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Regulation of Online Pharmacies: A Case for Cooperative Federalism

Sara E. Zeman*

INTRODUCTION

Changes in technology inevitably bring about changes in the legal rules governing technology. The explosion of e-commerce in the last several years has caused many to question whether the virtual realm ought to be more specifically regulated.¹ Health care providers and consumers are among those contributing to the growth of e-commerce. Increasingly, consumers have been using the Internet to obtain medical information to complement their visits to clinical providers.² Providers are responding to consumer demand for availability of products and services on the Internet, and consumers are responding to their increased online options by obtaining medical products and services online.³

As with most online industries, the medical information, products, and services that consumers are accessing through the

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1. For example, questions have arisen as to whether and how to apply tax laws to Internet commerce. David Cay Johnston, *Governors Criticize Internet Tax Panel*, N.Y. TIMES, Apr. 12, 2000, at C6. Identity theft is not a new crime, but the potential for its proliferation presented by the Internet presents a new enforcement challenge. Timothy L. O'Brien, *Officials Worried Over a Sharp Rise in Identity Theft*, N.Y. TIMES, Apr. 3, 2000 at A1. The legal field itself is facing questions of whether to implement uniform rules for online aspects of practice. David Beckman & David Hirsch, *The E-Commerce Manifesto: Lawyers of the World Unite—It's Time for Uniform Internet Regulations*, A.B.A. J., Mar. 2000, at 86. The Federal Elections Commission recently invited comments on the issue of how political activity on the Internet fits into schemes for regulating campaign regulations. Leslie Wayne, *Regulators Confront Web Role in Politics*, N.Y. TIMES, Apr. 21, 2000, at A1.

2. Gina Kolata, *Web Research Transforms Visit to the Doctor*, N.Y. TIMES, Mar. 6, 2000, at A1.

3. Ellen Almer, *Online Therapy: An Arm's-Length Approach*, N.Y. TIMES, Apr. 22, 2000, at A1.

Internet are of varying quality. Some health web sites are obviously reputable and reliable, some are outright scams, and some are of unknown pedigree. Basically, consumers are free to access whatever services are available and to set their own standards for health care quality. This status reflects the inherent freedom with which Internet businesses operate. However, the unprecedented free access and consumption come with a wealth of new problems.

This Article examines the regulatory challenges and responses arising from online pharmacies. Issues in regulating online pharmacy sites reflect the standard jurisdictional problems presented by e-commerce, as well as the special issues surrounding the delivery of health care services online. The article begins by describing the phenomena of online pharmacies and presenting the practical benefits and risks they pose.⁴ The particular regulatory challenges raised by online pharmacy operations are considered.⁵ Recent indications of a federal regulatory role will be explored, as well as voluntary efforts demonstrated by the pharmaceutical industries.⁶ The movement among state governments to grasp control of this nation-wide issue will be examined.⁷ Special consideration is given to the efforts of several states' Offices of Attorney General ("AG") to enforce state requirements on elusive Internet sites and the practitioners affiliated with them.⁸ The actions of attorneys general are surveyed and the role of the National Association of Attorneys General ("NAAG") is introduced.⁹ The authority of attorneys general to regulate pharmacies, pharmacists, and physicians is briefly demonstrated, along with a discussion of the efforts of other state agencies that emulate their actions. The major limitation faced by state attorneys general is jurisdictional; this problem and possibilities for overcoming it are examined.¹⁰ The section ends with an assessment of the laws upon which the actions of attorneys general are based and the ways state legislatures can contribute to the ultimate success of these actions.¹¹ A final note is made regarding the viability of the actions of attorneys

4. *Infra* Part I.A-B.

5. *Infra* Part II.

6. *Infra* Part III-IV.

7. *Infra* Part V.

8. *Infra* Part V.A.

9. *Infra* Part V.B.

10. *Infra* Part V.C.

11. *Infra* Part V.D.

general as an effective precursor to a cooperative model of state-led regulation in the online pharmaceutical services industry.¹²

I. ONLINE PHARMACIES

Ever since the U.S. Food and Drug Administration's ("FDA") implementation of the prescription and non-prescription classification of drugs, pharmaceutical intervention has represented a type of health care treatment where the boundaries between self-care and professional care have been clearly delineated. However, such distinctions are increasingly blurring as a result of the marketing of prescription drugs directly to consumers. Armed with the information this advertising imparts, patients have been requesting specific pharmaceutical interventions for their health care needs. Thus, selling pharmaceutical services online presents a marked potential for success.¹³

Traditional, so-called brick-and-mortar, pharmacies realize this opportunity, as do Internet entrepreneurs. In Fall 2000, the pharmaceutical giant Merck & Co. announced that its online pharmacy subsidiary, which combines pharmacy sales and pharmacy benefits management, passed a milestone of selling more than 100,000 prescriptions in one week; sales are expected to double by Fall 2001.¹⁴ In Summer 1999, the Rite Aid Corporation paid over \$7 million for ownership interests in an online pharmacy site; competitor CVS Corporation paid \$30 million for an online drugstore.¹⁵ Walgreens drug stores experienced a boost in its stock value after announcing its plans to launch online operations.¹⁶ More than half of Walgreens' recent quarterly sales of almost \$5 billion were in prescription drugs; their web

12. *Infra* Part VI.

13. *But c.f. A Dose of Reality: The Internet Looks Tailor-Made for Selling Prescription Drugs. So Why Are Web Pharmacies Doing So Badly?*, ECONOMIST, Dec. 11, 1999, at 56 [hereinafter *A Dose of Reality*] (stating that, while several online pharmacies are experiencing early losses, affiliations with pharmacy benefit managers and drug manufacturers, as well as the potential to profit from trading patient data profiles are buoying online pharmacies' long-term potential).

14. Julius A. Karash, *More Prescriptions Are Being Filled on the Net: There are Hundreds of Online Pharmacies, but Not All Will Survive*, KAN. CITY STAR, Oct. 22, 2000, at G1.

15. Susan Chandler, *Walgreen Opens Up on Plans for Web; E-commerce Venture to Debut in September*, CHI. TRIB., June 29, 1999, §4, at 1.

16. Bill Barnhart, *Stocks Advance in Thin Trading; Treasury Bond Rally Boosts Market Ahead of Fed Meeting on Rates*, CHI. TRIB., June 29, 1999, §4, at 6.

site was processing upwards of 2,000 prescriptions a day.¹⁷ Healtheon/WebMD, the much touted, Internet health services company, was founded by the creator of the major Internet browser company Netscape.¹⁸ Healtheon ultimately hopes to link physicians and consumers to nearly every health care service they can conceivably get online, including pharmaceutical services, and to digitize medical documentation processes such as drug prescribing.¹⁹ Online pharmacies clearly have entered the mix of e-commerce.²⁰

A. Benefits of Online Pharmacies

Online pharmacies offer elderly and disabled persons, as well as persons living in remote areas, an increased ability to access pharmaceutical services. Physicians and patients both may enjoy the efficiencies created by online pharmacies. For instance, orders can be placed directly from clinic examination rooms into systems that incorporate patients' insurance information and formulary options.²¹ In order to continue competing effectively with brick-and-mortar pharmacies, innovative sites can be expected to incorporate rapid delivery through affiliations with local pharmacies. Consumers also can obtain comprehensive profiles of their prescription and over-the-counter ("OTC") drug records at these sites.²²

Online pharmacies increase consumers' ability to comparison shop for drug price and availability. Sites whose operations are situated in foreign nations operate from different pricing structures than American retail pharmacies and may be able to offer substantially lower prices.²³ The increased price competition

17. Phat X. Chiem, *Record 1st Quarter for Walgreens; Drug Sales, Expense Control Help Profits*, CHI. TRIB., Jan. 4, 2000, at 4; see also Michele Fitzpatrick, *Local Lender to Open Online Bank for Small Businesses*, CHI. TRIB., Jan. 5, 2000, §4, at 1.

18. Milt Freudenheim, *Healtheon Agrees to Buy 2 Competitors*, N.Y. TIMES, Feb. 15, 2000, at C1.

19. *Id.*; see also Milt Freudenheim, *Confronting the Reality of a Health Care Vision*, N.Y. TIMES Feb. 28, 2000, at C1; David Cay Johnston, *A.M.A. and 6 Others Set Up Medical Internet Company*, N.Y. TIMES, Oct. 28, 1999, at C2.

20. *A Dose of Reality*, *supra* note 13.

21. Bruce Japsen, *Web Pharmacy Link Salves Allscripts*, CHI. TRIB., Jan. 21, 2000, §4, at 3.

22. Chandler, *supra* note 15.

23. U.S. GENERAL ACCOUNTING OFFICE ("GAO"), *PRESCRIPTION DRUGS - SPENDING CONTROLS IN FOUR EUROPEAN COUNTRIES*, REP.NO. GAO/HEHS-94-30 (1994); GAO, *PRESCRIPTION DRUGS—COMPANIES TYPICALLY CHARGE MORE IN THE UNITED STATES THAN IN THE UNITED KINGDOM*, REP. NO. GAO/HEHS- 94-29 (1994).

that foreign pharmaceutical retailers bring to drug sales can increase access to health care for many of America's elderly and uninsured.

Some online pharmacies allow patients to use their insurance benefits when filling prescriptions online, but most do not.²⁴ Insured consumers who willingly pay out-of-pocket may lose negotiated discounts, and managed care enrollees risk incurring higher prices from patronizing sites outside their retail pharmacy network or from accessing drugs outside their formularies.²⁵ As the number of sites that accept insurance reimbursement and that are included in managed care networks rises, however, savings can be expected. States already have begun to restrict limitations that health plans may place on enrollees' ability to patronize the pharmacy of their choice.²⁶ "Any-willing-provider" laws, which arose in response to managed care access restrictions, prohibit health plans from excluding a provider from their networks, or from otherwise discouraging the use of a provider, as long as the provider is willing to agree to the plan's terms.²⁷ "Any-willing-provider" laws applied in the pharmacy context should allow managed care enrollees to access online pharmacies without any financial penalty or reduction in benefits.

Additionally, online pharmacies offer an opportunity for increased reporting of side effects and adverse drug reactions.²⁸ The FDA relies on reports of adverse effects and drug quality from consumers to monitor and enhance the safety of drugs already on the market.²⁹

B. Risks of Online Pharmacies

The ultimate concern with online pharmacy operations is consumer protection. In January 1999, an Illinois newspaper article

24. Chandler, *supra* note 15.

25. *Id.*; see also *A Dose of Reality*, *supra* note 13.

26. DEL. CODE ANN. tit. 18, § 7303 (LEXIS through 2000 Sess.); MISS. CODE ANN. § 83-9-6(3) (LEXIS through 2000 Sess.); N.C. GEN. STAT. § 58-51-37(c) (LEXIS through 2000 Sess.) (prohibiting insurance plans from denying the use of pharmacies which have agreed to the terms of the plan).

27. See Peter R. Kongstvedt, *Essentials of Managed Health Care*, 463-65 (1997).

28. David B. Brushwood, *Legal and Policy Implications of Internet Pharmacies*, Address at the Institute for Health Law, Loyola University Chicago School of Law (Apr. 12, 2000) (notes on file with author).

29. Food & Drug Administration ("FDA"), *Medwatch, The FDA Medical Products Reporting Program*, at <http://www.accessdata.fda.gov/scripts/medwatch/> (last updated Apr. 3, 2001).

touted online pharmacies for their convenience, provision of medical information, and support group listings; it also explained how to locate sites.³⁰ Just five months later, that same newspaper reported the death of an Illinois resident from a heart attack.³¹ The man had obtained an online prescription for Viagra, a medication for erectile dysfunction, which should have been contraindicated given his family history of heart problems.³²

Patients who obtain their prescriptions through online pharmacies place themselves at risk of drug-related injury. While injuries can arise regardless of whether a patient obtains drugs through the Internet or through in-person visits to a local clinic and pharmacy, the risks can be amplified when prescription drug use is arranged exclusively through online pharmacies. Patients may suffer physical injury or harm as a result of taking improperly prepared drugs or drugs that are not appropriate for their conditions. They may also suffer harm from receiving poor quality medical or pharmaceutical advice, not learning of alternative therapies, or not receiving physical examinations or follow-up care.³³ The fault for these injuries lies with various parties: Patients may misrepresent their medical histories, physicians may not deliver bona fide medical consultations, or pharmacists may not require valid prescriptions.³⁴

II. REGULATORY CHALLENGES

The regulatory challenges that arise from the online practice of pharmacy and from the practice of medicine facilitated by the online pharmacies include professional practice standards and consumer protection concerns, as well as health care fraud and abuse issues. A brief introduction to these issues is presented below. Federal, state, and industry responses to these concerns also will be considered.³⁵

A. Professional Standards

An obvious regulatory concern is ensuring that online pharmacies do not provide an unfettered avenue for medical and

30. *Health*, CHI. TRIB., Jan. 15, 1999, §5, at 7.

31. Naftali Bendavid, *Prescriptions Via Internet Pose Dangers Doctors Fear Patients Will Skip Supervision, Checkups*, CHI. TRIB., June 16, 1999, §4, at 1.

32. *Id.*

33. *Id.*

34. *Id.*

35. Specific discussion of fraud and abuse concerns is limited to this section.

pharmaceutical practitioners to avoid professional licensing requirements, or for pharmacies to avoid quality and safety controls specific to preparing and dispensing drugs. Generally, states require physicians to have degrees from approved or accredited college medical educational programs and to have satisfied internship and residency requirements.³⁶ Physicians must have undertaken certain courses of study and passed state administered examinations to be licensed.³⁷ Physicians also are subject to scrutiny of moral character and must conform to professional conduct codes.³⁸

Pharmacists must comply with state requirements that they be of good moral character and fit to practice pharmacy.³⁹ States generally require that pharmacists hold pharmacy degrees from accredited programs and that they have satisfactorily completed an internship.⁴⁰ Pharmacists also are required to pass an examination given by the state pharmacy board.⁴¹ Pharmacies must comply with requirements as to the size and sanitation of their physical space.⁴² They also must maintain specific records and equip the pharmacy with the requisite supplies.⁴³ A separate license may be required for each physically distinct site of a pharmacy.⁴⁴ The stocking and dispensing of controlled substances requires pharmacies to keep special inventory records and submit to on-site inspections.⁴⁵

State laws mandate pharmacist involvement in pharmacy operations to various extents. Some states actually require phar-

36. CAL. BUS. & PROF. CODE §§ 2084, 2089(a) (Deering, LEXIS through 2001 Supp.); 225 ILL. COMP. STAT. 60/11 (LEXIS through 2000 Public Act 91-925); N.Y. EDUC. LAW § 6524(2) (LEXIS through 2000 Sess.); TEX. OCC. CODE ANN. § 155.003(a)(3)-(5) (LEXIS through 2000 Supp.).

37. CAL. BUS. & PROF. CODE §§ 2084, 2089(b) (Deering, LEXIS through 2001 Supp.); N.Y. EDUC. LAW § 6524(4) (LEXIS through 2000 Sess.); TEX. OCC. CODE ANN. §§ 155.054, 155.051, 155.002(3) (LEXIS through 2000 Supp.).

38. See 225 ILL. COMP. STAT. 60/9.7, 60/19(B) (LEXIS through 2000 Public Act 91-925); ILL. ADMIN. CODE tit. 68, § 1285.240 (2000), available at <http://www.dpr.state.il.us/WHO/ar/medicalrule.htm> (last modified Dec. 7, 2000); N.Y. EDUC. LAW § 6524(7) (LEXIS through 2000 Sess.); TEX. OCC. CODE ANN. § 155.003(a)(2) (LEXIS through 2000 Supp.).

39. See, e.g., 63 PA. CONS. STAT. ANN. § 390-3(a)(2) (LEXIS through Act 2000-86).

40. *Id.* § 390-3(a)(3), (4).

41. *Id.* § 390-3(a)(5).

42. *Id.* § 390-4(a).

43. *Id.*

44. CAL. BUS. & PROF. CODE § 4110(a) (Deering, LEXIS through 2001 Supp.).

45. 720 ILL. COMP. STAT. 570/302, 507/306 (LEXIS through 2000 Public Act 91-925).

macies to be owned by pharmacists,⁴⁶ but most states only require pharmacies to employ licensed pharmacists in managerial positions.⁴⁷ Pharmacists usually are required to be on-site and directly involved in the filling, compounding, and dispensing of prescriptions.⁴⁸

B. Consumer Protection

Identifying which entities are operating or affiliated with online pharmacies is not an easy task. Consumers may be unable to identify the pharmacies, pharmacists, physicians, and technicians serving them through online pharmacies.⁴⁹ Likewise, it may be difficult to identify who has patronized the particular online services.⁵⁰ Ordinary business communications become difficult for consumers, other businesses, and government agents in the context of the Internet. Thus, the virtual pharmacy interferes with the efficacy of several traditional regulatory functions. For example, it is difficult to know who should receive legal notices for official investigations, administrative actions, or law suits. Pharmacy inspections, including those of drug preparation and dispensing facilities and of controlled substance records, may be difficult to perform. Registration and disclosure of pharmacy ownership and staff, therefore, will be necessary for effective regulation of online pharmacy operations.

Increased drug injury from de facto self-prescribing and drug abuse from prescriptions that are not medically indicated are problems associated with the increased availability of prescription drugs through online pharmacies. The increased use of direct-to-consumer advertising has been shown to increase use of prescription drugs.⁵¹ The Internet has vastly expanded the ability of consumers to access medical information outside the

46. N.D. CENT. CODE § 43-15-35(5) (LEXIS through 2000 Act 200).

47. CONN. GEN. STAT. ANN. § 20-597(a)-(b) (LEXIS through 1999 Edition) (allowing a pharmacy to have one pharmacist fulfilling its managerial and supervisory requirements but prohibiting a pharmacist from simultaneously acting as manager for more than one pharmacy); see also GA. CODE ANN. § 26-4-110(d) (LEXIS through 2000 General Assembly); N.H. REV. STAT. ANN. § 318:38 (LEXIS through 2000 Sess.); OHIO REV. CODE ANN. § 4729.27 (Anderson, LEXIS through Mar. 1, 2001).

48. FLA. STAT. ANN. § 465.015(1)(b) (LEXIS through 2000 Sess.); 225 ILL. COMP. STAT. 85/15(a) (LEXIS through 2000 Public Act 91-925).

49. Bendavid, *Prescriptions Via Internet Pose Dangers*, *supra* note 31.

50. *Id.*

51. GAO, PRESCRIPTION DRUG COVERAGE, Rep. No. GAO/HEHS 00-84 (2000).

clinical context.⁵² Combining the services of online pharmacies with the effects of direct-to-consumer advertising and the plethora of information available online allows patients to self-diagnose conditions and self-treat with prescription drugs in an unprecedented way. This process circumvents the traditional notion that physicians generally act as intermediaries between drug availability and patient access to ensure safe use.⁵³ The ease of obtaining and filling prescriptions online removes the vital check physicians provide for consumer safety.

Illicit use of prescription drugs is replacing recreational use of street drugs.⁵⁴ College students, looking to enhance their academics or to just get high, risk death as a result of prescription drug abuse.⁵⁵ Pharmacists are an important link in monitoring prescription filling for signs of abuse. They are called upon to judge whether prescriptions presented by patients have been issued pursuant to illegitimate physician-patient relationships or whether other factors are present that indicate possible drug abuse.⁵⁶ One such factor is whether patients are traveling “unusual geographic distances” to see physicians and pharmacists.⁵⁷ Unfortunately, the use of online pharmacies weakens the ability of pharmacists to conduct such monitoring. Although some sites are incorporating patient prescription histories in their operations, it may be impossible to track a customer’s filling habits if multiple sites are used.

C. Business Practices

Another challenge of online pharmacies is the potential for health care fraud and abuse presented by affiliations among health care providers. Physicians and online pharmacies are affiliating with each other in order to enhance their respective issuing and dispensing of prescriptions; this can be accomplished through dual operations at one site or through links to another site offering the corollary service. Some online pharmacies offer consumers the ability to obtain prescriptions through online

52. Margaret A. Winker, et al., *Guidelines for Medical and Health Information Sites on the Internet: Principles Governing AMA Web Sites*, 283 JAMA 1600 (2000).

53. RICHARD R. ABOOD & DAVID B. BRUSHWOOD, *PHARMACY PRACTICE AND THE LAW* 246-47 (1997).

54. Paul Zielbauer, *New Campus High: Illicit Prescription Drugs*, N.Y. TIMES, Mar. 24, 2000, at A1.

55. *Id.* (stating that one-fifth of all college students interviewed had taken Ritalin at least once as a stimulant).

56. *Singh v. Dep’t of Prof’l Regulation*, 625 N.E.2d 656, 663 (Ill.App.Ct.1993).

57. *Id.*

physician consultations that are requested concurrently with on-line drug prescription orders.⁵⁸ One online pharmacy links patients needing a prescription to a site that offers physician consults and that also invites physicians who may be interested in providing online consultations to join its referral staff.⁵⁹ Companies involved in creating linkages among physicians and online pharmacies may pay physicians "commitment" fees, as well as fees for each prescription order placed.⁶⁰ Online pharmacies may hire physician "consultants" to issue prescriptions to patients so they can be filled on their site.⁶¹ Physicians who have set up Internet practices may affiliate with online pharmacies to round out their service offerings.⁶² While collaborative relationships between physicians and pharmacists have been validated as crucial to serving the welfare of patients,⁶³ collaborations aimed at increasing revenues rather than enhancing patient care are suspect.

To the extent health care providers and pharmacies deal with enrollees in federal health care programs, online affiliations may give rise to potential violations of Federal laws prohibiting self-referrals and kickbacks for patient referrals.⁶⁴ The Stark self-referral law generally prohibits physicians from referring patients for outpatient prescription drug services to entities in which they have vested interests.⁶⁵ The anti-kickback law generally prohibits pharmacies and physicians from arranging to pay one another for patient referrals.⁶⁶ However, as these laws are limited to federal health programs, state laws offer a better tool for widespread policing of abusive online pharmacy arrangements. Increased potential for the federal government to be-

58. Viagra Propecia Pharmacy, at <http://www12.tierranet.com/viagra-propecia-pharmacy.com/viagraonline-viagra-online.htm> (last visited Apr. 11, 2001); My Online Prescriptions.com, at <http://www.MyOnlinePrescriptions.com/itemdetail.ASP?CATEGORY=viagra> (last visited Apr. 11, 2001).

59. The Pill Box Pharmacy, at <http://www.thepillbox.com> (last visited Apr. 11, 2001); Physician Referral 2000, at <http://www.physicianreferral2000.com> (last visited Apr. 11, 2001).

60. Japsen, *supra* note 21.

61. Sheryl Gay Stolberg, *On-line Prescription Practices Create Headache for Regulators*, CHI. TRIB., June 27, 1999, §4, at 8.

62. Ranney V. Wiesemann, *On-line or On-call? Legal and Ethical Challenges Emerging in Cybermedicine*, 43 ST. LOUIS U. L.J. 1119, 1139 (1999).

63. DAVID B. BRUSHWOOD, *PHARMACY MALPRACTICE LAW AND REGULATIONS*, 15 (1998).

64. 42 U.S.C.A. §§ 1395nn, 1320a-7b(b) (West 2000) (limiting certain physician referrals and outlining illegal remunerations).

65. *Id.* §§ 1395nn(a)-(h).

66. *Id.* § 1320a-7b(b).

come involved in regulating online pharmacies is currently being considered; this will be examined in the next section.

These arrangements between physicians and online pharmacies may run afoul of state laws prohibiting kickbacks and state requirements regarding who may own pharmacies. State laws that can be applied in the online pharmacy context to protect against abusive pharmacy/physician arrangements model the federal fraud and abuse laws. State laws limit the ability of physicians and their families or affiliates to own pharmacies.⁶⁷ States also may restrict the ability of pharmacies to pay or split fees with prescribing providers or to operate exclusive communications links with prescribing providers.⁶⁸ These restrictions represent a concern that physicians may not prioritize patient interests when arranging prescriptions if they receive any type of financial benefit from the patient filling the prescription.⁶⁹ States also may require pharmacies to be owned in whole or substantial part by pharmacists.⁷⁰ This requirement presumes that a pharmacist is more likely to run a pharmacy in compliance with legal and professional standards.⁷¹

A pharmacy may be denied state licensure or have its license revoked for paying compensation to health care providers for their prescribing activities.⁷² In California, for example, pharmacy referrals based on volume or value may result in action

67. CAL. BUS. & PROF. CODE § 4111(a)(1) (Deering, LEXIS through 2001 Supp.); CONN. GEN. STAT. ANN. § 20-596(a) (LEXIS through 1999 Edition); MONT. CODE ANN. § 37-2-103(1) (LEXIS through 2000 Special Sess.); N.H. REV. STAT. ANN. § 318:29 (V)(i) (LEXIS through 2000 Sess.); NEV. REV. STAT. § 639.232 (1) (LEXIS through 1999 Sess.). Alternatively, a health care provider in Pennsylvania may hold an ownership interest in a pharmacy and refer a patient to that facility so long as she appraises the patient of her interest and also informs the patient of his right to choose which pharmacy to patronize. 35 PA. CONS. STAT. ANN. § 449.22(a) (LEXIS through Act 2000-86).

68. CONN. GEN. STAT. ANN. § 20-579(a)(8) and (11) (LEXIS through 1999 Edition); 225 ILL. COMP. STAT. 85/23 (LEXIS through 2000 Public Act 91-925); MONT. CODE ANN. § 37-2-103(2) (LEXIS through 2000 Special Sess.); N.H. REV. STAT. ANN. § 318:29 (V)(h) (LEXIS through 2000 Sess.).

69. ABOOD & BRUSHWOOD, *supra* note 53.

70. MICH. COMP. LAWS ANN. § 338.481 (LEXIS through 2000 Act 200); N.D. CENT. CODE § 43-15-35(5) (LEXIS through 2000 Act 200). Though the U.S. Supreme Court upheld the North Dakota law, there is some disagreement as to such a law's ability to protect the public health and its corresponding constitutionality. 14 Op. Mich. Atty Gen. 6676 (1991-92).

71. ABOOD & BRUSHWOOD, *supra* note 53, at 215.

72. ARIZ. REV. STAT. ANN. § 32-1930(B) (LEXIS through 7th Special Sess. of the 44th Legislature).

against a business' status as a professional corporation.⁷³ Such practices also may violate state fraud and abuse laws.

III. EXPANDING FEDERAL OVERSIGHT

The federal government is aware of the pressing need for the regulation of online pharmacies. The legislative and executive bodies have been contemplating the federal government's authority to become involved in this arena, with a more active enforcement role being postulated.

In late July 1999, Congress held a hearing to consider the benefits and risks posed by online pharmacies.⁷⁴ At this hearing, the Chairman of the Commerce Committee called for the creation of a joint federal-state task force to examine consumer protection in online pharmacies and to suggest possible legislative improvements.⁷⁵ The Chairman acknowledged the benefits these sites can provide to elderly, disabled, and busy consumers, but expressed concern regarding consumer reliance on those sites, and the physicians affiliated with them, that are not licensed to dispense drugs or that dispense drugs in manners violative of state or federal laws.⁷⁶ The Chairman endorsed state efforts to shut down rogue sites and emphasized the need to construct oversight and regulation carefully so as not to chill e-commerce development.⁷⁷

In Summer 1999, the Director of the FDA presented the agency's position on regulating online pharmacies.⁷⁸ The Director justified the FDA's regulatory approach for online pharmacies based on the agency's concern for public health and its "overall goal of developing and implementing risk-based strategies to protect public health and safety."⁷⁹ Particularly relevant to the FDA's role in governing new drug approval and drug pro-

73. CAL. BUS. & PROF. CODE § 650 (Deering, LEXIS through 2000 Sess.); CAL. CORP. CODE § 13408.5 (Deering, LEXIS through 2000 Sess.).

74. *Drugstores on the Net: The Benefits and Risks of On-line Pharmacies, Hearing Before the House Subcomm. on Oversight and Investigations, Comm. on Commerce, 106th Cong. (1999)* [hereinafter *July 1999 Hearing*].

75. *Id.* (statement of The Honorable Tom Bliley, Chairman of the House Subcommittee on Oversight and Investigations).

76. *Id.*

77. *Id.*; see also *Clinton Proposes Greater FDA Authority Over Online Pharmacies; Reactions Skeptical*, 9 Health L. Rep. (BNA) 12 (Jan. 6, 2000) [hereinafter *Clinton Proposes Greater FDA Authority*].

78. *July 1999 Hearing*, *supra* note 74 (statement of Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research ("DER")).

79. *Id.*

motion is its concern that the Internet may enable products to be marketed with false health claims and may enable sales of unapproved new drugs, corrupted drugs,⁸⁰ or prescription drugs without a valid prescription.⁸¹ Protecting against the harms of these practices was the founding mission of the FDA.⁸² The agency's concern also extended beyond these traditional areas of FDA involvement to the "apparent absence of a doctor-patient relationship in some Internet transactions."⁸³

The FDA's advice for a regulatory policy was to allow the private sector to spearhead safety initiatives and to restrict the federal government's role to fostering certification programs, enforcing existing drug laws, and making new laws sparingly and only when necessary to protect consumers.⁸⁴ While the FDA indicated its continuing involvement in efforts to assess jurisdiction for online pharmacy regulation, it stressed the need for the agency to retain its "traditional regulatory role" and to work cooperatively with state governments and other federal agencies in enforcing the Food, Drug & Cosmetic Act ("FDCA"), applicable state laws, and federal fraud laws.⁸⁵

The FDA's existing regulatory authority over activities that comprise online pharmacy operations includes investigating cases and referring them for criminal prosecution and civil enforcement.⁸⁶ It already has authority over some activities that comprise online pharmacy services, including "the sale or dispensing of a prescription drug without a valid prescription."⁸⁷ The FDA's enforcement activities have included issuing warning letters to domestic and foreign sites illegally selling drugs online, requesting voluntary removal of sites that violate the law, and enforcing drug marketing requirements in online drug promo-

80. The term corrupt is used to refer to expired, illegally diverted, or otherwise tainted drugs.

81. *July 1999 Hearing, supra* note 74 (statement of Janet Woodcock, M.D., Director, DER).

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.* The agency also stressed the need to work with foreign governments, especially given diverse drug approval and marketing approaches. *Id.*

86. *Id.*

87. 21 U.S.C.A. § 353(b)(1) (West 2000). The FDCA deems a drug misbranded if it is a prescription drug dispensed in a manner other than by a written prescription by an authorized practitioner (or by an oral prescription by authorized practitioner that is reduced promptly to writing by a pharmacist). *Id.*

tions.⁸⁸ Offices within the FDA continuously investigate possible violations of laws within the agency's purview.⁸⁹

In December 1999, then-President Clinton announced a proposal to expand the FDA's ability to regulate online pharmacies.⁹⁰ The proposal included expanding the FDA's investigative authority, with provisions granting subpoena power to the agency and an allocation of additional staff and other resources.⁹¹ Federal certification of pharmacies would have been required prior to selling online, and penalties would have been imposed for selling drugs without a valid prescription.⁹² The proposed budget for fiscal year 2001 allocated \$10 million to the FDA for this initiative.⁹³

By the Spring of 1999, the FDA had embraced Clinton's proposal for the agency to become more involved in regulating online pharmacies.⁹⁴ In testimony presented to Congress, the FDA Commissioner noted that while the private sector has a role in providing consumers with information, the FDA is the party challenged to give consumers the same protections as if they were at a corner drugstore.⁹⁵ The Commissioner mentioned the potential for the avoidance of state licensing systems that online businesses present.⁹⁶ She expressed concerns over the inadequacy or lack of bona fide physician-patient relations upon which online prescribing and dispensing can be based.⁹⁷ Recognizing the Agency's continued interest in collaborating with other regulatory and association officials and the plan for minimal federal involvement, the Commissioner welcomed the proposed expansion of FDA authority.⁹⁸

88. *July 1999 Hearing, supra* note 74 (statement of Janet Woodcock, M.D., Director, DER).

89. *Id.*

90. *Clinton Proposes Greater FDA Authority, supra* note 77.

91. *Id.*; see also *Roundup: Bliley Questions FDA E-Pharmacy Proposal*, 9 Health L. Rep. (BNA) 512 (Apr. 6, 2000) [hereinafter *Bliley Questions FDA*].

92. *Id.*

93. *Proposals to Expand Access to Coverage Headline Last Clinton Administration Budget*, 9 Health L. Rep. (BNA) 195 (Feb. 10, 2000). See also *Clinton Proposes Greater FDA Authority, supra* note 77.

94. Jane E. Henney, M.D., *e-Drugs: Who Regulates Internet Pharmacies?*, *Hearing Before the Senate Comm. on Health, Education, Labor, and Pensions*, 106th Cong. (2000), available at <http://www.fda.gov/ola/2000/pharmsales.html> (Mar. 21, 2000).

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.*

Federal legislation had already been introduced to expand FDA authority over online pharmacies by the time Clinton made his proposal. The Internet Pharmacy Consumer Protection Act proposed amending the FDCA, which is under FDA implementation and enforcement authority.⁹⁹ The bill prohibited online pharmacies from dispensing prescription drugs unless the web site disclosed information about who is selling the drugs.¹⁰⁰ It also required the identities of the pharmacist and medical consultant, and where those persons are licensed to practice, to be disclosed.¹⁰¹ The bill provided for primacy of state regulation where requirements for online pharmacies are at least as strict as the federal requirements and where sufficient resources are allocated for enforcement of those provisions.¹⁰² A procedure was contemplated whereby states obtain federal acknowledgment of their responsibility.¹⁰³

While Clinton's proposal to send a signal of "zero tolerance" for rogue sites was laudable,¹⁰⁴ not all were pleased with his proposed expansion of FDA authority. The Chairman of the House Commerce Committee believed the FDA's existing regulatory powers would allow the Agency to pursue more extensive measures without the need for new grants of authority.¹⁰⁵ This Committee would need to approve legislation to expand the FDA's authority, so reluctance on the part of its Chair is significant.¹⁰⁶ The recent change of Administration injects a measure of uncertainty as to how, or whether, this debate will evolve. The National Association of Boards of Pharmacy, which currently runs its own certification program, is unconvinced of the need for a certification program run by the FDA.¹⁰⁷ States also are unlikely to support a federal licensing system that would allow practitioners to bypass state licensing and encourage reliance upon the federal government as a primary enforcer of quality of care and professional practice standards. States are launching their own campaigns to comprehensively regulate online pharmacies; they may look to a narrowly tailored federal registration

99. H.R. 2763, 106th Cong. § 2 (1999).

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.*

104. *Clinton Proposes Greater FDA Authority, supra* note 77.

105. *Bliley Questions FDA, supra* note 91.

106. *Clinton Proposes Greater FDA Authority, supra* note 77.

107. *Id.*

system to assist their investigation and coordinate their enforcement efforts.

IV. VOLUNTARY CONTROLS

Industries often attempt self-regulation in the face of public pressure for stricter oversight. Accordingly, the pharmaceutical manufacturing and service industries have responded to the perceived need for increased consumer protections in online pharmacies. The range of self-regulatory measures spans from informal advisory communications to the implementation of sound business practices to an organized certification program. In August 1998, aware of widespread prescribing based on informal physician-patient relationships, the pharmaceutical company that manufactures Viagra requested that state medical boards stress to their physicians the necessity of performing a patient examination prior to prescribing the drug.¹⁰⁸

Online pharmacies can implement mechanisms to add greater legitimacy to the services they provide. For example, sites may refuse to offer a prescription issuing service and may implement procedures to verify the legitimacy of prescriptions that consumers submit.¹⁰⁹ One well-known online pharmacy, Planet Rx, will not fill a prescription until it has verified the prescription's validity with both the patient and the issuing physician and has verified the physician's credentials with the Drug Enforcement Agency.¹¹⁰ Furthermore, a pharmacist must verify the contact information for the physician and that the proper drug and dosage have been prescribed.¹¹¹ Planet Rx dispenses the drug after two more accuracy checks and maintains patient records to monitor refill behavior.¹¹²

In Spring 1999, the National Association of Boards of Pharmacy ("NABP") entered the arena of online pharmacy regulation by instituting a voluntary certification program for the pharmacies. NABP is a collaborative organization of state and national pharmacy boards as well as boards from Canada and Australia.¹¹³ NABP works to protect public health by developing uniform regulatory standards that can be implemented by

108. Bendavid, *Prescriptions Via Internet Pose Dangers*, *supra* note 31.

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.*

113. Verified Internet Pharmacy Practice Sites, at <http://www.nabp.net/vipps/intro.asp> (last modified Oct. 7, 1999) [hereinafter *VIPPS*].

the member boards. NABP's Verified Internet Pharmacy Practice Site ("VIPPS") program utilizes a verifiable logo at an online pharmacy's web site to indicate that the pharmacy is certified. NABP certification indicates the online pharmacy is in compliance with the licensing laws and inspection requirements of the states where they are located and where they dispense drugs.¹¹⁴ The certification also indicates the site complies with other standards dealing with matters that include patient privacy, authentication and security of orders, quality assurance, and the "provision of meaningful consultation between patients and pharmacists."¹¹⁵ NABP is particularly concerned about the risks that arise when patients do not visit a physician prior to patronizing an online pharmacy.¹¹⁶ At one point, NABP had identified approximately 3500 sites operating as online pharmacies, but had certified only a handful of them.¹¹⁷ NABP created the VIPPS program criteria in consultation with government, industry, and consumer groups.¹¹⁸ It is possible that increased FDA involvement would utilize the VIPPS program.¹¹⁹

Industry self-regulation on the part of pharmaceutical manufacturers is laudable; it reflects an awareness of the effects of pharmaceutical marketing and a desire to responsibly promote drugs in order to minimize misuse and injury. Direct-to-consumer advertising certainly plays a role in consumers' decisions to pursue and obtain prescription drugs online. Consumers' willingness to obtain medical examinations prior to starting drug therapy can be encouraged by the inclusion of strong, deliberate warnings of the need to be examined, along with the provision of information about contraindications, risks, and adverse effects of potential pharmaceutical treatments. Additionally, manufacturers' warnings that are crafted with online pharmacy operations in mind can assist pharmacies and pharmacists in identifying when drugs can be dispensed safely without a thorough clinical examination.

114. *Id.*; see also Carmen Catizone, *Legal and Policy Implications of Internet Pharmacies*, Address at the Institute for Health Law, Loyola University Chicago School of Law (Apr. 12, 2000) (notes on file with author).

115. *VIPPS*, *supra* note 113.

116. Catizone, *supra* note 114.

117. *Id.*

118. *VIPPS*, *supra* note 113.

119. Naftali Bendavid, *Plan to Regulate Over-the-Web Drug Sales Draws Fire Clinton Wants the FDA to Monitor Internet Pharmacies, but Some Wonder if the Agency is Right for the Job*, CHI. TRIB., Dec. 29, 1999, at 1.

Well-intentioned physicians who enable online pharmacy operations through online consultations and prescribing can be assisted in their ability to discern when an online consultation is not sufficient treatment with the help of manufacturer guidelines that contemplate online services. A change in prescribing standards could require a notation with each prescription indicating whether an in-person or online physician-patient consultation gave rise to the prescription. Notation of an online consultation then could alert pharmacists to implement a specified set of patient inquiries to further ensure that an in-person consultation would not be more desirable.

Relying on manufacturers' efforts to warn consumers, pharmacists, and physicians, however, will not ensure that standard prescribing and dispensing of online pharmacies will cease. To be successful, this approach requires physicians and pharmacies to heed informal manufacturer notices, yet not all online pharmacies and their enabling physicians will be well-intentioned. While there are benefits to involving manufacturers in changing drug labeling and promotion to reflect the online prescribing and dispensing phenomenon, a more systematic method of regulation is necessary to police more opportunistic online pharmacy ventures. A voluntary certification for online pharmacies is similarly limited; it will protect consumers only to the extent they are aware of and utilize the program. More comprehensive regulatory efforts are being undertaken by state governments, especially within states' Offices of Attorney General.

V. COOPERATIVE FEDERALISM

State efforts to control online pharmacies may entail applying existing legal requirements for pharmacies, pharmacists, and physicians to those operating online. States also can enact new legislation specifically addressing online pharmacies to improve their enforcement capacity. Several states' Offices of Attorney General are spearheading enforcement actions against online pharmacies and physicians affiliated with them, using both established and new laws to target potentially harmful practices. These initiatives contribute to a broader, collaborative movement among state governments to retain authority over practice standards and to protect against consumer fraud.

A. *The Enforcement Actions of Attorneys General*

Actions by states' attorneys general have been a widely publicized, recent state-level enforcement trend in regulating online pharmacies. With much fanfare, the Offices of Attorney General of a handful of states have been filing law suits against online pharmacies based on undercover investigations of the sites' involvement in the issuing of prescriptions and dispensing of prescription drugs across state lines. The suits seek to enjoin online pharmacies' operations for violating state medicine and pharmacy licensing requirements and state consumer fraud laws. With these actions, attorneys general are setting precedents for assessing these online practices. The attorneys general are supported in their endeavors by the National Association of Attorneys General ("NAAG"), an instigator of their actions and a general advocate for state regulatory authority.¹²⁰ Together, the attorneys general and NAAG are staking a substantial claim for states' roles in the future online pharmacy regulatory framework.

1. National Association of Attorneys General

NAAG has been conducting a working group for online pharmacies and has indicated future attorney general enforcement actions can be expected. NAAG is a coalition of federal, state, and regional attorneys general that works to "facilitate interaction among Attorneys General . . . thereby enhancing [their] performance . . . to respond effectively to emerging state and federal issues."¹²¹ NAAG's goals include apprising Offices of Attorneys General of legal developments through workshops, helping these offices exert coordinated efforts on interstate matters, and influencing state and national policy development.¹²²

At its recent conference exploring the impact of the Internet on attorney general functions, NAAG stressed the importance of attorneys general in fighting crime and protecting consumers while fostering access and privacy in the boundary-less realm of

120. Luther C. McKinney & Dewey J. Caton, *What to Do When the Attorney General Calls: State Regulation of National Advertising*, 3 DEPAUL BUS. L.J. 119, 121-25 (1991).

121. National Association of Attorneys General ("NAAG"), *About NAAG*, at <http://www.naag.org/about/index.cfm> (last visited Apr. 9, 2001).

122. NAAG, *Vision and Goals*, at <http://www.naag.org/about/vision.cfm> (last visited Apr. 9, 2001).

the Internet.¹²³ AG actions are occurring in criminal and civil contexts other than the sale of prescription drugs; financial fraud and crimes against children also are being addressed.¹²⁴ Indeed, NAAG sees attorneys general as pivotal in ensuring the Internet is made safe for all persons in all activities and, to this end, is advocating that they become involved in broader public protection initiatives. NAAG asserts that attorneys general are well-suited to examine current laws that protect the public for their relevancy to the Internet context. NAAG recommends that attorneys general propose new legal policies where necessary and undertake cooperative preventive efforts as well as enforcing existing laws online.¹²⁵

Given NAAG's involvement in online pharmacy regulation, it is not surprising that the actions against online pharmacies brought by a handful of attorneys general, thus far, are based on similar investigations, allegations, and policy concerns. In June 1999, the Kansas Attorney General, who now acts as NAAG's President,¹²⁶ brought the first AG action against online pharmacies. This action was based on a violation of state licensing and registration requirements for pharmacies.¹²⁷ Within weeks, other offices of attorneys general also initiated lawsuits.

2. Attorney General Actions

In July 1999, the Missouri Attorney General filed suit against online pharmacy sites based on their failure to confirm patients' health information, received through online consultations, prior to issuing prescriptions and dispensing drugs.¹²⁸ The Attorney General indicated the pharmacies' operations violated a state law requiring a Missouri license to issue and dispense prescriptions to Missouri residents and the state's consumer deception law.¹²⁹ Along with permanent injunctions barring the Texas-based online pharmacy operations from dispensing in Missouri,

123. NAAG, *The Impact of the Internet on the Mission of the Attorneys General*, available at <<http://www.naag.org/features/Internet%20Report.PDF>> (Mar. 12, 2000). [hereinafter *Impact of the Internet*].

124. *Id.*

125. *Id.*

126. NAAG, *Board of Directors*, at <http://www.naag.org/about/board.cfm> (last visited Apr. 9, 2001).

127. *Missouri: State AG Files Suit Seeking to Halt Internet Prescription Drug Sales*, 8 Health L. Rep. (BNA) 1139 (July 15, 1999) [hereinafter *Missouri State AG Files Suit*].

128. *Id.*

129. *Id.*

the Attorney General was able to have \$15,000 penalties imposed on the clinic, pharmacy, and physician defendants.¹³⁰ The sites now must indicate they cannot serve residents of Missouri and will be subject to additional \$5,000 fines if they do.¹³¹

The Missouri Attorney General intended its action to be a symbol of the State's intention to enforce its pharmacy and medical licensing requirements in the online context.¹³² Licensed pharmacy services must only fill prescriptions issued by Missouri licensed prescribers, and any patient consultations must include actual, physical patient examinations by physicians.¹³³ The Attorney General noted that these types of online pharmacy services are available for Missouri residents; the lawsuit did not target several sites that met these standards.¹³⁴ The Attorney General stressed that those who prescribe and dispense drugs in conformity with state's licensing laws offer consumers a greater degree of protection from health risks.¹³⁵ Essentially, the Attorney General's main concern was the offering of prescriptions to consumers who were deemed in need of more substantial physician consultation than they obtained online.¹³⁶

In October 1999, the Illinois Attorney General filed suit against four online pharmacies, alleging violations of the state's medical and pharmacy licensing requirements and violations of the state's consumer fraud law.¹³⁷ The Attorney General announced the lawsuits with representatives at his side from the American Medical Association, Illinois State Medical Society, Illinois Department of Professional Regulation, and the Illinois Pharmacists Association. The AG cases assert that the pharmacies acted illegally by having doctors not licensed in the state

130. *Missouri: Missouri Judge Blocks Internet Drug Sales By Texas Pharmacy Unlicensed in State*, 8 Health L. Rep. (BNA) 1721 (Oct. 28, 1999) [hereinafter *Missouri Judge Blocks Internet Drug Sales-October*].

131. *Id.* (citing *Missouri v. Miles*, Mo. Cir. Ct., No. 99CV217072-Div. 11 (Nov. 29, 1999)); *Missouri: Judge Blocks Internet Drug Sales By Texas Pharmacy Unlicensed in State*, 8 Health L. Rep. (BNA) 1869 (Dec. 2, 1999) (citing *Missouri v. Stalknecht*, Mo. Cir. Ct., No. 99CV212429-Div. 15 (Oct. 25, 1999)) [hereinafter *Missouri Judge Blocks Internet Drug Sales-December*].

132. *Missouri State AG Files Suit*, *supra* note 127.

133. *Missouri Judge Blocks Internet Drug Sales-October*, *supra* note 130.

134. *Id.*

135. *Missouri State AG Files Suit*, *supra* note 127.

136. *Missouri Judge Blocks Internet Drug Sales-December*, *supra* note 131.

137. *Illinois Files Suit Against Cyber Pharmacies, Alleges Illegal Sale of Prescription Drugs*, 8 Health L. Rep. (BNA) 1720 (Oct. 28, 1999); see also Office of the Illinois Attorney General, Press Release, *Ryan Sues to Protect Consumers Against Illegal Sales of Prescription Drugs Over the Internet*, available at <http://cait.wiu.edu:591/press/FMPro> (last visited Mar. 14, 2000).

issue prescriptions to Illinois residents, by having pharmacists not licensed in the state dispense prescription drugs to Illinois residents, and by representing to consumers that it is lawful for a pharmacy to deliver prescription drugs to Illinois residents without being properly registered.¹³⁸ The Attorney General's primary concern was that the prescriptions dispensed by the pharmacies did not arise from a "proper patient-physician relationship."

In December 1999, the Michigan Attorney General threatened to sue ten online pharmacies.¹³⁹ The Attorney General alleged violations of the state's consumer protections laws: The sites were not licensed in Michigan and did not disclose this lack of licensing to consumers.¹⁴⁰ The state's undercover investigations of the pharmacies revealed inadequate patient care. By mid-January 2000, all ten of the threatened businesses had agreed to discontinue sales of prescription drugs to residents of Michigan.¹⁴¹

In March 2000, the New Jersey Attorney General brought suit against eight online pharmacies.¹⁴² The complaints are strikingly similar to other attorney general actions, including the lack of state licensing of the pharmacists and physicians involved, their failure to disclose this lack of state licensing to consumers, and the inadequacy of the physicians' online examinations of patients.¹⁴³ The remedies sought were familiar, too, and included financial penalties and injunctions to prevent the pharmacies from doing business in New Jersey.¹⁴⁴ The Attorney General, while recognizing the prevalence of e-commerce, stressed the need to protect consumers from fraud and injury, noting that

138. See, e.g., *People v. ExpressMed Servs. Corp.*, Ill. Cir. Ct., No. 99-CH0452 (complaint filed Oct. 21, 1999).

139. *Michigan: AG Issues Warnings to Online Pharmacies For Illegally Selling Drugs Via Internet*, 8 Health L. Rep. (BNA) 2002 (Dec. 23, 1999) [hereinafter *Michigan AG Warnings*]. The Michigan AG, who likened the online pharmacy defendants to "the street corner drug pusher," was, in turn, sued by one of the online pharmacies on a claim that the AG action was an improper restraint on interstate commerce and on a defamation claim. Andre C. Frieden, *Legal and Policy Implications of Internet Pharmacies*, Address at the Institute for Health Law, Loyola University Chicago School of Law on (April 12, 2000) (notes on file with author).

140. *Michigan AG Warnings*, *supra* note 139.

141. *Michigan: State Officials Form Internet Prescription Task Force to Review Current Laws, Security*, 9 Health L. Rep. (BNA) (Jan. 20, 2000) [hereinafter *Michigan State Officials*].

142. *New Jersey: State Files Consumer Fraud Charges Against Eight Online Pharmacies*, 9 HEALTH L. REP. (BNA) 503 (Apr. 6, 2000).

143. *Id.*

144. *Id.*

“[p]harmacies and pharmacists must follow state laws whether they do business in New Jersey neighborhoods or on the Internet.”¹⁴⁵

The policy lessons derived from the actions of the attorneys general deal with the state governments’ roles in protecting public health. The attorneys general primarily are concerned with the increased ability of consumers to obtain prescriptions through quickly performed, online consultations with physicians and pharmacists whom the states cannot control. The ability to impose quality standards on those patient consultations will arise from the authority over the physicians and pharmacists that the practice of licensing gives to state agents.

States’ attorneys general clearly have authority to participate, along with specified state agencies, in enforcing professional pharmacy and medical practice requirements and state consumer protection laws. The attorneys’ general initiatives, however, may suffer for a lack of broad-scale remedial impact. They also require applicability of the state laws they seek to enforce—those dealing with licensing, disclosure and quality of care—to out-of-state, online practices. These policy issues are being addressed by state legislatures and attorneys general nationwide. NAAG is involved in efforts to improve the effectiveness and impact of attorneys general law enforcement on the Internet and can be expected to apply these principles in the context of online pharmacy regulation.¹⁴⁶ State legislatures are actively amending and drafting legislation to ensure online pharmacies do not escape their regulatory purview.

B. Enforcement Authority

The powers of attorneys general are enumerated by state legislatures and in state constitutions.¹⁴⁷ As states’ main law officers, they generally provide legal advice and services to state agencies and legislatures, as well as on behalf of the citizenry.¹⁴⁸ They have authority over the legal affairs of state agencies and the ability to be involved in any legal matters affecting state in-

145. *Id.*

146. *Impact of the Internet, supra* note 123.

147. 15 ILL. COMP. STAT. 205/4 (LEXIS through 2000 Public Act 91-925); N.Y. EXEC. LAW § 63 (LEXIS through 2000 Sess.); *see also* CAL. CONST. art. V, § 13.

148. McKinney & Caton, *supra* note 120.

terests.¹⁴⁹ Additionally, their authority to enforce certain laws may be specified in statutory provisions.¹⁵⁰

State medical and pharmacy boards, and the state agencies of which they are a part, traditionally have been the primary regulators of medical and pharmacy practices.¹⁵¹ These boards enforce state laws pertaining to physician and pharmacy licensing, which include standards for quality of care and professional conduct.¹⁵² With their broad legal powers, attorneys general may investigate and prosecute violations of laws that other state agencies have responsibility to execute,¹⁵³ including the enforcement of licensing requirements.¹⁵⁴ The initiatives of states' attorneys general may encourage other agencies to follow their lead in regulating online pharmacy practices.

In May 1999, the Illinois Department of Regulations temporarily suspended the license of an Illinois physician for his online prescribing.¹⁵⁵ The physician practiced in an Illinois clinic but was disciplined for his work as a consultant for the Pill Box Pharmacy in San Antonio, which included prescribing Viagra over the Internet without direct patient interaction.¹⁵⁶ The Department solicited the physician's online services undercover and then filed charges against him.¹⁵⁷ The Department expressed concern about the inability of the physician to verify patients' medical information.¹⁵⁸ Within weeks of the suspension, a settlement was reached whereby the physician's license was reinstated, but he was fined \$1,000 and given two years of probation, during which time he could not prescribe drugs over the Internet.¹⁵⁹ The agency emphasized the need to convey a tough

149. CAL. BUS. & PROF. CODE § 320 (Deering, LEXIS through 2001 Supp.); 15 ILL. COMP. STAT. 205/4; N.Y. EXEC. LAW § 63(1).

150. CAL. BUS. & PROF. CODE §§ 321, 16760(a)(1) (Deering, LEXIS through 2000 Sess.).

151. CAL. BUS. & PROF. CODE §§ 2220.5, 4110 (Deering, LEXIS through 2000 Sess.); 225 ILL. COMP. STAT. 60/7, 85/10-11 (LEXIS through 2000 Public Act 91-925); N.Y. EDUC. LAW §§ 6523, 6804 (LEXIS through 2000 Sess.).

152. See *supra* notes 36-48 and accompanying text.

153. 15 ILL. COMP. STAT. 205/4 (LEXIS through 2000 Public Act 91-925); N.Y. EXEC. LAW § 63(3) (LEXIS through 2000 Sess.).

154. 154 CAL. GOV'T CODE (Deering, LEXIS through 2001 Supp.); CAL. BUS. & PROF. CODE § 2224 (Deering, LEXIS through 2001 Supp.).

155. John Chase, *Probation for Doctor in Viagra Web Case*, CHI. TRIB., May 20, 1999, §4 at 1.

156. *Id.* The physician purportedly had tried to obtain advice from the state previously as to how to legally prescribe online. *Id.*

157. *Id.*

158. *Id.*

159. *Id.*

enforcement stance and to set a precedent for similar disciplinary actions in the future.¹⁶⁰

In February 1999, the Wisconsin Department of Regulation and Licensing filed a complaint against a physician for activities that included his online prescribing practices.¹⁶¹ While the physician did not perform consultations or issue prescriptions online, these services were provided to patients solicited through the physician's online and newspaper advertisements for his prescribing service.¹⁶² The physician also provided prescribing services for a Missouri pharmacy that solicited patient information online and forwarded it to his e-mail.¹⁶³ Ultimately, the physician's license to practice medicine was temporarily suspended and his authority to prescribe drugs was permanently revoked.¹⁶⁴ The physician's willingness to issue prescriptions without examining patients, along with his failure to inform patients of possible underlying illnesses and alternative treatments, violated the State's law on minimum competency requirements for physicians.¹⁶⁵

The extent to which state laws require patient examinations prior to prescribing drug treatments seems to be an important element in determining whether licensing agencies will scrutinize physician behavior. Authorities in both Illinois and Wisconsin expressed concern about the quality of medical consultations being provided prior to the issuance of prescriptions.

The penalties licensing agencies may impose on physicians prescribing online are uncertain at this stage. Although a prosecutor in the Wisconsin case indicated the action was one of the more serious actions undertaken recently, the physician who was disciplined in that case had been involved in significantly unprofessional conduct, such as inappropriate sexual and physical contact with minor children.¹⁶⁶ It is not likely that such a

160. *Id.* The message to physicians reportedly is "that they must be careful in prescribing medicine to patients they don't examine." *Id.*

161. *Wisconsin: State Officials Issue Complaint Against Physician Who Operated Viagra Web Site*, 8 Health L. Rep. (BNA) 276 (Feb. 18, 1999) [hereinafter *Wisconsin State Officials*]. The action also involved other allegations regarding the physician's fitness for practicing medicine. *Id.*

162. *Id.*

163. *Id.*

164. *Id.*

165. *Id.*; see also *Wisconsin: Medical Board Suspends, Restricts License of Physician Who Operated Viagra Web Site*, 8 Health L. Rep. (BNA) 1109 (Jul. 8, 1999).

166. *Wisconsin State Officials*, *supra* note 161.

severe license restriction would have been imposed absent the egregious circumstances of that case. Given the lack of prevailing standards, the penalties in the Illinois case—the fine and probation—seem more proportionate for activities presently characterized as license violations.

Investigative methods and penalties remain unclear, and a trend toward increasing online pharmacy practice and physician involvement does not provide a shield from actions against licenses. While the attorney for the Illinois physician noted that his client was just one of many online prescribers, the state clearly desired to set an example.¹⁶⁷

C. *Jurisdictional Limitations*

The type of relief sought by the state attorneys general actions does not implement any broad remedies against the online pharmacies; the main goal is to limit offending pharmacies' sales in particular states. While this approach does not systematically prevent injury or protect public safety, actions in many states increase the possibility that online pharmacy operations will be affected more broadly. If sites were to become blocked from business in a significant number of states unless they were to obtain licensing and demonstrate the offering of bona fide patient consultative services, there might be a surge of compliance in order to recapture business. It is easy to imagine parties blocked in one or two states continuing their operations elsewhere or in blocked states under aliases. It is not likely, however, that larger, more reputable online pharmacies will sacrifice name recognition and large revenue opportunities in order to avoid licensing and quality of care requirements.

The jurisdictional limitations of the attorney general actions are not going unexamined. The possibility for a large-scale effect arising from the individual actions of states' attorneys general reflects NAAG's method of affecting state and federal policy on interstate issues through facilitating uniform responses by attorneys general. NAAG also is involved in formulating specific programs to more directly achieve broad impact from state attorney general actions.

At its Internet conference, NAAG revealed proposals to further its vision of a concerted attorney general enforcement scheme.¹⁶⁸ These proposals include calls for legislation to en-

167. Chase, *supra* note 155.

168. *Impact of the Internet*, *supra* note 123.

able cross-state investigations and to expand state attorney general authority to bring actions in federal courts and obtain injunctions effective throughout all states.¹⁶⁹ NAAG plans to hold regular meetings for state attorneys general to share information on their online actions and investigations.¹⁷⁰ Common access to data is seen as vital to a collaborative enforcement strategy.

The realization of NAAG's vision of a dominant state attorney general regulatory presence may actually depend upon federal involvement in licensing and registration of online pharmacies. This type of federal regulatory role could address gaps in state regulation while respecting the states' ability and willingness to set standards and prosecute offenders. The ability of state attorney general actions to have broad scale impact relies on collaborative efforts. State-wide enforcement efforts can be assisted by a federal system of registration; a national data bank of online pharmacies and their affiliated practitioners can allow uniform communication of enforcement actions and enable collaborative investigations. This type of system could emulate the interstate sharing of adverse license action information among state medical boards.¹⁷¹ Programs such as the National Practitioner Data Bank represent a federal policy of assisting states in cooperative policing of physicians who practice in multiple states, without the need to implement an actual federal licensing program.¹⁷²

The type of plan laid out in the federal legislation proposed in Fall 1999 contemplated a measure of federal involvement that would respect states' traditional and primary authority in regulating medical and pharmacy practices. Care must be taken, however, in considering new federal proposals to ensure expansions of federal power do not encroach too heavily on states' authority to regulate practice standards and their ability to protect consumers. Where coordinated state enforcement is lacking, minimal federal requirements and enforcement actions could help.

169. *Id.*

170. *Id.*

171. William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701 (1999).

172. *Id.* at 1784. (citing the Health Care Quality Improvement Act of 1986, Pub. L. No. 99-660, 100 Stat. 3784 (codified as amended at 42 U.S.C. §§ 11101- 11152)).

D. Legal Bases for Action

The attorneys general actions against online pharmacies all are based on similar legal theories—allegations of violations of state licensing laws and laws requiring physicians to prescribe medications only pursuant to bona fide physician-patient relationships. Whether efforts by attorneys general to prosecute online pharmacy practitioners and physicians are successful depends on the applicability of state laws to online prescribing activities.

States may apply practice standards that do not regulate online pharmacies *per se* to these pharmacies' prescribing and dispensing activities. They also may amend existing pharmacy and medical regulations to specifically bring online pharmacies within their scope. Alternatively, states may pass comprehensive legislation setting particular standards for online pharmacies operating within their borders; both the Kansas and New York legislatures recently considered bills that included licensing, disclosure, and quality provisions. New York's proposed Internet Pharmacy Consumer Protection Act clearly designated violations by online pharmacies, pharmacists, or health care practitioners as professional misconduct and as misdemeanors.¹⁷³ The proposed Kansas Internet Pharmacy Consumer Protection Act designated that violations would be deemed violations of the state's consumer protection, pharmacy practice, and healing arts acts.¹⁷⁴ These types of specific penalty provisions would assist state agency and attorney general enforcement efforts in establishing clear violations.

Other states' legislatures have been undertaking careful consideration of the effects of online pharmacies and formulating legislative policies in response. In January 2000, Michigan formed a task force to examine the sale of prescription drugs online.¹⁷⁵ The task force included representatives from the state licensing agency, health care providers, and major purchasers of health benefits and was charged with the goal of forming legal

173. S.B. 7760, 223d Ann. Leg. Sess.

174. S.B. 385, 78th Leg., 2000 Reg. Sess.

175. *Michigan State Officials*, *supra* note 141. In a somewhat different vein, some legislation may attempt to broaden online pharmacy practices. *Id.* A proposal in Indiana sought to allow insurers to designate online pharmacies as acceptable network providers, but also sought to protect enrollees from being coerced into using particular online pharmacies through financial incentives such as lower co-payments. See S.B. 155, 111th Gen. Ass., 2d Reg. Sess.

recommendations for the state's licensing agency.¹⁷⁶ The group's scope of review included online pharmaceutical trends, relevant state and federal laws, and security and privacy issues.¹⁷⁷ Similarly, the Iowa legislative council was formally asked by the state's legislature to study the provision of pharmacy services through the Internet as a prelude to legislative action.¹⁷⁸

Following is an examination of the laws upon which the state attorney general actions rely and a survey of the types of recent legislative initiatives that can advance states' abilities to regulate pharmacies on the Internet.

1. Licensure and Disclosure

The attorney general actions complain of pharmacists and physicians who practice within their respective states without being licensed; they also complain of pharmacies dispensing to residents of their states without being registered. The claim that pharmacists and physicians are practicing in a particular state when they prescribe and dispense drugs to residents of that state from outside that state finds some precedent in established non-resident and telemedicine licensure provisions.¹⁷⁹

Indiana brings both Internet pharmacies as well as mail-order pharmacies under the purview of the state's professional licensing agency by requiring them to either be located in Indiana or be licensed as non-resident pharmacies.¹⁸⁰ California law specifically prohibits practicing medicine *from* California *into* another state or country without first satisfying the other jurisdiction's requirements for practicing medicine.¹⁸¹ The New York proposal required online pharmacies to comply with New York licensing requirements in order to deliver prescription drugs into New York.¹⁸² In 1999, Illinois passed a law that specifically brings Internet pharmacies within the regulatory purview of the State Board of Pharmacy of the Department of Professional Regulation by classifying them as mail-order pharmacies.¹⁸³ The New

176. *Michigan State Officials*, *supra* note 141.

177. *Id.*

178. H.C.R. 124, 78th Gen. Ass., 2d Sess. (Iowa); S.C.R. 120, 78th Gen. Ass., 2d Sess. (Iowa).

179. *See, e.g.*, 225 ILL. COMP. STAT. 85/16a, 60/49.5 (LEXIS through 2000 Public Act 91-925).

180. 225 IND. CODE § 25-26-18-1 (LEXIS through 2000 Sess.).

181. CAL. BUS. & PROF. CODE § 2234(g) (Deering, LEXIS through 2001 Supp.).

182. S.B. 7760, 223d Ann. Leg. Sess.

183. 225 ILL. COMP. STAT. 85/16a(a).

Hampshire legislature recently enacted a similar bill to bring Internet pharmacies into the scope of professional licensing regulations affecting mail-order pharmacies.¹⁸⁴

In the Illinois Attorney General actions, the online pharmacies allegedly violated the State's Consumer Fraud Act by failing to disclose to patrons that they were not licensed in Illinois and by representing to consumers that it "is lawful for doctors not licensed in Illinois to issue prescriptions drugs to Illinois residents, when . . . it is not lawful . . ." ¹⁸⁵ One of these allegations should fail, however, for pharmacies that represent it is lawful for them to dispense without a particular license cannot simultaneously fail to disclose that they are dispensing without such a license. The question of what is disclosed to consumers influences not just the substantive foundations for state actions, but the very ability of states to bring actions.

States need comprehensive information about who is operating online pharmacies in order to consistently apply their consumer protection standards. The family of the Illinois man who died from a heart attack after taking Viagra that he obtained from an online pharmacy could not pursue criminal or civil enforcement actions because the drug's origin was unknown.¹⁸⁶ Until harm can be linked to specific providers, prosecutions may proceed based on symbolic goals. The Illinois physician who faced suspension of his license, restrictions on his practice, and a fine was not investigated or indicted based on allegations of patient harm.

States recognize this problem and are considering policies that would require disclosure to consumers of who is operating online pharmacies. The Kansas bill required sites to disclose names and addresses of parties involved in issuing and dispensing prescriptions and sites' abilities to obtain liability waivers.¹⁸⁷ New York's proposed law also required the disclosure of pharmacies' and pharmacists' names, principal addresses, and phone numbers, as well as proof of compliance with New York licensure and registration laws.¹⁸⁸

184. H.B. 1467, 156th Gen. Ct., 2d Year, 156th Sess. (N.H. 2000).

185. *ExpressMed Servs. Corp.*, *supra* note 138.

186. Bendavid, *Prescriptions Via Internet Pose Dangers*, *supra* note 31.

187. S.B. 385, 78th Leg., 2000 Reg. Sess.

188. *Id.*

2. Quality of Care

Prescribing drugs without conducting a physical examination can be violative of a state's professional conduct standards.¹⁸⁹ California law prohibits prescribing and dispensing prescription drugs without first conducting a good faith examination and determining proper medical indication.¹⁹⁰ A bill recently passed in California's Legislature specifically prohibits online prescribing without a good faith prior medical examination and online dispensing without a valid prescription that is based on a good faith prior medical examination.¹⁹¹ Kansas's comprehensive bill required pharmacists and providers to conform to existing Kansas law setting standards for consultations that result in issuance of prescriptions.¹⁹² The New York bill mandated verification of prescriptions and placed restrictions on liability waivers. A separate New York bill prohibited the dispensing of controlled substances pursuant to an online pharmacy consultation or sale.¹⁹³

There is precedent outside of the online context for disciplinary actions against physicians who prescribed drugs without establishing proper physician-patient relationships.¹⁹⁴ The physicians involved were prescribing drugs without performing medical examinations and without otherwise verifying medical indications.¹⁹⁵ Although these cases generally involved illicit prescribing of drugs classified as controlled substances, the discipline actions arose from the physicians' willingness to conduct a professional activity (issuing prescriptions) outside the bounds of professional standards (not performing physical exams or assuring proper medical indication).¹⁹⁶

189. Vitauts M. Gulbis, *Wrongful or Excessive Prescription of Drugs as Ground For Revocation or Suspension of Physician's or Dentist's License to Practice*, 22 A.L.R. 4th 668 (1983, current through the Sept. 2000 Supp.).

190. CAL. BUS. & PROF. CODE §§ 2242, 4022 (Deering, LEXIS through 2001 Supp.).

191. S.B. 1828, 1999 Reg. Sess. (Cal. 2000).

192. S.B. 385, 78th Leg., Reg. Sess.

193. S.B. 1718, 222d Ann. Leg. Sess.

194. *Id.* (citing *Arkansas State Med. Bd. v. Grimmett*, 463 S.W.2d 662 (Ark. 1971); *Whitlow v. Bd. of Med. Exam'rs*, 56 Cal. Rptr. 525 (Cal. Ct. App. 1967); *Kolnick v. Bd. of Med. Quality Assur.*, 161 Cal. Rptr. 289 (Cal. Ct. App. 1980); *Scheininger v. Dep't of Prof'l Regulation*, 443 So. 2d 387 (Fla. Dist. Ct. App. 1983); *Dannenber v. Bd. of Regents*, 430 N.Y.S.2d 700, (N.Y. App. Div. 1980); *State ex rel. Oklahoma State Bd. of Med. Licensure & Supervision v. Ray*, 848 P.2d 46 (Okla. 1992).

195. *Id.*

196. *Id.*

New York recently passed rules requiring pharmacists to personally provide patient counseling in order to ensure patients receive professional pharmaceutical advice; the rules also require pharmacies to maintain patient drug profiles and check for drug interactions as part of their counseling.¹⁹⁷ The rules allow prescriptions to be filled electronically, rather than just pursuant to written or phone orders. In addition to meeting secure transmittal requirements, electronic prescriptions must be marked to indicate that they are from an authorized prescriber.¹⁹⁸ Rules such as these, along with clear legal requirements for medical examinations, present a counterbalance to the effects of inadequate online patient consultations and failure of online pharmacists to verify prescriptions.

VI. CONCLUSION

State attorneys general have exhibited an early willingness to commit consumer protection resources to abusive online pharmaceutical practices. State legislatures are contributing to their abilities by tailoring laws to apply traditional pharmacy and medical standards to evolving Internet practices. State licensing officials are following the lead of the attorneys general in experimenting with disciplining online activities. A narrowly crafted federal regulatory approach, such as the information disclosure requirements recently proposed by the U.S. GAO, could complement these state enforcement efforts.¹⁹⁹

The demonstration of cooperative federalism that the attorney general actions present does not ensure a consistent level of enforcement nationwide.²⁰⁰ It is impossible to guarantee all states will participate in forming comparable programs to police online pharmacies. If enough states with major populaces do participate, however, it is likely that their requirements will influence business practices. Some fear interstate cooperation because of the lack of public accountability that comes from

197. *New York: New Regulations Permit Pharmacists to Fill Prescriptions Received Via E-mail, Fax*, 8 Health L. Rep. (BNA) 724 (May 6, 1999).

198. *Id.*

199. U.S. GENERAL ACCOUNTING OFFICE, INTERNET PHARMACIES: ADDING DISCLOSURE REQUIREMENTS WOULD AID STATE AND FEDERAL OVERSIGHT, REP.NO. GAO-01-69 (2000).

200. For a discussion of some of the influences on cooperative federalism, see DAVID C. NICE & PATRICIA FREDERICKSON, *THE POLITICS OF INTERGOVERNMENTAL RELATIONS*, 128-29 (1995).

agency-level creation and implementation of policies.²⁰¹ In fact, NAAG has been criticized as a “shadow Congress.”²⁰² Many state legislatures, however, are becoming active in formulating policy for online pharmacies that is consistent with the assertion of cooperative state power represented by the attorney general actions. These laws and proposals lend credibility to the identification of a public safety threat by the attorneys general and validate their early efforts to control that threat.

201. *Id.*

202. McKinney & Caton, *supra* note 120.