line pharmacies. The traditional role and function of state government is to protect the health, welfare, and safety of its citizens.¹²⁵ What greater function does a state hold than to maintain solid health care protections by regulating the dissemination of drugs? In fact, states have traditionally maintained these standards and have uniquely packaged them to address local community concerns.¹²⁶

Over the last few years, the Supreme Court has reminded Congress that federalism still exists in the United States and that the federal government and state governments have distinct and separate roles.¹²⁷ More recently, the court has upheld state criminal codes, and the right to regulate schools and school grounds.¹²⁸

121. *Id.* at 475.

122. See Christopher S. W. Blake, *Note: Destination Unknown: Does the Internet’s Lack of Physical Situs Preclude State and Federal Attempts to Regulate It?*, 46 CLEV. ST. L. REV. 129 (1998).

123. See *Lipsitz*, 663 N.Y.S.2d at 468; *House Hearing*, *supra* note 14.

124. See *House Hearing*, *supra* note 14.

125. See generally *United States v. Lopez*, 514 U.S. 549, 549 (1995).

126. See *Scheppach & Shafroth*, *supra* note 103.

127. See generally *Kimel v. Fla. Bd. of Regents*, 2000 U.S. LEXIS 498 (2000); *Reno v. Condon*, 2000 U.S. LEXIS 503 (2000); *Lopez*, 514 U.S. at 549.

128. *Lopez*, 514 U.S. at 549.

Inherently, Internet commerce falls under interstate commerce because it crosses state lines. Proponents of federal commerce clause jurisdiction believe that the government needs to streamline regulation and erode the federalism theory of government. These scholars maintain that it is not cost-effective to have fifty superfluous licensing requirements across state lines.¹²⁹ They argue that it creates redundancy by maintaining fifty separate state efforts to achieve a similar or identical goal.¹³⁰ Moreover, repetitive state laws can exact costs associated with multiple adjudication of what is essentially one issue addressed by the separate laws of numerous states.¹³¹ In addition, industries, which must comply with numerous licensing laws, may have duplicative and costly state compliance fees that may impose a conflict of laws upon a single actor for a single transaction because of state-by-state differences.¹³² Advocates for a stronger federal role in pharmacy regulation and oversight argue that a traditional mail-order pharmacy can expand its operations on a state-by-state basis as it obtains licenses for each state in which it does business.¹³³ A start-up Internet pharmacy is by its very nature nationwide on the day it opens for business.¹³⁴ Unless an on-line pharmacy obtains all necessary licenses before operating its website, it may encounter trouble with state licensing laws.¹³⁵

The uniformity argument is minimized by the fact that legitimate mail-order pharmacies have been complying with state licensing and consumer laws since their inception. It follows that legitimate cyber-drugstores can also comply with state licensing laws by not delivering drugs into states in which it does not have a license. Teachers, doctors, and lawyers must be licensed or certified in each state in order to practice their professions. This licensure principle is one that needs to be maintained for pharmacists and pharmacies as a mechanism to uphold ethical and safety standards.

Throughout the history of the United States, the conflicting views of federalism have remained balanced. Technology should not be the downfall of our federalist society. One commentator suggested that “the

129. *See generally* Salibu, *supra* note 104.

130. *See id.*

131. *See id.* at 459.

132. *See id.*

133. *See* Kimberly Applequist, *Onlinedrugs.com: Legal Issues Raised By Online Pharmacies*, 11(5) *Drug Benefit Trends* 28, 37 (1999), at <http://www.medscape.com/SCP/DBT/1999/v.11.n05/d5613.appl/d5613.appl-01.html> (last visited Oct. 2000).

134. *See id.*

135. *See id.*

law as presently constituted will absorb the challenges posed by the Internet, as the law has absorbed challenges posed by previous technological innovations.¹³⁶ Governance in a federalist-Internet society entails compromise and partnership to ensure that protections are in place for a community's citizens and businesses.

B. Federalism as a Partnership

The partnership approach is based on a hybrid of the two divergent federalism theories. The federal government has the authority to use its Commerce Clause power to create legal mechanisms that recognize and facilitate state regulation and the licensing of professional entities that traditionally fall within state jurisdiction.

This is not a remote or shocking legal principle. Congress demonstrated its ability to partner with states when it enacted the federal telemarketing statute.¹³⁷ The federal telemarketing statute¹³⁸ gave the states the power to seek nationwide injunctive relief by filing suit in federal district court.¹³⁹ This provision enables a state, through its attorney general, to obtain an injunction effective nationwide, and yet does not prohibit action in state court based on individual state law.¹⁴⁰ The States' Attorneys General are advocating this position as a way to enhance enforcement of existing law to combat lawlessness occurring on the Internet.¹⁴¹ This approach would enable states to avoid duplicative enforcement proceedings against alleged illegal cyber-drugstores.

As the *Lipsitz* court inferred, existing laws are applicable to citizens using the Internet.¹⁴² Thus, rather than creating new authority for on-line pharmacies, states should look to existing statutes, not related to the Internet medium, for enforcement against criminal activity on the Internet. The federal government can take steps to assist state efforts by instituting national injunctive relief, thus forcing the industry to strengthen advertising and disclosure requirements.

136. Scheppach & Shafroth, *supra* note 103.

137. Telemarketing and Consumer Fraud and Abuse Prevention Act, 15 U.S.C. § 6103 (1994); Telemarketing Sales Rule, 16 C.F.R. § 310 (2000).

138. *Id.*

139. Telemarketing Sales Rule, 16 C.F.R. § 310.

140. *Id.*

141. See Nat'l Ass'n of Att'ys Gen., *supra* note 4; see also *Senate Hearing, supra* note 76 (statement of Carla Stovall, Kansas Att'y Gen.).

142. *Lipsitz*, 663 N.Y.S.2d at 468.

IV. ENFORCEMENT OF EXISTING LAWS TO ON-LINE PHARMACIES

According to testimony at the first Congressional hearing on the dangers of on-line pharmacies, all of the witnesses stressed that pre-existing laws can be applied to lawlessness on the Internet.¹⁴³ Currently, each state has the statutory authority to obtain a restraining order preventing unlicensed on-line pharmacies from doing business within a state's own borders.¹⁴⁴ Twenty states have already taken action against illegitimate on-line prescribers and distributors through pre-existing state laws.¹⁴⁵

New Jersey charged eight on-line pharmacies with consumer fraud violations for selling prescription medications via the Internet without a state license.¹⁴⁶ New Jersey law requires pharmacies, pharmacists, and physicians practicing in the state to be licensed with the New Jersey Division of Consumer Affairs.¹⁴⁷ The cyber-drugstores against which the state has brought suit are unlicensed entities in the State of New Jersey. The State alleged that the on-line pharmacies violated the state Consumer Fraud Act and committed an unconscionable commercial practice for failing to disclose to New Jersey consumers that they were not licensed to dispense prescription drugs or controlled dangerous substances in the state.¹⁴⁸

In Kansas, the Attorney General filed suit against eight on-line companies, six doctors, and four additional persons for participating in the illegal sale of prescription drugs to Kansans.¹⁴⁹ The Internet drugstores were unlicensed and required no in-person examination or consultation prior to prescribing and dispensing drugs.¹⁵⁰ The Attorney General based the case on the premise that

by prescribing drugs to Kansans, [the doctors] practiced medicine [in Kansas] without the required legal authority. By dispensing drugs to Kansans, [the defendants] practiced pharmacy in the state without the required legal authority. And

143. See generally *House Hearing, supra* note 14.

144. See *Senate Hearing, supra* note 76 (statement of Carla Stovall, Kansas Att'y Gen.).

145. *Id.*; GAO REPORT, *supra* note 11.

146. Press release, John L. Farmer, Jr., Att'y Gen., State of New Jersey (Mar. 30, 2000).

147. *Id.*

148. *Id.*

149. See *Senate Hearing, supra* note 76 (statement of Carla Stovall, Kansas Att'y Gen.).

150. *Id.*

by recklessly dispensing drugs without any doctor-patient relationship whatsoever, while failing to disclose to consumers material information, such as health risks associated with use of some of these drugs, all of the defendants committed deceptive and unconscionable acts in violation of our Consumer Protection Act.¹⁵¹

Other states, such as Texas, West Virginia, Wisconsin, Missouri, Washington, and Maryland are also enforcing existing laws against Internet pharmacies illegally dispensing drugs to their respective citizens.¹⁵² “Most of the Internet pharmacies that were sued voluntarily stopped shipping prescription drugs to consumers in those states.”¹⁵³ As a result, eighteen cyber drugstores stopped shipping drugs to residents in Illinois, Kansas, Michigan, Missouri, New Jersey, and Pennsylvania.¹⁵⁴

States are stopping the unlicensed cyber-pharmacies from doing business in their states and are seeking financial penalties and investigative costs. However, when a state successfully prosecutes an Internet pharmacy and prevents the pharmacy from dispensing drugs to residents of its state, the court action applies only in that state. By extending nationwide injunctive relief, states would be able to combine efforts and resources against the same bad actors, while leaving other states free to use limited resources to file against other offenders.

States that have not specifically taken action against Internet pharmacies also have existing laws that are enforceable. Statutes, such as the Connecticut mail-order statute discussed earlier, allow all inclusive dispensing, i.e. “in any manner,”¹⁵⁵ and thus are far reaching enough to incorporate the purchase and sale of drugs by and to Connecticut citizens over the Internet.

The federal government has set the precedent for applying already existing laws to sales over the Internet.¹⁵⁶ Since 1996, the FDA has started enforcing existing FDA regulations and laws against entities selling drugs over the Internet.¹⁵⁷ The FDA has been successful in using current wire

151. *Id.*

152. *See Lipsitz*, 663 N.Y.S.2d. 468; GAO REPORT, *supra* note 11.

153. GAO REPORT, *supra* note 11.

154. *Id.*

155. CONN. GEN. STAT. § 20-627(a) (1999).

156. *See House Hearing*, *supra* note 14.

157. *Id.* In November 1998, a defendant in California began serving a five year federal prison term after being convicted of selling online unapproved HIV home test kits which used fabricated test results. For the first time in history, the individual was convicted on wire fraud charges stemming from the use of the

fraud laws, which formerly only applied to telephone and facsimile, to convict individuals for illegally selling unapproved medical products over the Internet.¹⁵⁸

As previously discussed, Congress granted the FDA express authority¹⁵⁹ to regulate information and direct consumer advertising of prescription drugs.¹⁶⁰ Prescription drug advertising must contain the established name, list of ingredients, and a brief summary of side effects and any other information specified by regulation.¹⁶¹ The FDA, in its implementing regulation, construes the statutory provision broadly to include “advertising in published magazines, other periodicals, newspapers, and broadcast media such as radio, television, and telephone communication systems.”¹⁶² The FDA has not indicated whether these advertising regulations will encompass Internet sales and advertising. However, the fact that the FDA has expressed an interest in stricter enforcement, might

Internet to sell an illegal medical product. Previous wire fraud charges involving illegal medical products were based only on telephone and facsimile use. In November 1998, an Illinois drug overdose case OCI assisted in identifying the subject’s source of supply as an Internet site in Canada.; OCI was advised by a State Board of Pharmacy that an internet site was offering prescription drugs to U.S. customers from foreign manufacturers, by acting as authorized “buyers club” using the “personal importation” policy of FDA. The FDA in coordination with Customs Service (USCS) used high tech surveillance of the suspect and revealed a sophisticated operation centered out of an apartment building. OCI and USCS arrested the suspect and he was sentenced in federal court.

158. 18 U.S.C. § 1345 (2000) ; 21 U.S.C. § 332 (2000); *see also House Hearing, supra* note 14 (statement of Ivan K. Fong, Deputy Assistant Att’y Gen., U.S. DOJ and statement of Dr. Janet Woodcock, FDA). “As of September 1, 2000, 11 Internet pharmacies had been certified by NABP and 25 others had applied for certification.” GAO REPORT, *supra* note 11.

159. Pub. L. No. 87-781, 76 Stat. 780 (codified in scattered sections of 21 U.S.C.).

160. *Id.*

161. 32 GA. L. REV. 141., citing 21 U.S.C. 352(n) (1994) (providing that a prescription drug shall be deemed to be misbranded “unless the manufacturer, packer, or distributor thereof includes in all advertisements . . . such other information in brief summary relating to side effects, contradictions, and effectiveness as shall be required in regulations”). The Federal Trade Commission (FTC) retained jurisdiction over the advertising of nonprescription drugs. *See* 36 Fed. Reg. 18,539 (1971) (announcing applicable memorandum of understanding between the FDA and FTC); *Thompson Med. Co. v. FTC*, 791 F.2d 189, 192-93 (D.C. Cir. 1986) (holding that FDA review of labeling claims for nonprescription drugs did not prevent FTC enforcement action against advertising claims for such products.).

162. 21 C.F.R. § 202.1(l)(1) (1997).

lead the agency to include the on-line medium.¹⁶³ The FDA may start to enforce and regulate a pharmaceutical company's content on a website to conform to non-website standards.

The Federal Trade Commission (FTC) also has authority to protect consumers from on-line pharmacies. It may bring actions against specific deceptive practices that involve a misrepresentation or omission likely to mislead consumers.¹⁶⁴ Thus, the FTC could bring an enforcement action where an on-line pharmacy makes false or misleading claims about the products or services it provides.¹⁶⁵ The FTC also has under its unfairness jurisdiction the authority to "regulate marketing practices that cause or are likely to cause substantial consumer injury, which is not reasonably avoidable by consumers, and not outweighed by countervailing benefits to consumers or to competition."¹⁶⁶

These are examples of existing federal authority that do not explicitly regulate the Internet medium but can encompass entities doing business on the Internet. Moreover, not only can existing laws apply to the Internet, but the private sector also plays a role in regulating business on the Internet.

In response to public, state and federal regulatory agency concerns regarding the safety of pharmacy Internet prescribing and dispensing sites, The National Association of Boards of Pharmacy (NABP) developed a Verified Internet Pharmacy Practice Site (VIPPS).¹⁶⁷ This is a voluntary certification program for on-line pharmacies that wish to post the VIPPS seal of approval on their website.¹⁶⁸ It combines the "mandatory requirements of state regulation with Internet practice standards developed by an expert panel of providers, federal agencies, and state regulators."¹⁶⁹ The certified program is designed to provide

163. See *House Hearing, supra* note 14 (statement of Dr. Janet Woodcock, FDA).

164. See 15 U.S.C. § 45 (2000). Section 5 of the Federal Trade Act (FTC Act) enables the FTC to prevent deceptive or unfair acts or practices in commerce. See also *House Hearing, supra* note 14 (statement of Jody Bernstein, Director, Bureau of Consumer Protection, FTC).

165. See *House Hearing, supra* note 14 (statement of Jody Bernstein, Director, Bureau of Consumer Protection, FTC).

166. *Id.*

167. National Association of Boards of Pharmacies: Frequently Asked Questions, at <http://www.napb.net/vipps/faq.asp> (last visited July 2000) [hereinafter NABP].

168. *Id.*

169. See generally *House Hearing, supra* note 14 (statement of Carmen Catzone, Exec. Director, Nat'l Ass'n of Board Pharmacies).

consumers with vital information regarding on-line pharmacy licensure compliance.¹⁷⁰ The seal can be compared to the Good House Keeping Seal that notifies a consumer that the product is approved, legitimate, and can be used safely. Likewise, the VIPPS seal informs consumers that a site is complying with safety licensing standards and is a legitimate place to do business.

The Internet sites that receive this seal must demonstrate compliance with all mandatory licensure, statutory, and regulatory requirements of state practice acts.¹⁷¹ The NABP independently verifies this compliance directly with the states through its clearinghouse and onsite inspection of the site and affiliated facilities.¹⁷² “After all of the information is verified, and meets NABP’s requirements, the site will be listed on NABP’s web site and given permission to display the VIPPS Seal.”¹⁷³ The Seal includes a hyperlink to the NABP site to protect the integrity of the NABP seal. The NABP site will state if the pharmacy site is verified.¹⁷⁴ NABP has an elaborate security system in place to avoid misrepresentation or inappropriate duplication of the NABP VIPPS seal.¹⁷⁵ This industry certification program is one that resembles the legal practice’s professional code of conduct, which has created a self-policing professional industry.

The cooperation already occurring between the pharmacy industry, the states and the federal government is overwhelming evidence that the existing state-based structure of pharmacy practice can be applied to on-line pharmacies through a partnership that upholds federalism. Congress may need to evaluate and enhance existing federal and state laws to facilitate effective enforcement of questionable cyber-drugstore activity. One example of federal enhancement, discussed earlier, gives states the power to enforce national injunctive relief in federal district court. There may be other methods of enhancing existing law, such as explicitly creating legal requirements pertaining to information displayed on a pharmacy site and continuous coordination of the industry clearinghouse for all legal cyber-drugstores. However, Congress must use caution in its approach. The partnership approach, which encompasses coordination

170. See NABP, *supra* note 167.

171. See *House Hearing, supra* note 14 (statement of Carmen Catizone, Exec. Director, Nat’l Ass’n of Board Pharmacies).

172. *Id.*

173. See NABP, *supra* note 167.

174. *Id.*

175. See *House Hearing, supra* note 14 (statement of Carmen Catizone, Exec. Director, Nat’l Ass’n of Board Pharmacies).

between the states, the federal government, and the pharmacy industry, is the key to ensuring safety standards and education of the consumer.

CONCLUSION

Much of the debate that occurred when Congress enacted the FDCA and the establishment of the current state-based approach to regulating pharmacy practice is being revisited in the debate surrounding regulation of on-line pharmacies. While cyber-drugstores have renewed public focus and health professionals' concern over the drug distribution system, it is imperative to remember that for more than sixty years federal and state regulators have been working successfully within oversight structures to ensure the quality and integrity of the prescribing and dispensing process.¹⁷⁶ The fact that Congress answered the original debate with a state-based approach should make the current debate simpler.

The starting place should be to remain within the boundaries already imposed on citizens and the medical profession. The Internet has nonetheless created a different type of market from which consumers (1) purchase prescription drugs, (2) access more information, and (3) search for cheaper prescriptions. The federal government should continue to regulate advertising, safety, and classification of drugs and eventually may need to extend this regulatory power to the website pharmaceutical companies. However, Congress should be very cautious not to put too much power into the hands of the federal government and the FDA. Although the Internet almost undoubtedly falls under the Commerce Clause, illegal activity occurring over the Internet does not change merely because of the new medium in which it occurs.

In order to maintain a balance of power, the best approach is a partnership in which states are allowed federal injunctive relief against on-line pharmacies that break existing laws. The federal government needs to ensure consumer protection through education of residents of the United States about the dangers associated with cyber-drugstores so that consumers are better informed. A partnership between the industry, the state boards of pharmacy, the State's Attorneys General's offices and the federal government makes the most sense. Congress should make adjustments to the current state-based drug distribution system but not completely overhaul an adaptable framework.

176. See generally *House Hearing*, *supra* note 14.

